ORIGINAL

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

In the Matter of	)	
	)	
POM WONDERFUL LLC and	)	
ROLL GLOBAL LLC,	)	
as successor in interest to Roll	)	
International Corporation,	)	
	)	
companies, and	)	Docket No. 9344
	)	PUBLIC
	)	
STEWART A. RESNICK,	)	
LYNDA RAE RESNICK, and	)	
MATTHEW TUPPER, individually and	)	
as officers of the companies.	)	

RESPONDENTS' REPLY TO COMPLAINT COUNSEL'S PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW

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I. EXECUTIVE SUMMARY

A. Summary of Complaint and Answer

1. The FTC's Complaint

1. Respondents. POM Wonderful LLC ("POM") is the self-described largest grower and distributor of pomegranates and pomegranate juice in the United States. Roll Global LLC ("Roll Global"), a successor-in-interest of Roll International Corporation ("Roll International") (collectively, "Roll") is an umbrella company that provides services, such as advertising, public relations, consulting, and accounting to POM. POM and Roll are for-profit companies owned by Lynda and Stewart Resnick ("the Resnicks"). For at least ten years, the Resnicks have controlled and directly participated in the business activities of Roll and POM. In addition, Matthew Tupper, the head of POM since 2003, has controlled and directly participated in POM's business activities. (*See infra* Section II).

Response to Finding No. 1:

Complaint Counsel's proposed finding mischaracterizes evidence in the record to the extent it implies that Mr. Tupper's authority at POM was equal to the Resnicks or that he "controlled" POM. Mr. Tupper has no ownership interest or equity shares in POM. (CX1353 (Tupper, Dep. at 14); Tupper, Tr. 2973). Mr. Tupper reported directly to Stewart Resnick and had "dotted line" reporting to Lynda Resnick. (CX1364 (Tupper, Dep. at 14); Tupper, Tr. 2973; CX1375 (L Resnick, Tropicana Dep. at 33-34); (CX1357 (Kuyoomjian, Dep at 52)). Mr. Tupper had no more authority at POM than was delegated to him by Stewart Resnick. (S. Resnick, Tr. 1870). Mr. Tupper was involved in POM's operations, science research, and marketing. However none of these aspects of POM's business were under Mr. Tupper's ultimate control. (CX1363 (S. Resnick, Coke Dep. at 86); CX1348 (Perdigao, Dep. at 50, 60-61); CX1359 (L. Resnick, Dep. at 36); CX1362 (L. Resnick, Coke Dep. at 103-104). In Mr. Resnick's own words, he, not Mr. Tupper, was the "ultimate sole decision-maker on everything." (CX1367 (S. Resnick, Welch Dep. at 55)). Mr. Tupper consulted with Mr. Resnick or Mrs. Resnick for any major restructuring or personnel decisions. (Tupper, Tr. 903; CX1364 (Tupper, Coke Dep. at 31)). Mr. Tupper did not, independent of the Resnicks, develop the marketing direction or decide how POM products would be marketed. (Tupper, Tr. 2974-75;

(CX1368 (L. Resnick Welch's Dep. at 9); L. Resnick, Tr. 93; PX0327 (Glovsky Dep. at 36). Lynda Resnick, for example, had the final authority over advertising content and concepts. (CX1368 (L. Resnick, Welch Dep. at 9); L. Resnick, Tr. 93). Stewart Resnick had the ultimate ability to decide whether any advertisement would be run. (S. Resnick, Tr. 1870; Tupper, Tr. 2975). Stewart Resnick or Lynda Resnick, and not Mr. Tupper had the final authority to resolve any issues or disputes regarding advertising decisions. (CX1365 (Perdigao, Coke Dep. at 36-37)).

2. Complaint and Answer. On September 24, 2010, the Federal Trade Commission ("Commission" or "FTC") issued an administrative complaint charging Respondents POM, Roll, Lynda Resnick, Stewart Resnick, and Matthew Tupper with violations of Sections 5(a) and 12 of the FTC Act in connection with advertising claims made for POM Wonderful 100% Pomegranate Juice ("POM Juice"), POMx Pills, and POMx Liquid Extract ("POMx Liquid") (collectively, "POM Products"). (CX1426).[1] On October 18, 2010, Respondents filed an answer admitting that they manufactured, advertised, labeled, offered for sale, sold, and distributed to the public the POM Products, but denying that they had violated the FTC Act as charged. (PX0364). (*See infra* Section III).

Response to Finding No. 2:

Respondents have no specific response.

3. Challenged Claims. This proceeding concerns Respondents' advertising claims ("Challenged Claims") for the POM Products, specifically (*see infra* Section V and Appendix A (Chart Categorizing the Heart, Prostate, and ED Establishment and Efficacy Advertising Representations Made By Respondents)):

   a. False establishment claims related to heart disease. The complaint alleges that Respondents falsely represented, expressly or by implication, through advertising and promotional materials that clinical studies, research, and/or trials prove that drinking eight ounces of POM Juice daily, or taking one POMx Pill or one teaspoon of POMx Liquid daily, treats, prevents, or reduces the risk of heart disease, including by (1) decreasing arterial plaque, (2) lowering blood pressure, and/or (3) improving blood flow to the heart. (CX1426_00017-18).

   b. Unsubstantiated efficacy claims related to heart disease. The complaint further alleges that Respondents represented without an adequate basis, expressly or by implication, through advertising and promotional materials, that drinking eight ounces of POM Juice daily, or taking one POMx Pill or one teaspoon of POMx

[1] On September 27, 2010, proposed respondent Mark Dreher Ph.D., the Vice President of Science & Regulatory Affairs of POM Wonderful LLC from approximately August 2005 to May 2009, entered into a consent agreement with the Commission (available at http://www.ftc.gov/os/caselist/0823122/100927pomagree.pdf).

Liquid daily, treats, prevents or reduces the risk of heart disease, including by (1) decreasing arterial plaque, (2) lowering blood pressure, and/or (3) improving blood flow to the heart. (CX1426_00019-20).

c. False establishment claims related to prostate cancer. The complaint alleges that Respondents falsely represented, expressly or by implication, through advertising and promotional materials, that clinical studies, research, and/or trials prove that drinking eight ounces of POM Juice daily, or taking one POMx Pill or one teaspoon of POMx Liquid daily, treats, prevents, or reduces the risk of prostate cancer, including by prolonging prostate-specific antigen doubling time ("PSADT"). (CX1426_00018).

d. Unsubstantiated efficacy claims related to prostate cancer. The complaint further alleges that Respondents represented without an adequate basis, expressly or by implication, through advertising and promotional materials, that drinking eight ounces of POM Juice daily, or taking one POMx Pill or one teaspoon of POMx Liquid daily, treats, prevents or reduces the risk of prostate cancer, including by prolonging PSADT. (CX1426_00019-20).

e. False establishment claims related to erectile dysfunction. The complaint alleges that Respondents falsely represented, expressly or by implication, through advertising and promotional materials, that clinical studies, research, and/or trials prove that drinking eight ounces of POM Juice daily treats, prevents, or reduces the risk of erectile dysfunction. (CX1426_00019).

f. Unsubstantiated efficacy claims related to erectile dysfunction. The complaint further alleges that Respondents represented without an adequate basis, expressly or by implication, through advertising and promotional materials, that drinking eight ounces of POM Juice daily treats, prevents, or reduces the risk of erectile dysfunction. (CX1426_00019-20).

Response to Finding No. 3:

Respondents do not dispute that Complaint Counsel made the listed allegations in the Complaint, but vehemently deny they ever made establishment or unsubstantiated efficacy claims with regard to heart disease, prostate cancer or erectile dysfunction. As discussed in detail in Respondents' Post-Trial Brief and Findings of Fact (as well as in their reply papers), Respondents' advertisements do not and have not conveyed "treat", "prevent" or "reduce the risk" claims in any of the challenged arenas—heart disease, prostate cancer or erectile dysfunction. The science is, however, strong enough to support such claims. (*See* Respondents' Post-Trial Brief Sections VI-IX; RFF 27-52, 378-447, 568-2799; Respondents' Reply Post-Trial Brief Sections I.B., II; RRFF 175-

1130; Respondents' Appendix of Advertisements ("Appendix of Advertisements"); Respondents' Reply Appendix of Advertisements ("Reply Ad Appendix").

4. Evidentiary Hearings. Complaint Counsel presented its case-in-chief on May 24-27, June 6-9, June 13, and June 15, 2011. Respondents presented their case on August 30-September 2, and October 11-12, 2011. Complaint Counsel presented rebuttal testimony on September 14, October 14, and November 4, 2011. Twenty-four witnesses testified: 10 fact witnesses[2] (including one rebuttal fact witness) and 14 expert witnesses (including two rebuttal experts). The transcripts of hearings consist of more than1,400 pages and approximately 1,875 exhibits were admitted into evidence. The evidentiary record closed on November 18, 2011.

Response to Finding No. 4:

Over nineteen hundred exhibits, containing approximately sixty-five thousand pages, were designated prior to the hearing, over 1,500 of which were admitted into evidence. (JX2 Attachment A). The additional exhibits found on in JX2 Attachment B were conditionally admitted subject to objections to be raised during the parties post-trial briefing. Respondents submitted into evidence more than ninety scientific studies and reports sponsored by the POM. (See, PX Exhibit Nos. 2-12, 14-23, 38-41, 49-51, 53-66, 68-71, 73-77, 81-130, 136-148, 174-175). The testimonial portion of the trial concluded on November 4, 2011 after 19 days of trial. The hearing record was closed on November 18, 2011, pursuant to Commission Rule 3.44(c), by Order dated November 18, 2011.

5. Respondents Made the Challenged Claims. The evidence presented by Complaint Counsel demonstrates that Respondents: 1) intended to convey specific disease efficacy claims to consumers; and 2) indeed conveyed the Challenged Claims to consumers through various media advertising and marketing techniques. (*See infra* Sections V and Appendix A (Chart Categorizing the Heart, Prostate, and ED Establishment and Efficacy Advertising Representations Made By Respondents)).

Response to Finding No. 5:

Respondents deny they made any of the Challenged Claims in any of the Challenged Advertisements. The evidentiary record proves just the opposite: (1) Respondents never

[2] Three fact witnesses testified in the affirmative cases of both Complaint Counsel and Respondents.

intended to convey specific disease efficacy (or establishment) claims to consumers; and (2) Respondents never conveyed the Challenged Claims to consumers through various media and marketing techniques. (RFF 2209-16; 2252-2622; Appendix of Advertisements; *see infra* RRFF 325-615; Reply Ad Appendix; RCOL 17-46; *see infra* RRCOL10-41).

First, Respondents genuinely believe in the health benefits of the Challenged Products and in the scientific integrity of POM's research (RFF 502-20). Thus, it is not surprising that POM's ads summarize some of Respondents' scientific research on the Challenged Products in the areas of cardiovascular, prostate and erectile health and talk about the healthful properties of the Challenged Products, including that the Challenged Products contain abundant antioxidants and that they are wholly derived from pomegranate fruit. (RFF 493-99, 2478-2505, 2518-44). Respondents, however, strenuously dispute that they ever intended to convey that the Challenged Products treat, prevent or reduce the risk of heart disease, prostate cancer and erectile dysfunction or that they are "clinically proven" to do so. (RFF 496, 535, 538, 540, 545-50, 2209-11, 2280; CX1372 (S. Resnick, Trop. Dep. at 57-59); CX1375 (L. Resnick, Trop., Dep. at 79-81)). Complaint Counsel presented no evidence directly contradicting the Individual Respondents' testimony.

Second, the Challenged Advertisements do not convey the disease messages that Complaint Counsel assert are expressly made in the advertisements. (RFF 2209-2210; 2264-2622; Appendix of Advertisements; Reply Ad Appendix). Nowhere do Respondents expressly (*i.e.*, unequivocally and directly) state that the Challenged Products are "clinically proven" to "prevent," "treat," or "reduce the risk" of heart disease, prostate cancer and erectile dysfunction; and nowhere do Respondents expressly (*i.e.*, unequivocally and directly) state that the Challenged Products "prevent," "treat," or "reduce the risk" of heart disease, prostate cancer and erectile dysfunction. (RFF 2210; 2264-2622; Appendix of Advertisements; Reply Ad Appendix; *see infra* RRFF 325-578)

Third, the Challenged Advertisements do not convey the disease messages that Complaint Counsel assert are impliedly made in the advertisements. (RFF 2211, 2216, 2264-2622; Appendix of Advertisements; Reply Ad Appendix; *see infra* RRFF325-578). It is impossible for Complaint Counsel to "conclude with confidence" that POM's advertisements convey efficacy claims or "clinically proven" claims to prevent, treat or reduce the risk of disease, as alleged, on the face of the Challenged Advertisements. (RFF 2211-16, 2264-2622; Appendix of Advertisements; Reply Ad Appendix; *see infra* RRFF 325-578). In their net impression analysis, Complaint Counsel ignore, among other elements, the overt puffery, outrageousness and humor in the headlines, sub-headlines and imagery, the fact that the ads emphasize that the Challenged Products are an abundant and potent source of antioxidants and fact that the Challenged Products are 100% fruit juice or derived from 100% fruit. (RFF 2264-2622; Appendix of Advertisements; Reply Ad Appendix; *see infra* RRFF 325-578). Viewing the Challenged Advertisements as a whole, including the interaction of headlines, body copy and visual imagery, among other elements, the Challenged Ads, do not clearly and conspicuously convey to a reasonable consumer that the Challenged Products (1) prevent, treat or reduce the risk of heart disease, prostate cancer and erectile dysfunction; or (2) are "clinically proven" to prevent, treat or reduce the risk of heart disease, prostate cancer and erectile dysfunction. (RFF 2209-16; 2252-2622; Appendix of Advertisements; Reply Ad Appendix; *see infra* RRFF 325-578; RCOL 17-43; *see infra* RRCOL10-41).

To the extent a "proven" claim can be implied from any of the Challenged Advertisements (which it cannot), the overall impression of any ad is not that the Challenged Products are "proven" to be 100% effective in preventing, treating or reducing the risk of heart disease, prostate cancer or erectile dysfunction because "proven" in science means the "average person in the study benefitted." "Proven" does not mean that "everyone in the study necessarily benefitted." (RFF 2211(g); Heber, Tr.

2011; Butters, Tr. 2893-94; PX0361 (Sacks, Dep. at 81)). To the extent a "treat" claim can be implied from any of the Challenged Advertisements (which it cannot), the overall net impression of any ad is not that the Challenged Products are a substitute for conventional medical treatment. (RFF 2211(h); Butters, Tr. 2821-22; Appendix of Advertisements; Reply Ad Appendix). To the extent a "reduce the risk" claim can be implied from any of the Challenged Advertisements, the overall net impression of any ad is not that the Challenged Products "reduce the risk" of heart disease, prostate cancer or erectile dysfunction, like a drug with a single target of action, but "reduce the risk" like a healthy diet of fruits and vegetables and exercise "reduce the risk" of disease. (RFF 2211(i); Butters Tr. 2817-18; Appendix of Advertisements; Reply Ad Appendix).

Last, because Complaint Counsel's facial analysis is wholly defective in demonstrating the efficacy or "clinically proven" claims Complaint Counsel assign to the Challenged Advertisements, extrinsic evidence is thus necessary to interpret the claims. (RFF 2212-14). Complaint Counsel, however, make no mention of any extrinsic evidence on the meaning of the ads or what a reasonable person would take away from them in their post-trial brief. (RFF 2214-17, 2684-85). Accordingly, because Complaint Counsel failed to present any reliable extrinsic evidence on the meaning of the ads or what a reasonable person would take away from them, they have failed to meet their burden that a preponderance of the credible evidence shows that the implied establishment or efficacy disease claims as alleged were actually conveyed by the Challenged Ads to a substantial segment of the reasonable consumer. (RFF 2214-14; Appendix of Advertisements; Reply Ad Appendix; *see infra* RRFF 579-615).

6. The Challenged Claims are Material. The record evidence, including Respondents' testimony and documents, also show that the Challenged Claims were material to consumers' purchasing decisions by virtue of the nature of the claims. (*See infra* Section VI).

Response to Finding No. 6:

Respondents deny that the Challenged Claims were material to consumers' purchasing decision. The evidentiary record proves just the opposite for two separate and independent reasons. First, Respondents adduced evidence to rebut any presumption of materiality by introducing Professor David Reibstein's Survey of POM Wonderful 100% Pomegranate Juice Users ("Reibstein Survey") which demonstrates that the Challenged Claims are not material because very few consumers purchase, repurchase or recommend POM Juice because they believe it prevents or cures any specific disease. (RFF 2623-2628). Second, Complaint Counsel failed to sustain their burden of proving that the Challenged Claims were material to prospective consumers purchasing decisions because they (1) never offered any affirmative proof or expert opinion to support a finding that the Challenged Claims were material (*see* RFF 2680-89), (2) failed to discredit the Reibstein Survey, which directly contradicted the initial presumption of materiality, and (3) relied on methodologically flawed and unreliable evidence that shed no light on the materiality of the Challenged Claims.

Because the presumption of materiality has dropped out, "'the inquiry … turns from the few generalized factors that establish [the presumption] to the specific proofs and rebuttals … the parties have introduced.'" *In the Matter of Novartis Corp.*, 127 F.T.C. 580, 686 (1999) (quoting *St. Mary's Honor Ctr. v. Hicks*, 509 U.S. 502, 506 (1993)). Complaint Counsel, however, adduced no "specific proofs and rebuttals" that give rise to any initial presumption that the Challenged Claims were material. This total lack of evidence is fatal to Complaint Counsel's ability to prove deception under the FTC Act. See FTC Policy Statement on Deception ("FTC Policy Statement") (stating that a claim "must be a material one for deception to occur" under the FTC Act), appended to *In re Cliffdale Assocs.*, 103 F.T.C. 110, 165 (1984) (holding the materiality of a claim to a consumer's purchase decision is an essential element under the FTC Act).

7. The Challenged Claims Are False or Unsubstantiated. Evidence presented by Complaint Counsel, through expert witnesses and through Respondents' own testimony and documents, demonstrates that Respondents: 1) lacked the requisite scientific support for the Challenged Claims; 2) knew that their substantiation was insufficient; and 3) continued to make the Challenged Claims in disregard of the law. (*See infra* Section VII).

Response to Finding No. 7:

Incorrect. Respondents strongly dispute Complaint Counsel's proposed finding of fact as contrary to, and completely unsupported by, the evidence in the record. Respondents have a vast body of scientific research that more than adequately substantiates any health benefit claim that POM has made. (See infra; see also, RFF 568-761; RPTB Part II, Sec. E) (the consensus among competent and reliable scientists is that if you are talking about a (1) safe 100% whole food product or its derivative, like the Challenged Products, and (2) the product is not offered as a substitute for conventional medical care or treatment, then it is appropriate to favor disclosure, and you may rely on basic science for substantiation and RCTs are not required); (RFF 991-1020; RPTB Part II, Sec. E.2.c) (the Challenged Products are safe 100% whole food products); (RFF 524-550, 2197-2417; RPTB Part II, Sec. E.2.c) (the Challenged Products are not offered in place of conventional medical treatment); (RFF 1021-1569; RPTB Part II, Sec. F) (POM's heart health claims are true and substantiated by competent and reliable scientific evidence); (RFF 1923-2196; RPTB Part II, Sec. G) (POM's erectile claims are true and substantiated by competent and reliable scientific evidence); (RFF 1577-1922; RPTB Part II, Sec. H) (POM's prostate health claims are true and substantiated by competent and reliable scientific evidence.)).

8. Respondents Are Liable. The evidence presented by Complaint Counsel shows that Respondents are liable for violating Sections 5 and 12 of the FTC Act, which prohibit, respectively, unfair or deceptive acts or practices, and false advertisements for food, drugs, devices, services, or cosmetics in or affecting commerce. 15 U.S.C. §§ 45(a) and 52. (*See infra* Complaint Counsel's Proposed Conclusions of Law, Section VIII). Entry of the notice order against Respondents is the appropriate remedy.

Response to Finding No. 8:

Incorrect. Complaint Counsel have failed to meet their burden. Specifically, they have not met their burden by a preponderance of the evidence that the ads are false and misleading. If Complaint Counsel asserts that they are false because they convey "treat," "reduce the risk" and "prevent" claims like a drug, they do not, as conveyed by the products and advertisements themselves. Moreover, assuming arguendo that treat, prevent, and reduce the risk claims were made, Respondents have competent and reliable evidence for those claims and the claims were at all times truthful. Those claims, if made were made 3 to 8 years ago and hardly constitute a basis for injunctive relief now. In addition, Complaint Counsel have failed to meet their burden of materiality and rebut the testimony of Professor Reibstein who confirmed what was obvious from a facial analysis of the ads themselves—that consumers, and less than 1.5% of them, buy the product because of any disease related reasons.

II. RESPONDENTS

A. Individual Respondents

1. Stewart and Lynda Resnick

9. At all times relevant to the Complaint, Respondents Stewart and Lynda Resnick ("the Resnicks") have been the sole trustees and beneficiaries of the Stewart and Lynda Resnick Revocable Trust dated December 27, 1988 ("the Resnick Trust"). (CX1426_0001, Compl. ¶ 1; PX0364-0001, Answer ¶ 1; CX1421_0002-03; CX1384_0008).

Response to Finding No. 9:

Respondents have no specific response.

10. At all times relevant to the Complaint, the Resnick Trust has owned Roll International Corporation and POM. (JX0001 ¶¶ 10, 11, 18; CX1426_0001-02, Compl. ¶¶ 1,2; PX0364-0001, Answer ¶¶ 1, 2).

Response to Finding No. 10:

Respondents have no specific response.

11. The Resnicks own Roll Global, the successor-in-interest to Roll International, and its affiliated companies, including POM. (JX0003 ¶ B.2; *see also* CCFF ¶ 93).

Response to Finding No. 11:

Respondents have no specific response.

12. Roll Global is an approximately $2 billion corporation that includes the companies Teleflora, Fiji Water, Paramount Farms (which sells Wonderful Pistachios and Wonderful Almonds), Paramount Citrus (which sells Cuties), Justin Vineyards and Winery, and Suterra. (JX0003 ¶ B.3; S. Resnick, Tr. 1629-30; Perdigao, Tr. 593-94).

Response to Finding No. 12:

Respondents have no specific response.

13. At all times relevant to the Complaint, Stewart Resnick ("Mr. Resnick") has been the chairman of POM, and the director, chairman, and president of Roll International. (JX0001 ¶¶ 12, 18; S. Resnick, Tr. 1629; CX1426_0002, Compl. ¶ 3; PX0364-0001, Answer ¶ 3; CX1384_0008).

Response to Finding No. 13:

Respondents have no specific response.

14. At all times relevant to the Complaint, Lynda Resnick ("Mrs. Resnick") has been a director and vice-chairman of Roll International. (JX0001 ¶ 18; L. Resnick, Tr. 287; CX1359 (L. Resnick, Dep. at 24-25)).

Response to Finding No. 14:

Respondents have no specific response.

15. Mr. Resnick is chairman and president, and Mrs. Resnick is vice-chairman of Roll Global. (S. Resnick, Tr. 1629; CX1426_0002, Compl. ¶ 3; PX0364-0001, Answer ¶ 3; CX1384_0008; L. Resnick, Tr. 287; CX1359 (L. Resnick, Dep. at 24-25)).

Response to Finding No. 15:

Respondents have no specific response.

16. Mr. and Mrs. Resnick each maintain a business address at 11444 West Olympic Blvd., 10th Floor, Los Angeles, CA 90064, which is also the business address for POM and Roll. (PX0277-0002-03; *see also* PX0276-0002).

Response to Finding No. 16:

Respondents have no specific response.

17. Michael Perdigao ("Mr. Perdigao"), the president of Roll's advertising agency, Fire Station, and Roll's Corporate Communications department, reports to the Resnicks. (CX1376 (S. Resnick, OS Dep. at 145); JX0001 ¶ 18; Perdigao, Tr. 590, 594).

Response to Finding No. 17:

Respondents have no specific response.

18. Mrs. Resnick does not have a specific corporate title at POM. (L. Resnick, Tr. 287; CX1359 (L. Resnick, Dep. at 37)).

Response to Finding No. 18:

Respondents have no specific response.

19. Over the years, Mrs. Resnick has used the title "POM Queen" and the business email address "lresnick@pomqueen.com." (CX0001_0001; CX1359 (L. Resnick, Dep. at 37); L. Resnick, Tr. 163).

Response to Finding No. 19:

Respondents have no specific response.

20. Mrs. Resnick's work for POM and Roll has been to build the company brands. (L. Resnick, Tr. 72-73).

Response to Finding No. 20:

Respondents object to Complaint Counsel's proposed finding as vague and ambiguous as to "build" and "company brands."

21. Mrs. Resnick's work on brand building includes both marketing strategy and advertising. (L. Resnick, Tr. 73-74; *see also* CX1375 (L. Resnick, Trop. Dep. at 130)).

Response to Finding No. 21:

Respondents have no specific response.

22. From POM's inception, Mrs. Resnick has directed the creative development of the company and the vision of the POM Juice and POMx advertising campaigns. (CX0001_0006-07; 0013-14; *see also* CCFF ¶¶ IX.B.1.187, IX.B.2.197-IX.B.2.209, IX.B.5.237-40, IX.B.6.280).

Response to Finding No. 22:

Respondents object to "directed" as vague and ambiguous.

Respondents also object to the proposed finding to the extent that Complaint Counsel construe the underlying documents and statements as evidence of intent. Stewart Resnick, Lynda Resnick, and Matt Tupper testified specifically that POM never intended *to convey or conveyed the claim* that the Challenged Products are "clinically proven" to treat, prevent, or reduce the risk of disease, and certainly not in the same sense as a drug treats, prevents, or reduces the risk of disease. (Tupper, Tr. 992, 3008; L. Resnick, Tr. 194, 196-97, 217-19; CX1363 (S. Resnick, Coke Dep. at 81); CX1376 (S. Resnick, Ocean Spray Dep. at 135); CX1372 (S. Resnick, Tropicana Dep. at 52, 56-59); CX1364 (Tupper, Coke Dep. at 297, 299); CX1374 (Tupper, Ocean Spray Dep. at 7); CX1362 (L. Resnick, Dep. at 283-84)). Moreover, POM never states, expressly or by implication, conspicuously on the face of any of the Challenged Ads that scientific tests "prove" that the Challenged Products "prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction," or even that they "prevent, treat or reduce the risk of heart

disease, prostate cancer or erectile dysfunction." (Respondents' Appendix of Advertisements). Throughout its advertising, POM highlights that POM Juice is a 100% juice product wholly-derived from the pomegranate fruit, and that POMx has the same content as the pomegranate fruit itself and is 100% derived from the exact same fruit. (*See* RFF 494). Indeed, Respondents have never advertised their products as a pharmaceutical drug, nor intended to advertise their products as drugs. (RFF 495-96). Rather, Respondents have always marketed the Challenged Products for what they intrinsically are: whole-food products. (RFF 497-99). Accordingly, it is far more logical (and the evidence demonstrates) that reasonable consumers would view the Challenged Products the way they perceive any other extremely healthy whole food, like broccoli, blueberries, grapes or tomatoes, which may help prevent or improve your odds against disease, but not like a drug with a single target of action against a particular disease or condition.

23. According to Mrs. Resnick, when it comes to marketing and creative issues, everyone has a "dotted line" to her, meaning she is in a position of authority even though she may not have day-to-day responsibilities for each employee. (CX1375 (L. Resnick, Trop. Dep. at 24); L. Resnick, Tr. 287-88).

Response to Finding No. 23:

Respondents have no specific response.

24. Of his various businesses, Mr. Resnick spends the second greatest amount of his time on the POM business. (CX1363 (S. Resnick, TCCC Dep. at 56)).

Response to Finding No. 24:

Respondents have no specific response.

25. Mr. Resnick's responsibilities include making final decisions about POM's investments and corporate expansion. (S. Resnick, Tr. 1631; CX1360 (S. Resnick, Dep. at 20-21); *see also* CX1357 (Kuyoomjian, Dep. at 154-56) (testifying that Mr. Resnick's participation in POM's business included involvement in strategic planning and financial decisions as well as providing feedback on POM's advertising)).

Response to Finding No. 25:

Respondents have no specific response.

26. Mr. Resnick also sets the overall budgets for POM, including the marketing and advertising budget and the medical research budget. (S. Resnick, Tr. 1631-32; CX1367 (S. Resnick, Welch Dep. at 55)).

Response to Finding No. 26:

Respondents have no specific response.

27. With regard to the medical research budget, Mr. Resnick reviews and approves the POM research budget annually, and when necessary if any changes occur during the year. (CX1376 (S. Resnick, OS Dep. at 227)).

Response to Finding No. 27:

Respondents have no specific response.

28. Over the years, Mr. and Mrs. Resnick have entered into research contracts to fund studies of POM's products. (CX0610; S. Resnick, Tr. 1675-76; CX0568; S. Resnick, Tr. 1722-23).

Response to Finding No. 28:

The evidence cited does not support Finding No. 28 and Complaint Counsel pointed to no other record evidence in support of the proposition that Mr. and Mrs. Resnick personally entered into research contracts to fund studies of POM's products. The evidence cited by Complaint Counsel only highlights that the Stewart and Lynda Resnick Revocable Trust entered into contracts to fund research (CX0610; S. Resnick, Tr. 1675-76; S. Resnick, Tr. 1722-23).

29. Regardless of which Resnick-controlled organization has paid for pomegranate research, the money ultimately comes from the Resnicks. (S. Resnick, Tr. 1657; *see also* CX1376 (S. Resnick, OS Dep. at 229-30)).

Response to Finding No. 29:

Respondents have no specific response.

30. Mr. Resnick has been intimately involved in the development of POM's scientific research program, for example, by engaging and communicating with scientific consultants, participating in scientific advisory board meetings, and convening company-sponsored research summits. (CX1360 (S. Resnick, Dep. at 85, 110-12); Tupper, Tr. 1027-28; Liker, Tr. 1880, 1889, 1891; CX0589).

Response to Finding No. 30:

Respondents object to "intimately involved" because it is vague and ambiguous.

31. Mr. Resnick reviews the results of the scientific research he sponsors, and, for example, has seen the results of all the important tests and bigger draft manuscripts before they were published. (S. Resnick, Tr. 1656-57).

Response to Finding No. 31:

Respondents object to "important tests" and "bigger draft manuscripts" as vague and ambiguous.

Respondents also object to the proposed finding to the extent that Complaint Counsel construe Mr. Resnick's statements as evidence that Respondents believed that cell, animal, or small human studies is not scientifically valid or cannot serve as a supporting basis for POM's advertising. In fact, the record reflects just the opposite. Respondents believe that all of POM's sponsored research—including cell studies, animal research, and its small human studies are scientifically valid and add valuable knowledge to understanding where future research should go and how it might be connected to other areas of health. (RFF 282-284). Mr. Resnick has repeatedly stated that he was primarily interested in understanding the how the Challenged Products work in the human body and whether and to what extent there may be a health benefit. (RFF 270-275). His motivation has never been to artificially power up studies just to reach statistical significance. (RFF 274, 277). In fact, Mr. Resnick has even chosen study designs with

fewer humans even when he has been advised the results would not yield "positive" or statistically significant results. (RFF 274, 277). Further, the experts have also testified that larger studies are not necessarily better and that smaller human studies can provide valid scientific evidence. (RFF 1249-1251). In fact, the evidence shows that, in some significant part, cell studies, animal research, and small human studies, including non-RCT studies are better indicators of whether and to what extent a benefit exists and are more efficient models for studying a food or nutrient. (RFF 346-377, 568-656).

Further, Respondents also object to the extent that Complaint Counsel imply that by in looking at results Mr. Resnick interfered with the publication of any of the research results. (RFF 441-442).

32. Mr. Resnick also meets with POM and its scientific advisors about POM-sponsored research "10 to 12 times a year officially" and three to four additional times to review what has been learned and where the company's research may go. (CX1376 (S. Resnick, OS Dep. at 223-24); *see also* CX0585**)**.

Response to Finding No. 32:

Complaint Counsel incorrectly cite to CX0585, as this evidence does not support Finding No. 32.

33. When Mrs. Resnick has chosen to involve him, Mr. Resnick has been involved at a high level with POM's advertising and marketing campaigns, including seeing headlines on occasion before ads were disseminated. (CX1376 (S. Resnick, OS Dep. at 140-42); CX1360 (S. Resnick, Dep. at 50-51)).

Response to Finding No. 33:

Mr. Resnick has not regularly involved himself with POM's advertising and marketing. Mr. Resnick is not involved in the day-to-day decisions related to the advertising of POM's products. (S. Resnick, Tr. 1869-70). Stewart Resnick, in consultation with POM's legal advisors, nevertheless maintains the ultimate decision-making authority to advertise the health benefits of POM's pomegranate products. (Tupper, Tr. 2975).

Stewart Resnick had the ultimate ability to decide whether any advertisements would be run. (S. Resnick, Tr. 1870; Tupper, Tr. 2975).

34. Mrs. Resnick participated in POM's business on almost a daily basis in the company's early years, and on a weekly or biweekly basis thereafter and through 2010. (L. Resnick, Tr. 93, 157-58; *see also* CX1375 (L. Resnick, Trop. Dep. at 19-22, 78); CX1359 (L. Resnick, Dep. at 108)).

Response to Finding No. 34:

Respondents have no specific response.

35. As recently as May 2010, Mrs. Resnick stated that she attended POM business meetings about once every two weeks. (CX1368 (L. Resnick, Welch Dep. at 28)).

Response to Finding No. 35:

Respondents have no specific response.

36. Mrs. Resnick testified that in 2011, she is still the chief marketing person at POM (L. Resnick, Tr. 289), and that was her role in 2010 and 2009. (CX1375 (L. Resnick, Trop. Dep. at 24); CX1362 (L. Resnick, TCCC Dep. at 47, 77-78)).

Response to Finding No. 36:

Respondents have no specific response.

37. Mrs. Resnick also has participated in the hiring and firing of heads of marketing at POM. (L. Resnick, Tr. 183-84, 227-28). POM has had at least nine different heads of marketing in the span of eight years. (*See* CCFF ¶IX.B.182).

Response to Finding No. 37:

Respondents have no specific response.

38. Mrs. Resnick has worked with POM's marketing department and Roll's ad agency, Fire Station, to develop creative concepts for POM marketing pieces and campaigns. (L. Resnick, Tr. 87-89; *see also* CX0409; CX0410; CX1359 (S. Resnick, Dep. at 70)).

Response to Finding No. 38:

Respondents object to "worked with" as vague and ambiguous. Complaint Counsel object to the proposed finding to the extent that Complaint Counsel attempt to use construe the documents and testimony as evidence supporting their theory that Firestation actively participated in the alleged misconduct or should be held liable under the common enterprise theory.

An advertising agency (or related agency) may be held liable for a deceptive advertisement if the agency was an active participate in the preparation of the detriment and if it knew or should have known that the advertisement was deceptive. *Standard Oil Co.*, 84 F.T.C. 1401, 1475 (1974), *aff'd and modified*, 577 F.2d 653 (9th Cir. 1978). An ad agency does not have to substantiate independently the claims or scientifically reexamine the advertiser's substantiation. *Bristol-Myers Co.,* 102 F.T.C. 21, 364 (1983).

Here, the undisputed testimony from employees working at FireStation, the consulting department, and the PR department of Roll, is that the science and research to be integrated into the advertisements, press release and the like, came from and was formulated by POM. (RFF 70-71; Perdigao, Tr. 660). None of the various departments undertook to separately examine whether the science was "substantiated" to levels required by the FDA, FTC or any other government agency. (RFF 70-71; Perdigao, Tr. 660). Any why would they? The science was peer-reviewed, often published in prestigious journals, performed by scientists and medical doctors alike, and provided in a form from persons they had had no reason to doubt as to substantiation. (RFF 378-435; 312-345; 266-269). In other words, Roll any other agency servicing a client, had no reason to suspect or have reason to investigate the advertisements may have been deceptive for any reason, let alone that the science given to them was allegedly unsubstantiated.

Accordingly, under *Standard Oil,* 84 F.T.C. 1401 and *Bristol-Myers Co.*, 102 F.T.C. 21 (1983), Roll cannot be held liable for their conduct.

Furthermore, by Complaint Counsel's own admission, the common enterprise theory exists for situations where corporations are so entwined that a judgment of no liability against one defendant would provide another defendant "with a clear mechanism for avoiding the terms of the order." *Nat'l Urological Group*, 645 F.Supp.2d at 1182. However, a finding of no liability against Roll, whose only alleged "involvement" in the alleged actionable conduct of POM, was providing advertising services to POM, through its separate advertising agency, "Firestation.", would not provide POM with a clear mechanism for avoiding the terms of any order. *Id*. Firestation operates like any other advertising agency. (Perdigao, Tr. 616-17). It takes instructions regarding the advertising from its clients, such as POM. (Leow, Tr. 462-63) POM's marketing department, not Firestation, decides whether to disseminate an ad or PR piece. (Perdigao, Tr. 615, 639). Thus, Roll did not, independent of POM, actively participate or control the decision to disseminate any of the challenged advertisements and thus cannot be found liable for claims made in POM's advertisements.

39. POM's marketing department received input and direction on creative briefs from Mrs. Resnick and Mr. Resnick. (CX1357 (Kuyoomjian, Dep. at 39-40)).

Response to Finding No. 39:

Complaint Counsel grossly mischaracterize Ms. Kuyoomijian's testimony. Ms. Kuyoomijian did not testify that Stewart and Lynda Resnick were substantively involved in creative briefs. She testified:

> Q: What other sources outside of Marketing would have input [in creative briefs].
> A. It could be Lynda Resnick.
> Q. Stewart Resnick?

> A. I think there were – again, not to generalize, but I think there were occasions where I would, either directly or indirectly, be aware that Stewart would have an opinion or some – some ideas or direction.

(CX1357 (Kuyoomijian, Dep. at 40)). As her testimony reveals, Ms. Kuyoomijian did not testify that POM's Marketing department received "direction" from Lynda Resnick. CX1357 (Kuyoomijian, Dep. at 40)). Moreover, Ms. Kuyoomijian's testimony regarding Mr. Resnick is extremely hesitant and vague and relies on hearsay (*e.g.*, she was purportedly "indirectly" "aware" of certain unidentified actions by Mr. Resnick. (CX1357 (Kuyoomijian, Dep. at 40)). Respondents also object that the terms "input" and "direction" are vague and ambiguous.

Respondents also object to the proposed finding to the extent Complaint Counsel construe specific language in POM's creative briefs to bolster their argument that Respondents intended to convey the claims that the Challenged Products treat, prevent or reduce the risk of heart disease, prostate cancer and erectile dysfunction. First, although Respondents genuinely believe in the healthful benefits of the Challenged Products and in the integrity of POM's research program (RFF 50 2-20), they dispute that they ever intended to convey or that the Challenged Ads do convey the claim that the Challenged Products treat, prevent or reduce the risk of heart disease, prostate cancer and erectile dysfunction or that they are "clinically proven" to do so. (RFF 496, 535, 538, 540, 545-50, 2209-11, 2280; CX1375 (L. Resnick, Trop., Dep. at 79-81)).

Second, specific language in POM's creative briefs do not counter the available evidence on Respondents' intent in POM's advertising. (RFF 496, 535, 538, 540, 545-50, 2209-11, 2280; CX1375 (L. Resnick, Trop., Dep. at 79-81)). Creative briefs were typically prepared by junior POM marketing employees. (Perdigao, Tr. 2790; Tupper, Tr. 921; CX1356 (Leow, Dep. 40)). Mrs. Resnick and Mr. Tupper seldom, if ever, saw, reviewed or provided feedback on creative briefs. (CX1359 (L. Resnick, Dep. 102-03, 109);

Tupper, Tr. 923-24; CX1353 (Tupper, Dep. 224); Perdigao, Tr. 623-24, 2790-91; (CX1348 (Perdigao, Dep. 170, 268); Leow, Tr. 459-60; CX1356 (Leow, Dep. 54-55)). Mrs. Resnick testified that she typically did not discuss any particular creative brief with POM marketing employees. (CX01359 (L. Resnick, Dep. 109). There is no evidence that Mr. Resnick has ever seen a creative brief. (Perdigao, Tr. 2791). Indeed, the evidence shows that he had very little involvement in the marketing of POM's products and no day-to-day involvement. (RFF 75-76; Perdigao, Tr. 604; Leow, Tr. 419, 465-66).

There is also only a tenuous relationship between creative briefs and final advertisement. The creative process is collaborative and fluid, with lots of people involved, which results in the final advertisement being vastly different than the rough idea initially discussed in the creative brief. (Perdigao, Tr. 609-14, 621-22, 2790-91; Leow, Tr. 458-59, 463-65; Tupper, Tr. 920, 929). Indeed, the ideas of the junior marketing staff expressed in creative briefs were frequently modified, altered and rejected. (Perdigao, Tr. 2790; Leow, Tr. 460). This is simply the nature of the creative process as implemented at Fire Station and POM. Creative briefs serve the administrative function of initiating a Fire Station work order. (Perdigao, Tr. 616-17, 2790). They also provided Fire Station a basic overview on a particular marketing project. (Tupper, Tr. 921; Perdigao, Tr. 622-23; Leow, Tr. 451). Because creative briefs were preliminary in nature, they were very general. (Rushton, Tr. 1396). Thus, the purpose of creative briefs was merely to generate creative ideas around a concept, not dictate specific wording, graphics or claims to be included in the advertisement. (Tupper, Tr. 921; Perdigao, Tr. 621-23).

Once a Fire Station received a creative brief, a creative team or teams was assigned to develop concepts for the proposed advertisement. (Perdigao, Tr. 619, 621-22; CX1348 (Perdigao, Dep. 54); Leow, Tr. 453). The concepts were then shown to Liz Leow, Fire

Station's Creative Director, who might like them, dislike them, adjust them, or send them back to the drawing board. (Perdigao, Tr. 621-22; CX1348 (Perdigao, Dep. 55); Leow, Tr. 458-59). If Ms. Leow liked the concepts, they went to Mr. Perdigao, head of Firestation advertisement agency, for review and then to POM marketing for comment. (Perdigao, Tr. 615; CX1348 (Perdigao, Dep. 55); Leow, Tr. 459). There were often multiple rounds of revisions to the concepts at this stage of the creative process. (Leow, Tr. 459). Sometimes the larger creative concepts were rejected by POM and Fire Station had to start the creative process from the beginning. (Leow, Tr. 460; CX1356 (Leow, Dep. 42-43)).

In sum, because the ad that actually ran typically did not reflect the creative brief prepared by the junior POM marketing employee, it is not accurate to describe creative briefs as reflective of the "intent" of an advertisement. (Perdigao, Tr. 2791). Mr. Michael Perdigao was asked several questions about the use of the "creative brief" at Firestation, in connection with POM:

> Q. All right. Are the creative briefs typically seen by Mrs. Resnick?
> A. No.
> Q. Are they typically seen by Mr. Resnick?
> A. No.
> Q. Are they typically seen by the legal department?
> A. No.
> Q. Do the ads that actually are run typically reflect the creative brief that started the process by this junior person writing a creative brief?
> A. Not generally with POM, no.
> Q. All right. If I wanted to determine the intention of the company or the people that run the company, would I look to the creative briefs to show that intention?
> A. No.

(Perdigao, Tr. 2790-2791). Accordingly, creative briefs provide no basis to infer Respondents' intent to convey the Challenged Claims

40. Mrs. Resnick has had a principal role in approving advertising content since POM's inception. (CX1368 (L. Resnick, Welch Dep. at 9); *see also* CX1357 (Kuyoomjian, Dep. at 127 (noting Mrs. Resnick's request that all ad copy be submitted for her approval); CX1357 (Kuyoomjian, Dep. at 56-57) (stating that Mrs. Resnick approved POM's advertising campaigns); CX1357 (Kuyoomjian, Dep. at 77) (noting that more often than not, Mrs. Resnick provided final approval of headlines used in POM's ads); CX1346 (Rushton, Dep. at 42) (approved website designs); CX0147). Mrs. Resnick, Mr. Tupper, and POM's senior marketing officer have final say over advertising content. (L. Resnick, Tr. 87; *see also* CX1357 (Kuyoomjian, Dep. at 50-51) (POM's former Senior Vice President of Marketing testified that she went to Mrs. Resnick and Mr. Tupper for approvals on advertising)).

Response to Finding No. 40:

Respondents have no response other than to object to the extent Complaint Counsel insinuate that Mr. Tupper was involved in every single aspect of marketing or that he had final decision making authority over marketing decisions. Ms. Kuyoomjian, when asked about the hierarchy of approval in marketing decisions, said "the only thing I [can] say is Matt reported to Lynda." (CX1357 (Kuyoomjian, Dep at 52). Mr. Tupper did not, independent of the Resnicks, develop the marketing direction or decide how POM products would be marketed. (Tupper, Tr. 2974-75; (CX1368 (L. Resnick Welch's Dep. at 9); L. Resnick, Tr. 93; PX0327 (Glovsky Dep. at 36).

41. POM's former Senior Vice President of Marketing testified that Mrs. Resnick and Mr. Tupper determined which health conditions – such as cardiovascular health, prostate health, or diabetes – to discuss in POM's advertising. (CX1357 (Kuyoomjian, Dep. at 199-200); *see also* L. Resnick, Tr. 268-69 (stating that decisions about when to use a particular study in POM advertising likely are joint decisions made by Mr. Resnick, Mr. Tupper, and other advisors at POM)).

Response to Finding No. 41:

Respondents have no response other than to object to the extent Complaint Counsel insinuate that Mr. Tupper and Mrs. Resnick were solely responsible for reviewing scientific research or to the extent Complaint Counsel imply Mr. Tupper had final decision making authority over advertising.

Respondents have relied heavily upon the advice and counsel of esteemed scientists and scientific advisers in connection with the conduct of POM's research program. (Liker, Tr. 1894). POM has a scientific advisory board composed of individuals who do not conduct the research for POM but who are experts in certain health areas. (Liker, Tr. 1889-93). Members of the advisory board discuss and review completed, ongoing and potential future studies and meet with Respondents to discuss the same. (Liker, Tr. 1859, 1892-93).

Ms. Kuyoomjian, when asked about the hierarchy of approval in marketing decisions, said "the only thing I [can] say is Matt reported to Lynda." (CX1357 (Kuyoomjian, Dep at 52). Mr. Tupper was involved in POM's operations, science research, and marketing. However none of these aspects of POM's business were under Mr. Tupper's ultimate control. (CX1363 (S. Resnick, Coke Dep. at 86); CX1348 (Perdigao, Dep. at 50, 60-61); CX1359 (L. Resnick, Dep. at 36); CX1362 (L. Resnick, Coke Dep. at 103-104).

42. Mrs. Resnick developed, implemented, and relied on consumer and marketing research. (CX1359 (L. Resnick, Dep. at 76-78); CCFF ¶ IX.G.1.596).

Response to Finding No. 42:

Complaint Counsel mischaracterizes the testimony of Mrs. Resnick. Mrs. Resnick did not testify that she "developed, implemented, and relied on consumer and marketing research". Rather, Mrs. Resnick testified generally regarding consumer research, and Complaint Counsel presents no evidence regarding reliance on the results of the Bovitz Survey. The evidence presented is merely a generalized overview of POM Wonderful's use of consumer research and Mrs. Resnick's personal opinion about the importance of brevity in advertising.

43. Mrs. Resnick also provided input on and was involved in approving POM's media plans. (CX1357 (Kuyoomjian, Dep. at 82-84) (noting that the Vice President of Marketing at POM, Mr. Tupper, Fire Station, including Mr. Perdigao, and Mr. Resnick were involved in approving POM's media plans as well, but final approval would come from Mrs. Resnick)).

Response to Finding No. 43:

Complaint Counsel mischaracterizes Ms. Kuyoomijan's testimony. Ms. Kuyoomijan never testified that final approval of media plans came from Mrs. Resnick, rather she testified that, "the person whose approval ultimately I would be looking for is Lynda." (CX1357 (Kuyoomijan, Dep. at 84).

44. Over the years, Mrs. Resnick has delivered speeches, made public and media appearances, and written a book that promote the health benefits of POM's products. (CX1382_0010-11; CX1426_00032-35, Ex. E-6; CX0001; CX0285_0011; CX0472).

Response to Finding No. 44:

Irrelevant. Respondents deny this proposed finding of fact to the extent Complaint Counsel insinuate that a book, speeches or public/media appearances by Mrs. Resnick's constitute advertising. These activities are not actionable advertising as defined by the FTC in *In the Matter of R.J. Reynolds Tobacco Co., Inc.*, 9206, 111 F.T.C. 539 (1988. Mrs. Resnick's primary purpose in authoring her book, delivering speeches and making public and media appearances was not to promote POM products but instead was to share her business acumen as well as her unique views on marketing and advertising. (See RFF 2549, 2556, 2586, 2601). Further, Mrs. Resnick's references to the health-giving properties of pomegranates during most of the cited interviews were very small. (See RFF 2557, 2571, 2588, 2602). Moreover, Complaint Counsel has failed to introduce any evidence whatsoever that any of the statements by Mrs. Resnick were material to consumers' decisions to purchase POM Juice. (RFF 2551).

2. Matthew Tupper

45. Respondent Matthew Tupper joined Roll in May 2001 as vice president of strategy. (JX0003 ¶ B.5).

Response to Finding No. 45:

Respondents have no specific response

46. Mr. Tupper joined POM as a full-time employee in 2003, as Chief Operating Officer. (JX0001 ¶¶ 12, 18; Tupper, Tr. 886-87).

Response to Finding No. 46:

Respondents have no specific response.

47. In 2005, his title at POM changed to President, but his responsibilities did not change from those in his position as Chief Operating Officer. (JX0001 ¶¶ 12, 18; Tupper, Tr. 886-87).

Response to Finding No. 47:

Respondents have no specific response.

48. Respondents admit that "Mr. Tupper, as an officer of POM Wonderful LLC, together with others, formulates, directs, or controls the policies, acts, or practices of POM Wonderful, LLC." (PX0364-0002, Answer ¶ 5).

Response to Finding No. 48:

Respondents add the following explanatory facts to this proposed finding. Mr. Tupper has no ownership interest or equity shares in POM. (CX1353 (Tupper, Dep. at 14); Tupper, Tr. 2973). Mr. Tupper reported directly to Stewart Resnick and had "dotted line" reporting to Lynda Resnick. (CX1364 (Tupper, Dep. at 14); Tupper, Tr. 2973; CX1375 (L Resnick, Tropicana Dep. at 33-34); (CX1357 (Kuyoomjian, Dep at 52)). Mr. Tupper had no more authority at POM than was delegated to him by Stewart Resnick. (S. Resnick, Tr. 1870). Mr. Tupper was involved in POM's operations, science research, and marketing. However none of these aspects of POM's business were under Mr. Tupper's ultimate control. (CX1363 (S. Resnick, Coke Dep. at 86); CX1348 (Perdigao, Dep. at 50, 60-61); CX1359 (L. Resnick, Dep. at 36); CX1362 (L. Resnick, Coke Dep. at 103-104). In Mr. Resnick's own words, he not Mr. Tupper, was the "ultimate sole decision-maker on everything." (CX1367 (S. Resnick, Welch Dep. at 55)). Mr. Tupper consulted with Mr. Resnick or Mrs. Resnick for any major restructuring or personnel decisions. (Tupper, Tr. 903; CX1364 (Tupper, Coke Dep. at 31)). Mr. Tupper did not, independent

of the Resnicks, develop the marketing direction or decide how POM products would be marketed. (Tupper, Tr. 2974-75; (CX1368 (L. Resnick Welch's Dep. at 9); L. Resnick, Tr. 93; PX0327 (Glovsky, Dep. at 36). Lynda Resnick, for example, had the final authority over advertising content and concepts. (CX1368 (L. Resnick, Welch Dep. at 9); L. Resnick, Tr. 93). Stewart Resnick had the ultimate ability to decide whether any advertisement would be run. (S. Resnick, Tr. 1870; Tupper, Tr. 2975). Stewart Resnick or Lynda Resnick, and not Mr. Tupper had the final authority to resolve any issues or disputes regarding advertising decisions. (CX1365 (Perdigao, Coke Dep. at 36-37)).

49. Mrs. Resnick likewise has described Mr. Tupper as "[her] partner at POM since 2003." (CX0001_0037; L. Resnick, Tr. 230).

Response to Finding No. 49:

Complaint Counsel's proposed finding mischaracterizes evidence in the record to the extent it implies that Mr. Tupper's authority at POM was equal to the Resnicks. Mr. Tupper has no ownership interest or equity shares in POM. (CX1353 (Tupper, Dep. at 14); Tupper, Tr. 2973). Mr. Tupper reported directly to Stewart Resnick and had "dotted line" reporting to Lynda Resnick. (CX1364 (Tupper, Dep. at 14); Tupper, Tr. 2973; CX1375 (L Resnick, Tropicana Dep. at 33-34); (CX1357 (Kuyoomjian, Dep at 52)). Mr. Tupper had no more authority at POM than was delegated to him by Stewart Resnick. (S. Resnick, Tr. 1870). Mr. Tupper was involved in POM's operations, science research, and marketing. However none of these aspects of POM's business were under Mr. Tupper's ultimate control. (CX1363 (S. Resnick, Coke Dep. at 86); CX1348 (Perdigao, Dep. at 50, 60-61); CX1359 (L. Resnick, Dep. at 36); CX1362 (L. Resnick, Coke Dep. at 103-104). In Mr. Resnick's own words, he not Mr. Tupper, was the "ultimate sole decision-maker on everything." (CX1367 (S. Resnick, Welch Dep. at 55)). Mr. Tupper consulted with Mr. Resnick or Mrs. Resnick for any major restructuring or personnel decisions. (Tupper, Tr. 903; CX1364 (Tupper, Coke Dep. at 31)). Mr. Tupper did not, independent

of the Resnicks, develop the marketing direction or decide how POM products would be marketed. (Tupper, Tr. 2974-75; (CX1368 (L. Resnick Welch's Dep. at 9); L. Resnick, Tr. 93; PX0327 (Glovsky Dep. at 36). Lynda Resnick, for example, had the final authority over advertising content and concepts. (CX1368 (L. Resnick, Welch Dep. at 9); L. Resnick, Tr. 93). Stewart Resnick had the ultimate ability to decide whether any advertisement would be run. (S. Resnick, Tr. 1870; Tupper, Tr. 2975). Stewart Resnick or Lynda Resnick, and not Mr. Tupper had the final authority to resolve any issues or disputes regarding advertising decisions. (CX1365 (Perdigao, Coke Dep. at 36-37)).

50. POM's former Senior Vice President of Marketing testified that she "would never do something [Mr. Tupper] wasn't involved in. He was [her] boss." (CX1357 (Kuyoomjian, Dep. at 51)).

Response to Finding No. 50:

Respondents have no response other than to object to the extent Complaint Counsel insinuate that Mr. Tupper was involved in every single aspect of marketing or that he had final decision making authority over marketing decisions. Ms. Kuyoomjian, when asked about the hierarchy of approval in marketing decisions, said "the only thing I [can] say is Matt reported to Lynda." (CX1357 (Kuyoomjian, Dep at 52). Mrs. Resnick has said, "I'm the head person in marketing." (CX1362 (L. Resnick, Coke Dep. at 77). Mr. Tupper did not, independent of the Resnicks, develop the marketing direction or decide how POM products would be marketed. (Tupper, Tr. 2974-75; (CX1368 (L. Resnick Welch's Dep. at 9); L. Resnick, Tr. 93; PX0327 (Glovsky Dep. at 36). Lynda Resnick, for example, had the final authority over advertising content and concepts. (CX1368 (L. Resnick, Welch Dep. at 9); L. Resnick, Tr. 93).

51. Mr. Tupper was responsible for managing the day-to-day affairs of POM, which employs roughly 350 people worldwide. (JX0003 ¶ B.6).

Response to Finding No. 51:

Respondents have no specific response.

52. Mr. Tupper reported to Mr. and Mrs. Resnick. (CX1367 (S. Resnick, Welch Dep. at 53)).

Response to Finding No. 52:

Respondents have no specific response.

53. Mr. Tupper interacted with Mr. Resnick on all aspects of the business (*e.g.*, financial, marketing, manufacturing, sales, and medical research) from once a week to several times a week. (Tupper, Tr. 891-92; CX1353 (Tupper, Dep. at 9-10); S. Resnick, Tr. 1632; CX1376 (S. Resnick, OS Dep. at 223)).

Response to Finding No. 53:

The cited evidence does not support Complaint Counsel's proposed finding of fact. Mr. Tupper did not have weekly interactions with Mr. Resnick regarding "marketing" or "medical research." Complaint Counsel's citations contain no reference to Mr. Tupper and Mr. Resnick interacting regarding "medical research." Mr. Resnick merely said that he discussed "some research" with Mr. Tupper at meetings. (CX1376 (S. Resnick, Ocean Spray Dep. at 223)). Additionally, Mr. Tupper only had "occasional" interactions with Mr. Resnick regarding marketing. (Tupper, Tr. 892). Likely because "not all the people engaged in the sales and marketing of the [Challenged Products] report[ed] either directly or indirectly to [Mr. Tupper]." (CX1353 (Tupper, Dep. at 10)). Finally, while Mr. Tupper was involved in POM's operations, science, and marketing none of those aspects of POM's business were under Mr. Tupper's ultimate control. (CX1363 (S. Resnick, Coke Dep. at 86); CX1348 (Perdigao, Dep. at 50, 60-61); CX1359 (L. Resnick, Dep. at 36); CX1362 (L. Resnick, Coke Dep. at 103-104). Rather, in Mr. Resnick's own words, he not Mr. Tupper, was the "ultimate sole decision-maker on everything." (CX1367 (S. Resnick, Welch Dep. at 55)).

54. At POM, nine or ten people have directly reported to Mr. Tupper, including the Vice President of Marketing, the Vice President of Clinical Development (currently Bradley Gillespie ("Dr. Gillespie")), and the head of the Operations Department. (Tupper, Tr. 888-89, 2974; CX1353 (Tupper, Dep. at 24-25).

Response to Finding No. 54:

Respondents have no specific response.

55. Mark Dreher, Ph.D., POM's former Vice President of Scientific and Regulatory Affairs, ("Dr. Dreher"), reported to Mr. Tupper. (Dreher, Tr. 527, 529; L. Resnick, Tr. 249).

Response to Finding No. 55:

Respondents have no specific response.

56. Fiona Posell ("Ms. Posell"), former Vice President of Corporate Communications at Roll and POM, reported to Mr. Tupper and Mrs. Resnick. (Posell, Tr. 299, 321, 325).

Response to Finding No. 56:

Respondents have no specific response.

57. Mr. Tupper had responsibility over POM's consumer affairs department, and he had access to, and received weekly summaries of, correspondence from consumers regarding POM's products. (L. Resnick, Tr. 255; Tupper, Tr. 1046; *see also* CX0454-56 (examples of consumer correspondence)).

Response to Finding No. 57:

Respondents dispute this proposed finding as contrary to evidence in the record. Mr. Tupper was not directly responsible for POM's consumer affairs department, he did not have regular access to their records and only occasionally did he receive weekly reports regarding correspondence from consumers. Mrs. Resnick, when asked if the consumer affairs department was under Mr. Tupper's direct supervision, testified "maybe not directly but indirectly." (L. Resnick, Tr. 255). Mr. Tupper did not testify he had access to consumer correspondence records he merely said that he "[could] get access to them."

(Tupper, Tr. 1046). Finally when asked if he got weekly summaries of consumer correspondence he testified only that "sometimes" he did. (Tupper, Tr. 1046).

Additionally, Respondents previously objected to exhibits CX0454, CX0455 and CX0456 (listed on Attachment B to JX2 as a conditionally admitted exhibits) on the grounds that the exhibits contain excerpts of an available original document and therefore do not constitute the best evidence. Moreover, Respondents object to these exhibits on the ground that they lack a foundation and lack authentication.

58. Mr. Tupper has hired and fired POM employees, including the head of POM's marketing department ("POM Marketing"), on his own, or, depending on the situation, in consultation with either Mr. or Mrs. Resnick. (Tupper, Tr. 902-03; *see also* CX1360 (S. Resnick, Dep. at 22-23); CX1359 (L. Resnick, Dep. at 41, 45); CX1353 (Tupper, Dep. at 24-25)).

Response to Finding No. 58:

Just like managers at all levels of a business Mr. Tupper would on occasion hire and fire low level employees. However, Mr. Tupper testified that he had to consult with Stewart Resnick or Lynda Resnick for any major restructuring or personnel decisions at POM. (Tupper, Tr. 903). In Mr. Resnick's own words, he not Mr. Tupper, was the "ultimate sole decision-maker on everything." (CX1367 (S. Resnick, Welch Dep. at 55))

59. In consultation with Mr. Resnick, Mr. Tupper eliminated the position of Vice President of Scientific Affairs and created the position of Vice President of Clinical Development at POM. (CX1353 (Tupper, Dep. at 30-31)).

Response to Finding No. 59:

Respondents have no response other than to object to the extent Complaint Counsel insinuate that Mr. Tupper had the authority to eliminate and restructure senior positions on his own. Mr. Tupper testified that he had to consult with Stewart Resnick or Lynda Resnick for any major restructuring or personnel decisions at POM. (Tupper, Tr. 903).

In Mr. Resnick's own words, he not Mr. Tupper, was the "ultimate sole decision-maker on everything." (CX1367 (S. Resnick, Welch Dep. at 55)).

Mr. Tupper oversaw and administered POM's budget for all departments, and had authority to sign checks and contracts on behalf of the company. (Tupper, Tr. 904, 912-13; CX0606_0003).

60. Mr. Tupper oversaw and administered POM's budget for all departments, and had authority to sign checks and contracts on behalf of the company. (Tupper, Tr. 904, 912-13; CX0606_0003).

Response to Finding No. 60:

Respondents dispute this proposed finding as contrary to the evidence in the record to the extent Complaint Counsel insinuate that Mr. Tupper had ultimate budgeting authority at POM. In reality, Mr. Tupper only administrated budgets set by Mr. Resnick. (S. Resnick, Tr. 1631). Mr. Resnick makes the ultimate decisions about what POM will invest and how the business will expand. (S. Resnick, Tr. 1631). Additionally Mr. Resnick set all budgets for POM including those for marketing and advertising. (S. Resnick, Tr. 1631).

61. When she reduced her day-to-day involvement in POM's business, Mrs. Resnick felt confident that Mr. Tupper would be able to take care of the marketing aspects of the business. (L. Resnick, Tr. 229).

Response to Finding No. 61:

Respondents dispute this proposed finding as contrary to the evidence in the record to the extent Complaint Counsel insinuate that Mr. Tupper ever had ultimate marketing authority at POM. Mrs. Resnick continues to be in involved in the POM business. Mrs. Resnick has said, "I'm the head person in marketing." (CX1362 (L. Resnick, Coke Dep. at 77). Mr. Tupper never had final approval authority in deciding POM's marketing, advertising content, concepts or media plans independent of the Resnicks. (Tupper, Tr.

2974-75; CX1368 (L. Resnick Welch's Dep. at 9); L. Resnick, Tr. 93; PX0327 (Glovsky Dep. at 36). The Resnicks had the ultimate authority in developing the direction of POM marketing and how to market POM products, and Mr. Tupper merely implemented the direction, once it was decided upon by the Resnicks. (Tupper, Tr. 2974-75). Lynda Resnick, for example, had the final authority over advertising content and concepts. (CX1368 (L. Resnick, Welch Dep. at 9); L. Resnick, Tr. 93). Stewart Resnick had the ultimate ability to decide whether any advertisement would be run. (S. Resnick, Tr. 1870; Tupper, Tr. 2975). Stewart Resnick or Lynda Resnick, and not Mr. Tupper had the final authority to resolve any issues or disputes regarding advertising decisions. (CX1365 (Perdigao, Coke Dep. at 36-37).

62. One of Mr. Tupper's responsibilities was to understand the science and help POM's marketing team "wade through it." (L. Resnick, Tr. 261; Tupper, Tr. 899, 914).

Response to Finding No. 62:

Respondents object to the extent Complaint Counsel insinuate that Mr. Tupper was solely responsible for understanding and conveying scientific research information to POM's marketing department. The marketing department received information from a variety of sources including synopses of research prepared by third parties as well as from individuals like Dr. Dreher or Dr. Gillespie. (CX1357 (Kuyoomjian, Dep. at 106-07, 164-66)).

63. Mr. Tupper was considered a senior leader at POM, and organized meetings to review advertising copy from a scientific perspective prior to dissemination. (Dreher, Tr. 530).

Response to Finding No. 63:

Respondents' object to Complaint Counsel's use of Dr. Dreher's testimony for the proposition that Mr. Tupper lead and organized meetings to review advertising copy from a scientific perspective prior to dissemination. Dr. Dreher testified that he "was not involved in that" process and therefore has no personal knowledge about any advertising

copy review procedure. (Dreher, Tr. 530). Respondents' further object that Complaint Counsel's finding of fact is inadmissible hearsay, lacking any exception, and is being offered as proof of the matters stated therein.

64. According to POM's former Senior Vice President of Marketing, Mr. Tupper was the primary person from whom she received information on POM's medical research, including information that would appear in consumer advertising copy, and Mr. Tupper generally provided input as to how to describe the medical research used in ad copy. (CX1357 (Kuyoomjian, Dep. at 164-66); *see also* CX0906_0001-02 (providing guidance on what types of studies should be used in newsletters and websites)).

Response to Finding No. 64:

Respondents object to the extent Complaint Counsel insinuate that Mr. Tupper was the sole means by which Ms. Kuyoomjian, POM's former Senior Vice President of Marketing, received information about POM's research. Ms. Kuyoomjian received information from a variety of sources including synopses of research prepared by POM and third parties. (CX1357 (Kuyoomjian, Dep. at 164-166). In addition, Ms. Kuyoomjian, at various times, received research updates from both Dr. Dreher and Dr. Gillespie. (CX1357 (Kuyoomjian Dep. at 106-07). While Mr. Tupper did work to connect POM's scientific research with the POM's marketing he did not do so independently or without the guidance of other individuals. (Tupper, Tr. 2976). In fact, POM has a scientific advisory board composed of individuals who do not conduct the research for POM but who are experts in certain health areas. (Liker, Tr. 1889-93). Members of the advisory board discuss and review completed, ongoing and potential future studies and meet with Respondents to discuss the same. (Liker, Tr. 1859, 1892-93).

65. Sometimes, Mr. Tupper would provide the specific words to use when presenting medical research facts, and in other instances, POM Marketing or Fire Station employees would "take a stab at writing [this information] and send it to [Mr. Tupper] to approve." (CX1357 (Kuyoomjian, Dep. at 169-70)).

Response to Finding No. 65:

Respondents dispute this proposed finding as contrary to the evidence in the record to the extent Complaint Counsel insinuate that Mr. Tupper was the marketing department's sole source regarding research information or that Mr. Tupper ever had ultimate marketing authority at POM.

POM's marketing department and Fire Station received information from a variety of sources including synopses of research prepared by POM and third parties. (CX1357 (Kuyoomjian, Dep. at 164-166). In addition, Ms. Kuyoomjian, at various times, received research updates from both Dr. Dreher and Dr. Gillespie. (CX1357 (Kuyoomjian Dep. at 106-07). While Mr. Tupper did work to connect POM's scientific research with the POM's marketing he did not do so independently or without the guidance of other individuals. (Tupper, Tr. 2976). In fact, POM has a scientific advisory board composed of individuals who do not conduct the research for POM but who are experts in certain health areas. (Liker, Tr. 1889-93). Members of the advisory board discuss and review completed, ongoing and potential future studies and meet with Respondents to discuss the same. (Liker, Tr. 1859, 1892-93).

Mr. Tupper never had final approval authority in deciding POM's marketing, advertising content, concepts or media plans independent of the Resnicks. (Tupper, Tr. 2974-75; CX1368 (L. Resnick Welch's Dep. at 9); L. Resnick, Tr. 93; PX0327 (Glovsky Dep. at 36). The Resnicks had the ultimate authority in developing the direction of POM's marketing and how to market POM products, and Mr. Tupper merely implemented the direction, once it was decided upon by the Resnicks. (Tupper, Tr. 2974-75). Lynda Resnick, for example, had the final authority over advertising content and concepts. (CX1368 (L. Resnick, Welch Dep. at 9); L. Resnick, Tr. 93). Stewart Resnick had the ultimate ability to decide whether any advertisement would be run. (S. Resnick, Tr.

1870; Tupper, Tr. 2975). Stewart Resnick or Lynda Resnick, and not Mr. Tupper had the final authority to resolve any issues or disputes regarding advertising decisions. (CX1365 (Perdigao, Coke Dep. at 36-37).

66. Mr. Tupper would inform the head of marketing when the monetary figure of what POM spent on medical research (*e.g.*, "Only POM is backed by $28 million in medical research conducted at the world's leading universities.") needed to be updated in advertising copy. (CX1357 (Kuyoomjian, Dep. at 222-23); *see* CX0319_0002).

Response to Finding No. 66:

Respondents have no response other than to object to the extent Complaint Counsel insinuate that Mr. Tupper was individually and solely responsible for keeping track of POM's research expenses.

67. Mr. Tupper has reviewed work on each of POM's large advertising campaigns at the concept stage before they were shown to Lynda Resnick. (Leow, Tr. 459-60).

Response to Finding No. 67:

Respondents dispute this proposed finding as contrary to the evidence in the record. Complaint Counsel cite to only a portion of Ms. Leow's testimony wherein she says, "I recall that [Matt Tupper] reviewed work on each of the large campaigns before they were shown to Lynda." The very next line reads, in its totality, "I wasn't always present at that time, but . . . ."(Leow, Tr. 460). Complaint Counsel's finding of fact offers the impression that Ms. Leow has personal knowledge of Mr. Tupper reviewing every large campaign, however, Ms. Leow's own testimony proves that proposition is false. Respondent's object to this finding of fact as inadmissible hearsay because Ms. Leow lacks personal knowledge of facts Complaint Counsel allege support this finding.

Furthermore, Respondents dispute this proposed finding as contrary to the evidence in the record to the extent Complaint Counsel insinuate that Mr. Tupper independently developed marketing concepts or direction. Mr. Tupper did not have final approval

authority in deciding POM's marketing and advertising content, concepts and media plans independent of the Resnicks. (Tupper, Tr. 2974-75; CX1368 (L. Resnick Welch's Dep. at 9); L. Resnick, Tr. 93; PX0327 (Glovsky Dep. at 36). The Resnicks had the ultimate authority in developing the direction of POM marketing and how to market POM products, and Mr. Tupper merely implemented the direction, once it was decided upon by the Resnicks. (Tupper, Tr. 2974-75).

68. Mr. Tupper would have discussions with POM Marketing about individual parts or elements of creative briefs. (Tupper, Tr. 924). Mr. Tupper reviewed and made decisions about headlines to be used for a new advertising campaign. He also reviewed advertising copy and, depending on the project, had final say over POM advertising content and, which advertisements should or should not run. (L. Resnick, Tr. 87; Leow, Tr. 423, 464, 466; Tupper, Tr. 925-27; S. Resnick, Tr. 1870; CX1357 (Kuyoomjian, Dep. at 141-42)).

Response to Finding No. 68:

Respondents dispute portions of this finding of fact as contrary to the evidence in the record. Mr. Tupper actually testified that he would be "one of the decision-makers in terms of choosing the headline" not the ultimate decision maker. (Tupper, Tr. 925). Mr. Tupper did not have the final approval authority in deciding POM's marketing and advertising content or concepts. (CX1368 (L. Resnick Welch's Dep. at 9); L. Resnick, Tr. 93; PX 1347 (Glovsky, Dep. at 36); CX1357 (Kuyoomjian, Dep. at 84). Ms. Leow testified that Mr. Tupper participated in reviewing advertising content but she never said he had final authority to approve it. (Leow, Tr. 423, 464, 466). Mr. Resnick testified that Mr. Tupper had no more authority at POM than was "delegate[d] to him." (S. Resnick, Tr. 1870).

69. Mr. Tupper participated in meetings in which Fire Station and POM personnel presented and reviewed advertising concepts and advertising. (L. Resnick, Tr. 91-92; Tupper, Tr. 929).

Response to Finding No. 69:

Respondents dispute this proposed finding as contrary to the evidence in the record to the extent Complaint Counsel insinuate that Mr. Tupper independently developed "advertising concepts and advertising." Mr. Tupper did not have final approval authority in deciding POM's marketing and advertising content, concepts and media plans independent of the Resnicks. (Tupper, Tr. 2974-75; CX1368 (L. Resnick Welch's Dep. at 9); L. Resnick, Tr. 93; PX0327 (Glovsky Dep. at 36). The Resnicks had the ultimate authority in developing the direction of POM marketing and how to market POM products, and Mr. Tupper merely implemented the direction, once it was decided upon by the Resnicks. (Tupper, Tr. 2974-75).

70. When there was no current senior leader for the marketing department, Mr. Tupper would step in to some extent, and would at times take the lead in communicating with Fire Station. (L. Resnick, Tr. 185; Perdigao, Tr. 611-12).

Response to Finding No. 70:

Respondents dispute this proposed finding as contrary to the evidence in the record to the extent Complaint Counsel insinuate that Mr. Tupper had final decision making power for the marketing department. Mr. Tupper did not have final approval authority in deciding POM's marketing and advertising content, concepts and media plans independent of the Resnicks. (Tupper, Tr. 2974-75; CX1368 (L. Resnick Welch's Dep. at 9); L. Resnick, Tr. 93; PX0327 (Glovsky Dep. at 36). The Resnicks had the ultimate authority in developing the direction of POM marketing and how to market POM products, and Mr. Tupper merely implemented the direction, once it was decided upon by the Resnicks. (Tupper, Tr. 2974-75).

71. On average, Mr. Tupper has interacted with Michael Perdigao, head of Fire Station creative agency, once a week. (Perdigao, Tr. 613).

Response to Finding No. 71:

Respondents have no specific response.

72. Mr. Tupper attended most of the marketing meetings with Mrs. Resnick ("LRR Meetings"), at which the highest-level executives involved in marketing discussed how to better market POM's products. (Perdigao, Tr. 624-25).

Response to Finding No. 72:

Respondents have no specific response.

73. Mr. Tupper and Mrs. Resnick approved the "Comic Book" (or "Super Hero") campaign and approved the decision in 2008 to bring back the prior "Dressed Bottle" advertising campaign. (CX1357 (Kuyoomjian, Dep. at 51-52); Perdigao, Tr. 628).

Response to Finding No. 73:

Respondents dispute this proposed finding as contrary to the evidence in the record to the extent Complaint Counsel insinuate that Mr. Tupper's approval was necessary for a marketing campaign to go forward. Ms. Kuyoomjian, when asked about the hierarchy of approval in marketing decisions, said "the only thing I [can] say is Matt reported to Lynda." (CX1357 (Kuyoomjian, Dep at 52). Mr. Tupper did not, independent of the Resnicks, develop the marketing direction or decide how POM products would be marketed. (Tupper, Tr. 2974-75; (CX1368 (L. Resnick Welch's Dep. at 9); L. Resnick, Tr. 93; PX0327 (Glovsky Dep. at 36). Lynda Resnick, for example, had the final authority over advertising content and concepts.

74. Mr. Tupper, as President of the company, contributed statements to POM's website, gave verbal statements that were then transcribed and posted on the website, and provided input on the wording that appeared on POM's website. (Tupper, Tr. 918; CX0336_0001, 0003, 0009; CX0049; CX0050).

Response to Finding No. 74:

Respondents object to Complaint Counsel's proposed finding that Mr. Tupper "provided input on the wording that appeared on POM's website" as unsupported by the evidence

in record. Respondents previously objected to exhibits CX0049 and CX0050 (listed on Attachment B to JX2 as conditionally admitted exhibits) on the grounds that the exhibits constitute unreliable hearsay, lacking any exception, and are being offered as proof of the matters stated therein. As a result, these exhibits should be excluded from record.

75. Mr. Tupper appeared on a Fox Business News Channel program to discuss POM's products, and has been interviewed many times by newspapers and magazines in his capacity as President of POM. (Tupper, Tr. 919-20; CX1426, Ex. E-7).

Response to Finding No. 75:

Respondents dispute this proposed finding as contrary to the evidence in the record to the extent Complaint Counsel insinuate that Mr. Tupper's Fox Business interview is an "advertisement" that would be actionable under the FTCA.

76. If Mrs. Resnick was not available to approve headlines for press releases, Mr. Tupper has performed this function. (L. Resnick, Tr. 262).

Response to Finding No. 76:

The cited evidence does not support Complaint Counsel's proposed finding of fact. Mrs. Resnick was asked if she had approved a specific headline for a specific press release in 2007. She responded "not necessarily." (L. Resnick, Tr. 262). Mrs. Resnick was then asked who would have approved of the headline to which she replied Mr. Tupper. From this exchange regarding a single headline in single specific press release Complaint Counsel inaccurately infer that Mr. Tupper would approve every headline in every press release if Mrs. Resnick was unavailable – which is not supported by the evidence.

77. Typically, Mr. Tupper would review press releases for accuracy. (Posell, Tr. 368; CX0062; CX0127).

Response to Finding No. 77:

Respondents dispute this proposed finding as contrary to the evidence in the record. Ms. Posell was asked about a specific press release from 2003 about which she testified "I

mean, typically, I think, you know, Matt Tupper would look at something like this, make sure it was accurate. I can't recall if he looked at this one. I don't even recall if he was actually involved in the business at this point." (Posell, Tr. 368) (Emphasis added). From this exchange regarding a single press release from 2003 Complaint Counsel inaccurately insinuate that Mr. Tupper would "typically review" all press releases for accuracy – which is not supported by the evidence.

78. Mr. Tupper testified that he had a significant degree of involvement in the medical and scientific research aspects of POM's business, and his responsibilities included discussing which research areas are appropriate for funding, participating in decisions as to what medical research to fund, and overseeing clinical trials on POM's products that were conducted by research institutions. (Tupper, Tr. 895-96, 906; *see also* CX0770; CX0779; CX0800; CX0919; CX0920 (showing Tupper's participation in managing POM's medical and scientific research)).

Response to Finding No. 78:

Respondents dispute this proposed finding as contrary to the evidence in the record to the extent Complaint Counsel insinuate that Mr. Tupper was solely responsible for overseeing clinical trials or that he had authority to make final decisions as to what research POM would fund. In fact, Respondents have relied heavily upon the advice and counsel of esteemed scientists and scientific advisers in connection with the conduct of POM's research program. (Liker, Tr. 1894). POM has a scientific advisory board composed of individuals who do not conduct the research for POM but who are experts in certain health areas. (Liker, Tr. 1889-93). Members of the advisory board discuss and review completed, ongoing and potential future studies and meet with Respondents to discuss the same. (Liker, Tr. 1859, 1892-93). Mr. Tupper was involved in POM's operations, science research, and marketing. However none of these aspects of POM's business were under Mr. Tupper's ultimate control. (CX1363 (S. Resnick, Coke Dep. at 86); CX1348 (Perdigao, Dep. at 50, 60-61); CX1359 (L. Resnick, Dep. at 36); CX1362 (L. Resnick, Coke Dep. at 103-104).

Additionally, Respondents previously objected to CX0770; CX800; CX0919; CX0920 (listed on Attachment B to JX2 as a conditionally admitted exhibits) on the grounds that these exhibits lack foundation and constitute unreliable hearsay, lacking any exception, and are being offered as proof of the matters stated therein. As a result, these exhibits should be excluded from record.

79. Mr. Tupper considers himself knowledgeable about health issues, physiology, nutrition and nutrition science, although he does not have any formal training. (Tupper, Tr. 898-99).

Response to Finding No. 79:

Respondents dispute this proposed finding as contrary to the evidence in the record to the extent Complaint Counsel insinuate that Mr. Tupper has any expertise in physiology, health issues, nutrition science or nutrition. Mr. Tupper is not a doctor or research scientist. Mr. Tupper has an MBA and a bachelor's degree in political science. (Tupper, Tr. 889).

80. One of Mr. Tupper's roles was to act as a liaison between marketing staff and researchers conducting studies sponsored by POM. (L. Resnick, Tr. 261). Mr. Tupper had direct contact with research scientists who were working on POM's products, including substantive discussions of the underlying science. (Tupper, Tr. 899, 914).

Response to Finding No. 80:

Respondents object to the extent Complaint Counsel insinuate that Mr. Tupper was solely responsible for understanding and conveying scientific research information to POM's marketing department.

81. Mr. Tupper's responsibilities included keeping up to date on the status of medical research on POM's products, as well as reviewing the unpublished and published data that result from studies on POM's products. (Tupper, Tr. 913-14, 941; S. Resnick, Tr. 1720-21).

Response to Finding No. 81:

Respondents dispute this proposed finding as contrary to the evidence in the record to the extent Complaint Counsel imply that Mr. Tupper was solely responsible for keeping up to date on and reviewing POM's published and unpublished research. In fact, Respondents have relied heavily upon the advice and counsel of esteemed scientists and scientific advisers in connection with the conduct of POM's research program. (Liker, Tr. 1894). POM has a scientific advisory board composed of individuals who do not conduct the research for POM but who are experts in certain health areas. (Liker, Tr. 1889-93). Members of the advisory board discuss completed, ongoing and potential future studies and meet with Respondents to discuss the same. (Liker, Tr. 1859, 1892-93).

82. Mr. Tupper, along with Mr. Resnick, would meet with Harley Liker, M.D ("Dr. Liker"), POM's Medical Director, to communicate the scientific research areas that POM was interested in exploring. (Liker, Tr. 1880; *see also* CX1353 (Tupper, Dep. at 32-34)).

Response to Finding No. 82:

Respondents dispute this proposed finding as contrary to the evidence in the record to the extent Complaint Counsel imply that Mr. Tupper and Dr. Liker independently determined what areas of scientific research POM would explore and thereafter communicated the same to Mr. Resnick. Actually Mr. Tupper, Dr. Liker and Mr. Resnick, among others, would meet to discuss, as a group, research options at POM. (Liker, Tr. 1892-94).

83. Mr. Tupper prepared detailed medical research summaries with Dr. Dreher, to summarize POM's research portfolio; for example, Mr. Tupper drafted the "where do we go from here" sections of the medical summaries, and edited the documents. (Dreher, Tr. 555-56, 558; CX1015_0001; CX1029).

Response to Finding No. 83:

Respondents dispute this proposed finding as contrary to the evidence in the record to the extent Complaint Counsel imply Mr. Tupper was primarily responsible for preparing medical research summaries or they were prepared on a regular basis. It was Dr. Dreher

who prepared the "scientific/technical" partitions of the research summary. (Dreher, Tr. 557-558). Mr. Tupper merely offered his opinion, from a business prospective as President, about POM's potential goals and research options. (Dreher, Tr. 557). Furthermore, Complaint Counsel asked Mr. Dreher about two specific research portfolios. (Dreher, Tr. 556-566). Complaint Counsel cite to no other evidence or testimony that would support any implication that Mr. Tupper and Dr. Dreher prepared research portfolios on a regular basis.

84. Mr. Tupper, along with Mr. Resnick, participated in meetings with POM's scientific advisors to review medical summaries prepared in part by Mr. Tupper, discuss medical research results, and come up with future plans for additional research. (Liker, Tr. 1889, 1915, 1925; Dreher, Tr. 555-56). Some of these scientific research meetings also included Dr. Liker, POM's scientific director at the time (either Risa Schulman, Dr. Dreher, or Dr. Gillespie), Dr. Heber, or Dr. David Kessler ("Dr. Kessler"), an advisor to POM. (Liker, Tr. 1889; Heber, Tr. 2068 (stating that Mr. Tupper participated in discussions with Dr. Heber regarding the results of sponsored research); Heber, Tr. 2072; S. Resnick, Tr. 1859).

Response to Finding No. 84:

Respondents object to this proposed finding as contrary to the evidence in the record to the extent Complaint Counsel imply that Mr. Tupper had final authority to determine what research POM would do. Mr. Tupper was involved in POM's operations, science research, and marketing. However none of these aspects of POM's business were under Mr. Tupper's ultimate control. (CX1363 (S. Resnick, Coke Dep. at 86); CX1348 (Perdigao, Dep. at 50, 60-61); CX1359 (L. Resnick, Dep. at 36); CX1362 (L. Resnick, Coke Dep. at 103-104). In Mr. Resnick's own words, he not Mr. Tupper, was the "ultimate sole decision-maker on everything." (CX1367 (S. Resnick, Welch Dep. at 55)).

85. Mr. Tupper also has participated in meetings with Mr. Resnick, Dr. Liker, Dr. Heber, and Dr. David Kessler, to consider whether POM's research was sufficient to get an FDA-approved health claim for its products. (CX0959; Heber, Tr. 2072-73).

Response to Finding No. 85:

Respondents have no response other than to object to the extent Complaint Counsel insinuate that POM believes that FDA approval is necessary to substantiate health claims.

86. Mr. Tupper participated in regular research summits, which were meetings with scientists that helped POM interpret the results of scientific research and facilitated discussions about future research. (Liker, Tr. 1890-92).

Response to Finding No. 86:

Respondents have no specific response.

B. Corporate Respondents

1. POM Wonderful LLC

87. POM is the self-described largest grower and distributor of pomegranates and pomegranate juice in the United States. (CX1398_0003; CX1399_0003).

Response to Finding No. 87:

Respondents have no specific response.

88. POM is a Delaware limited liability company with its principal office or place of business at 11444 West Olympic Boulevard, Los Angeles, California 90064. (PX0364-0001, Answer ¶ 1; CX1426_0002, Compl. ¶ 1).

Response to Finding No. 88:

Respondents have no specific response.

89. POM is organized as a for-profit business. (S. Resnick, Tr. 1630).

Response to Finding No. 89:

Respondents have no specific response.

90. POM is a member-managed company and the Resnick Trust is the sole member. (JX0001 ¶ 11).

Response to Finding No. 90:

Respondents have no specific response.

91. POM has no wholly or partially owned subsidiaries. (JX0001 ¶ 11).

Response to Finding No. 91:

Respondents have no specific response.

2. Roll Global LLC

92. At all times relevant to the Complaint, Roll International was a Delaware corporation with its principal office or place of business at 11444 West Olympic Boulevard, Los Angeles, California 90064. (PX0364-0001, Answer ¶ 2; CX1426_0002, Compl. ¶ 2).

Response to Finding No. 92:

Respondents have no specific response.

93. Roll International was reorganized at the end of 2010; as a result, Roll Global is the successor in interest to Roll International. (JX0003 ¶ B.1; *POM Wonderful LLC,* No. 9344, Order Granting Consent Motion to Substitute Roll Global LLC as Respondent (Mar. 22, 2011)).

Response to Finding No. 93:

Respondents have no specific response.

94. Roll has provided services to POM, including advertising, public relations, consulting, accounting, tax, human resources, and information technology. (JX0001 ¶ 18; PX0364-0001).

Response to Finding No. 94:

Respondents object to this finding to the extent that Complaint Counsel construe Roll's provision of services as evidence of Roll's active participation in the alleged violation or liability through the theory of common enterprise.

Complaint Counsel gratuitously seek an order against Roll for, among others reasons, that its in-house advertising, public relations, and consulting departments provided services to POM with regard to its advertising and marketing of the Challenged Products. (CC's Post-Trial Brief at 54-55). Such an order is neither necessary nor supported by the law, given that these various Roll departments merely provided services in the same fashion as outside agencies hired for the same purpose would and lacked any knowledge that the science behind the advertising was allegedly unsubstantiated. (RFF 70-71 Perdigao, Tr. 660).

An advertising agency (or related agency) may be held liable for a deceptive advertisement if the agency was an active participate in the preparation of the detriment and if it knew or should have known that the advertisement was deceptive. Standard Oil Co., 84 F.T.C. 1401, 1475 (1974), *aff'd and modified*, 577 F.2d 653 (9th Cir. 1978). An ad agency does not have to substantiate independently the claims or scientifically reexamine the advertiser's substantiation. *Bristol-Myers Co.*, 102 F.T.C. 21, 364 (1983).

Here, the undisputed testimony from employees working at Firestation, the consulting department, and the PR department of Roll, is that the science and research to be integrated into the advertisements, press release and the like, came from and was formulated by POM. (RFF 70-71 Perdigao, Tr. 660). None of the various departments undertook to separately examine whether the science was "substantiated" to levels required by the FDA, FTC or any other government agency. (RFF 70-71 Perdigao, Tr. 660). Any why would they? The science was peer-reviewed, often published in prestigious journals, performed by scientists and medical doctors alike, and provided in a form from persons they had had no reason to doubt as to substantiation. (RFF 378-435; 312-345; 266-269.) In other words, Roll any other agency servicing a client, had no reason to suspect or have reason to investigate the advertisements may have been

deceptive for any reason, let alone that the science given to them was allegedly unsubstantiated.

Accordingly, under *Standard Oil*, 84 F.T.C. 1401 and *Bristol-Myers Co.*, 102 F.T.C. 21 (1983), Roll cannot be held liable for their conduct.

Furthermore, by Complaint Counsel's own admission, the common enterprise theory exists for situations where corporations are so entwined that a judgment of no liability against one defendant would provide another defendant "with a clear mechanism for avoiding the terms of the order." *Nat'l Urological Group*, 645 F.Supp.2d at 1182. However, a finding of no liability against Roll, whose only alleged "involvement" in the alleged actionable conduct of POM, was providing advertising services to POM, through its separate advertising agency, "Firestation.", would not provide POM with a clear mechanism for avoiding the terms of any order. *Id*. Firestation operates like any other advertising agency. (Perdigao, Tr. 616-17). It takes instructions regarding the advertising from its clients, such as POM. (Leow, Tr. 462-63) POM's marketing department, not Firestation, decides whether to disseminate an ad or PR piece. (Perdigao, Tr 615, 639). Thus, Roll did not, independent of POM, actively participate or control the decision to disseminate any of the challenged advertisements and thus cannot be found liable for claims made in POM's advertisements.

95. Roll has a full-service internal advertising agency called Fire Station. (JX0001 ¶ 18; L. Resnick, Tr. 88-89; Leow, Tr. 493; Perdigao, Tr. 593-94).

Response to Finding No. 95:

Respondents have no specific response.

96. Prior to Fire Station's creation in approximately January 2008, Roll provided advertising services to its affiliated companies through advertising personnel employed by Teleflora. (Perdigao, Tr. 592).

Response to Finding No. 96:

Respondents have no specific response.

97. This group of advertising professionals at Teleflora and later Fire Station has also been known as "The Agency." (Perdigao, Tr. 592; L. Resnick, Tr. 88-89).

Response to Finding No. 97:

Respondents have no specific response.

98. POM uses Fire Station for all or virtually all of its domestic ad agency needs. (Tupper, Tr. 920-21).

Response to Finding No. 98:

Respondents object to "all or virtually all" as vague and ambiguous.

99. Through Fire Station, Roll has actively participated in POM's advertising and marketing practices, by working with POM to create content for, determine the placement of, and monitor and report on the effectiveness of print, outdoor, online, and direct mail advertisements for POM's products. (PX0364-0001, Answer ¶ 2; CX1426_0003, Compl. ¶ 2; CX1381_0011; Tupper, Tr. 920 (agreeing that POM and Fire Station work collaboratively to create POM's marketing materials, including advertisements)).

Response to Finding No. 99:

Respondents object to this finding vague and ambiguous as to the phrases "actively participated" and "working with POM." Respondents also object to this finding as argumentative to the extent that Complaint Counsel construe Firestation's and/or Roll's conduct at the direction of POM as evidence of Roll's active participation in the alleged violation or liability through the theory of common enterprise.

Complaint Counsel gratuitously seek an order against Roll for, among others reasons, that its in-house advertising, public relations, and consulting departments provided services to POM with regard to its advertising and marketing of the Challenged Products. (CC's Post-Trial Brief at 54-55). Such an order is neither necessary nor supported by the law,

given that these various Roll departments merely provided services in the same fashion as outside agencies hired for the same purpose would and lacked any knowledge that the science behind the advertising was allegedly unsubstantiated. (RFF 70-71 Perdigao, Tr. 660).

An advertising agency (or related agency) may be held liable for a deceptive advertisement if the agency was an active participate in the preparation of the detriment and if it knew or should have known that the advertisement was deceptive. *Standard Oil Co.*, 84 F.T.C. 1401, 1475 (1974), *aff'd and modified*, 577 F.2d 653 (9th Cir. 1978). An ad agency does not have to substantiate independently the claims or scientifically reexamine the advertiser's substantiation. *Bristol-Myers Co.*, 102 F.T.C. 21, 364 (1983).

Here, the undisputed testimony from employees working at Firestation, the consulting department, and the PR department of Roll, is that the science and research to be integrated into the advertisements, press release and the like, came from and was formulated by POM. (RFF 70-71 Perdigao, Tr. 660). None of the various departments undertook to separately examine whether the science was "substantiated" to levels required by the FDA, FTC or any other government agency. (RFF 70-71 Perdigao, Tr. 660). Any why would they? The science was peer-reviewed, often published in prestigious journals, performed by scientists and medical doctors alike, and provided in a form from persons they had had no reason to doubt as to substantiation. (RFF 378-435; 312-345; 266-269). In other words, Roll any other agency servicing a client, had no reason to suspect or have reason to investigate the advertisements may have been deceptive for any reason, let alone that the science given to them was allegedly unsubstantiated.

Accordingly, under *Standard Oil*, 84 F.T.C. 1401 and *Bristol-Myers Co.*, 102 F.T.C. 21 (1983), Roll cannot be held liable for their conduct.

Furthermore, by Complaint Counsel's own admission, the common enterprise theory exists for situations where corporations are so entwined that a judgment of no liability against one defendant would provide another defendant "with a clear mechanism for avoiding the terms of the order." *Nat'l Urological Group*, 645 F.Supp.2d at 1182. However, a finding of no liability against Roll, whose only alleged "involvement" in the alleged actionable conduct of POM, was providing advertising services to POM, through its separate advertising agency, "Firestation.", would not provide POM with a clear mechanism for avoiding the terms of any order. *Id*. Firestation operates like any other advertising agency. (Perdigao, Tr. 616-17). It takes instructions regarding the advertising from its clients, such as POM. (Leow, Tr. 462-63) POM's marketing department, not Firestation, decides whether to disseminate an ad or PR piece. (Perdigao, Tr 615, 639). Thus, Roll did not, independent of POM, actively participate or control the decision to disseminate any of the challenged advertisements and thus cannot be found liable for claims made in POM's advertisements.

100. POM's former Senior Vice President of Marketing testified that she "worked very closely with [T]he [A]gency" when at POM, and their relationship was "very collaborative." (CX1357 (Kuyoomjian, Dep. at 88-89)).

Response to Finding No. 100:

Respondents object to this finding to the extent that Complaint Counsel construe the statements of the witness as evidence of Firestation or Roll's active participation in the alleged misconduct or as support for their theory of common enterprise.

Complaint Counsel gratuitously seek an order against Roll for, among others reasons, that its in-house advertising, public relations, and consulting departments provided services to POM with regard to its advertising and marketing of the Challenged Products. (CC's Post-Trial Brief at 54-55). Such an order is neither necessary nor supported by the law, given that these various Roll departments merely provided services in the same fashion as

outside agencies hired for the same purpose would and lacked any knowledge that the science behind the advertising was allegedly unsubstantiated. (RFF 70-71 Perdigao, Tr. 660).

An advertising agency (or related agency) may be held liable for a deceptive advertisement if the agency was an active participate in the preparation of the detriment and if it knew or should have known that the advertisement was deceptive. *Standard Oil Co.*, 84 F.T.C. 1401, 1475 (1974), *aff'd and modified*, 577 F.2d 653 (9th Cir. 1978). An ad agency does not have to substantiate independently the claims or scientifically reexamine the advertiser's substantiation. *Bristol-Myers Co.*, 102 F.T.C. 21, 364 (1983).

Here, the undisputed testimony from employees working at Firestation, the consulting department, and the PR department of Roll, is that the science and research to be integrated into the advertisements, press release and the like, came from and was formulated by POM. (RFF 70-71 Perdigao, Tr. 660). None of the various departments undertook to separately examine whether the science was "substantiated" to levels required by the FDA, FTC or any other government agency. (RFF 70-71 Perdigao, Tr. 660). Any why would they? The science was peer-reviewed, often published in prestigious journals, performed by scientists and medical doctors alike, and provided in a form from persons they had had no reason to doubt as to substantiation. (RFF 378-435; 312-345; 266-269). In other words, Roll any other agency servicing a client, had no reason to suspect or have reason to investigate the advertisements may have been deceptive for any reason, let alone that the science given to them was allegedly unsubstantiated.

Accordingly, under *Standard Oil*, 84 F.T.C. 1401 and *Bristol-Myers Co.*, 102 F.T.C. 21 (1983), Roll cannot be held liable for their conduct.

Furthermore, by Complaint Counsel's own admission, the common enterprise theory exists for situations where corporations are so entwined that a judgment of no liability against one defendant would provide another defendant "with a clear mechanism for avoiding the terms of the order." *Nat'l Urological Group*, 645 F.Supp.2d at 1182. However, a finding of no liability against Roll, whose only alleged "involvement" in the alleged actionable conduct of POM, was providing advertising services to POM, through its separate advertising agency, "Firestation.", would not provide POM with a clear mechanism for avoiding the terms of any order. *Id.* Firestation operates like any other advertising agency. (Perdigao, Tr. 616-17). It takes instructions regarding the advertising from its clients, such as POM. (Leow, Tr. 462-63) POM's marketing department, not Firestation, decides whether to disseminate an ad or PR piece. (Perdigao, Tr 615, 639). Thus, Roll did not, independent of POM, actively participate or control the decision to disseminate any of the challenged advertisements and thus cannot be found liable for claims made in POM's advertisements.

101. Generally, Fire Station would be responsible for coming up with specific creative ideas or media plans, and POM's marketing department would help guide the process and provide input. (CX1357 (Kuyoomjian, Dep. at 88-89)).

Response to Finding No. 101:

POM's involvement and control in the creation of an advertisement is greater than is indicated by the proposed fact. Ms. Kuyoomjian testified, "I would be involved in helping guide that process, giving input." (CX1357 (Kuyoomjian, Dep. at 88-89)). Thus, Ms. Kuyoomjian was describing her own involvement as former Senior Vice President of Marketing—not the entire story of the involvement of POM's marketing department.

102. POM's marketing department and Fire Station typically would jointly present projects to Mr. Tupper, Mrs. Resnick, and occasionally to Mr. Resnick. (CX1357 (Kuyoomjian, Dep. at 89)).

Response to Finding No. 102:

Respondents incorporate by reference Response to Finding No. 94.

103. Roll provides public relations and related services through its Corporate Communications department which, among other things, is responsible for writing and issuing press releases and press kits for POM, managing press and media relations, handling celebrity outreach, and preparing the Resnicks for press interviews. (Posell, Tr. 305, 308-11, 314-16).

Response to Finding No. 103:

Respondents incorporate by reference Response to Finding No. 94. Additionally, Respondents object to this finding to the extent that Complaint Counsel seek to establish that Roll, through the Corporate Communications department, is in violation of the FTCA under a theory of active participation. The evidence does not reflect that any of the activities by the Corporate Communications department that are spelled out in this proposed finding resulted in any allegedly deceptive advertising claims.

104. Roll's affiliated businesses, like POM, use Roll's internal consultants ("Roll Consulting"), to assist with projects, such as improving business performance and facilitating company growth and acquisitions. Over the years, Roll Consulting has assisted POM with projects related to product development, juice processing, business expansion, consumer research, and sales and marketing. (Perdigao, Tr. 633; CX1365 (Perdigao, TCCC Dep. at 0189); CX1364 (Tupper, TCCC Dep. at 15-16); CX0359 (Knight, Trop. Dep. at 159-60); CX1357 (Kuyoomjian, Dep. at 234-35)).

Response to Finding No. 104:

Respondents incorporate by reference Response to Finding No. 94. Respondents also object to this finding to the extent that Complaint Counsel seek to establish that Roll, through POM's use of Roll's internal consultants, is in violation of the FTCA under a theory of active participation. The evidence does not reflect that any of the activities engaged in by Roll consulting on behalf of POM that are spelled out in this proposed finding resulted in any allegedly deceptive advertising claims.

105. On at least one occasion, a Roll Consulting employee served as POM's interim head of marketing for a period of time. (CX1374 (Tupper, OS Dep. at 191-92) (noting that Grant Beggs was a Roll Consulting, not POM, employee)).

Response to Finding No. 105:

Respondents incorporate by reference Response to Finding No. 94. Respondents also object to this finding to the extent that Complaint Counsel seek to establish that Roll, by the fact that Mr. Beggs serving as POM's interim head of marketing, is in violation of the FTCA under a theory of active participation. The evidence does not reflect that by virtue of the fact that Mr. Beggs served as the interim head of marketing for a period of time resulted in any allegedly deceptive advertising claims.

Respondents also object to the phrase "for a period of time" as vague and ambiguous. The record does not show the length of time that Mr. Beggs served as interim head of marketing for POM.

106. Roll has actively participated in POM's medical research, for example by:

- Dr. Liker signing a protocol agreement for pomegranate research as a Medical Consultant for Roll (CX0739_0003);
- Mr. Resnick signing an agreement on behalf of Roll for Dr. Liker to work as POM's Medical Director (CX0548_0001; CX0706_0001);
- Karen Edwards, a Roll employee, providing the study beverages and assisting the researchers in writing the journal article for a POM-sponsored erectile dysfunction study (CX1337 (Forest, Dep. at 60-61, 181-87)); and
- Roll's Chief Financial Officer signing an agreement on behalf of POM and Roll with the Prostate Cancer Foundation. (CX0710_0004).

Response to Finding No. 106:

Respondents incorporate by reference Response to Finding No. 94. Respondents also object to this proposed finding to the extent that Complaint Counsel use it as argument for the proposition that Roll actively participated in the alleged deceptive conduct by virtue of the fact that a consultant and employees of Roll signed agreements or provided

assistance in conducting the research of POM's research. The signing of agreements, including Mr. Resnick's signature on an agreement on behalf of Roll for Dr. Liker to work as POM's medical director, does not show that Roll actively participated in the allegedly deceptive or misleading advertising practices in violation of the FTCA. Indeed, none of the activities listed in the proposed finding are in any way, shape, or form connected to the alleged violations in this case.

107. Roll has sponsored and/or funded studies on POM products. (CX0588_0001 (showing Roll as the sponsor on a letter of intent for a POM study); CX1065_0001 (listing Roll as funding a cardiovascular study on pomegranate juice); CX0665_0005 (showing Roll as the point of contact for the Resnick Trust, the listed sponsor in the clinical study agreement for an erectile dysfunction study); CX0785 0009, 0013, *in camera*

; CX1118_0001, *in camera*
); CX0604_0022 (stating that "Roll Int'l will reimburse Technion directly" even though POM was listed as the study sponsor)).

Response to Finding No. 107:

Respondents object to this proposed finding to the extent that Complaint Counsel use it as argument for the proposition that Roll actively participated in the alleged deceptive conduct by virtue of the fact that Roll funded or sponsored POM's research. This alone does not show that Roll actively participated in the allegedly deceptive or misleading advertising practices in violation of the FTCA. Indeed, the funding and sponsorship of research in and of itself is not deceptive and does not show that this conduct by Roll is in any way, shape, or form connected to the alleged advertising violations in this case.

3. Roll and POM Operate as a Common Enterprise

108. Mrs. Resnick describes Roll as "the umbrella company for all of our businesses" and others that work for Respondents describe Roll similarly and consider POM to be part of Roll. (CX0001_00011; Posell, Tr. 298, 305; Tupper, Tr. 894; Perdigao, Tr. 593).

Response to Finding No. 108:

Respondents have no specific response.

109. POM is headquartered in the same building as Roll, in many cases with employees of both companies occupying the same floor. (Tupper, Tr. 888; Leow, Tr. 418; PX0277-0002-03 (listing the offices of Roll employees Mr. Perdigao and Elizabeth Leow Hendry ("Ms. Leow"), Fire Station's Creative Director, on the same floor as the offices of Mrs. Resnick, Mr. Resnick, Mr. Tupper, and several POM employees)).

Response to Finding No. 109

Respondents have no specific response.

110. The Resnicks own both Roll and POM, as they are the sole trustees and sole beneficiaries of the Resnick Trust. (JX0001 ¶¶ 10, 11, 18; PX0364-0001, Answer ¶¶ 1-2; CX1426_0002-03, Compl. ¶¶ 1-2; CX1421_0002-03).

Response to Finding No. 110:

Respondents have no specific response.

111. The Resnicks have had ultimate say over all business functions of Roll and POM. They have set policy and supervised the senior executives of both companies, disregarding corporate formalities. For example, Mrs. Resnick has had complete oversight over POM's business, despite lacking any formal position with the company. (CX1368 (L. Resnick, Welch Dep. at 8-9); CX1362 (L. Resnick, TCCC Dep. at 45-46); CX1374 (Tupper, OS Dep. at 18-19); *see also* CX0001_0037 (characterizing Mrs. Resnick's involvement at POM as a partnership with Mr. Tupper since 2003); S. Resnick, Tr. 1631 (stating that Mrs. Resnick is very involved in setting POM's marketing and advertising budget); L. Resnick, Tr. 184 (stating that she has interviewed candidates for the chief marketing officer or other senior vice president positions at POM); JX0001 ¶ 18; CX276_0003; Posell, Tr. 321, 325 (stating that while Vice President of Corporate Communications, Ms. Posell reported to Mr. Tupper and Mrs. Resnick)).

Response to Finding No. 111:

Complaint Counsel's proposed phrase describing Mrs. Resnick's relationship with Mr. Tupper as a "partnership" mischaracterizes the record evidence to the extent it implies that Mr. Tupper's authority at POM was equal to the Resnicks. In fact, Mr. Tupper has no ownership interest or equity shares in POM. (CX1353 (Tupper, Dep. at 14); Tupper, Tr. 2973). Mr. Tupper reported directly to Stewart Resnick and had "dotted line" reporting to Lynda Resnick. (CX1364 (Tupper, Dep. at 14); Tupper, Tr. 2973; CX1375 (L Resnick, Tropicana Dep. at 33-34); (CX1357 (Kuyoomjian, Dep at 52)). Mr. Tupper was involved in several aspects of POM's operations, science, advertisements and

general POM theme. However none of these aspects of POM's business were under Mr. Tupper's ultimate control. (CX1363 (S. Resnick, Coke Dep. at 86); CX1348 (Perdigao, Dep. at 50, 60-61); CX1359 (L. Resnick, Dep. at 36); CX1362 (L. Resnick, Coke Dep. at 103-104). Mr. Tupper consulted with Mr. Resnick or Mrs. Resnick for any major restructuring or personnel decisions. (Tupper, Tr. 903; CX1364 (Tupper, Coke Dep. at 31)). Mr. Tupper did not, independent of the Resnicks, develop the marketing direction or decide how POM products would be marketed. (Tupper, Tr. 2974-75; (CX1368 (L. Resnick Welch's Dep. at 9); L. Resnick, Tr. 93; PX0327 (Glovsky Dep. at 36). Lynda Resnick, for example, had the final authority over advertising content and concepts. (CX1368 (L. Resnick, Welch Dep. at 9); L. Resnick, Tr. 93). Stewart Resnick had the ultimate ability to decide whether any advertisement would be run. (S. Resnick, Tr. 1870; Tupper, Tr. 2975). Stewart Resnick or Lynda Resnick, and not Mr. Tupper had the final authority to resolve any issues or disputes regarding advertising decisions. (CX1365 (Perdigao, Coke Dep. at 36-37).

112.

(CX1354 (Bryant, Dep. at 23, 27, 52-53), *in camera*; *see also* CX1355 (Hemmati, Dep. at 52-54) (stating that Roll provided information about the Resnick Trust's payments for medical research to POM); CX1276_0003).

Response to Finding No. 112:

Respondents have no specific response.

113. Respondents have used Teleflora and "Paramount Agribusiness" email addresses to conduct POM business. (*See, e.g.,* CX0098_0001; CX0092_0001; CX0086_0001; CX0072_0001).

Response to Finding No. 113:

Respondents object to the phrase "conduct POM business" as vague and ambiguous. Further, citation to documents with the language "Paramount Agribusiness" and

"Teleflora" in the email address alone and without accompanying explanatory testimony does not establish that these individuals were conducting business on behalf of POM.

114. POM's Consumer Affairs representative would typically respond to consumer complaints; however, "if necessary, [they] might get escalated" to others at POM or Roll, such as Roll's Corporate Communications, which may respond directly to the consumer. (CX1357 (Kuyoomjian, Dep. at 204-09) (stating that Rob Six in Corporate Communications was involved in discussions on how to respond to consumer complaints about the "Cheat Death" ad)).

Response to Finding No. 114:

Respondents object to the proposed finding as overly broad, vague, and ambiguous. The nature and extent of Roll's involvement is not established.

115. Roll admitted that not all expenses, such as advertising and marketing services, provided to POM were reimbursed. Roll has provided various services over the years to POM relating to POM Juice, POMx Pills, and POMx Liquid "with some portion charged back to POM . . . ." (CX1383_0014; CX1357 (Kuyoomjian, Dep. at 235)). For example, the former Vice President of Corporate Communications at Roll testified she was not required to keep track of her time based on whether she was working on a POM project or a project for another Roll company. (Posell, Tr. 325).

Response to Finding No. 115:

Despite being in-house, Firestation functions like any other advertising agency. Mike Perdigao, the President of Firestation, testified at trial that although Firestation is an in-house company, it still has a "form of allocating costs back to the clients." (Perdigao, Tr. 616). This requires that a formal "work order" be opened so that Firestation can bill time against the project. (Perdigao, Tr. 617).

116. Roll also provides risk management, human resources, consulting, and travel services to POM without any reimbursement. (CX1354 (Bryant, Dep. at 41-42, 48-50, 55-64) (stating that his knowledge concerning Roll's billing of POM for incurred expenses was limited to the time period after he became Chief Financial Officer in June 2009)).

Response to Finding No. 116:

Respondents have no specific response.

117. Roll also interacts with POM for the purposes of joint cash management, as noted by Roll's Chief Financial Officer, Robert Bryant, who stated that Roll "pool[s] together the cash from each one of [its] operating companies and will invest that cash . . . overnight for purposes of investments . . . [o]r if [Roll has] debt outstanding on [its] working capital lines, then [Roll] will use that cash to pay down those working capital . . . lines." (CX1354 (Bryant, Dep. at 67)).

Response to Finding No. 117:

Respondents have no specific response.

118. POM's medical research program was sponsored and funded by various Resnick entities (*e.g.*, Roll, POM, and the Resnick Trust). (CX1118_0001; CX0604_0022 (stating that "Roll Int'l will reimburse Technion [Institute] directly," even though POM was listed as the research sponsor); CX0628_0001 (describing a study on pomegranate juice as the "Roll Beverage Study"); *see also* CCFF ¶ 106)).

Response to Finding No. 118:

Respondents incorporate by reference Response to Finding No. 94. Respondents also object to this proposed finding to the extent that Complaint Counsel use it as argument for the proposition that Roll actively participated in the alleged deceptive conduct by virtue of the fact that Roll funded or sponsored POM's research. This alone does not show that Roll actively participated in the allegedly deceptive or misleading advertising practices in violation of the FTCA. Indeed, the funding and sponsorship of research in and of itself is not deceptive and does not show that this conduct by Roll is in any way, shape, or form connected to the alleged advertising violations in this case.

119. Mr. Resnick has testified on numerous occasions that ultimately, the funding for medical research comes from him and Mrs. Resnick, regardless of the intermediary source. (S. Resnick, Tr. 1657; CX1363 (S. Resnick, TCCC Dep. at 61) (whether a study is sponsored by Roll or POM, "[t]he money comes out of the same pockets"); (CX1376 (S. Resnick, OS Dep. at 228-30) (the $34 million dollars referenced in a POM advertisement is ultimately "our money, however it comes"); *see also* L. Resnick, Tr. 198-99).

Response to Finding No. 119:

Respondents have no specific response.

120. Mr. Tupper's responsibilities were the same with respect to all studies conducted on POM's products, regardless of whether they were funded by POM or any other Resnick-owned entity. (Tupper, Tr. 911). In addition, Mr. Tupper gave input on which Resnick entity would be cited as the source of funding in published medical studies. (CX0043).

Response to Finding No. 120:

Respondents object to the first sentence of the proposed finding as vague and ambiguous and unsupported by the cited evidence. Mr. Tupper testified that he was not aware of which entity was funding POM's research or the parties that signed the agreements for POM's research and did not testify about his responsibilities with respect to the studies. (Tupper, Tr. 911).

Respondents also object to the second sentence of the proposed finding to the extent that Complaint Counsel use this statement as evidence that Mr. Tupper actively participated in the alleged violations.

Additionally, Respondents also object to the statement "gave input" as vague and ambiguous and unsupported by the cited evidence. The referenced exhibit merely shows that Mr. Tupper was cc'd on an email sent from Fiona Posell to Mrs. Resnick that where Ms. Posell discusses an acknowledgment of "Lynda Resnick, Stewart Resnick, Dr. Harley Liker, MD, Matt Tupper, and Karen Edwards at the Resnick Foundation. (CX0043). Ms. Posell states "I have discussed with matt and he agrees with the proposed language" but then asks Mrs. Resnick for her further input. (CX0043). Mr. Tupper does not have the final say or authority over the cited source of funding, and the cited exhibit does not show to what extent Mr. Tupper gave input into the proposed language for the citation of funding source.

121. Because Roll and POM were controlled by the same individuals and shared officers, engaged in interrelated business transactions, especially those involving advertising and scientific research, shared office space, and commingled funds, they have functioned as a common enterprise. (*See* CCFF ¶¶ 108-120).

Response to Finding No. 121:

Respondents incorporate by reference Response to Findings No. 108-120. Complaint Counsel's own admission, the common enterprise theory exists for situations where corporations are so entwined that a judgment of no liability against one defendant would provide another defendant "with a clear mechanism for avoiding the terms of the order." *Nat'l Urological Group, 645 F.Supp.2d at 1182*. However, a finding of no liability against Roll, whose only alleged "involvement" in the alleged actionable conduct of POM, was providing advertising services to POM, through its separate advertising agency, "Firestation.", would not provide POM with a clear mechanism for avoiding the terms of any order. *Id*. Firestation operates like any other advertising agency. (Perdigao, Tr. 616-17). It takes instructions regarding the advertising from its clients, such as POM. (Leow, Tr. 462-63) POM's marketing department, not Firestation, decides whether to disseminate an ad or PR piece. (Perdigao, Tr 615, 639). Thus, Roll did not, independent of POM, actively participate or control the decision to disseminate any of the challenged advertisements and thus cannot be found liable for claims made in POM's advertisements.

III. THE POM PRODUCTS

A. Description of the POM Products

122. Respondents have manufactured, advertised, labeled, offered for sale, sold, and distributed products to the public, including POM Juice, POMx Pills, and POMx Liquid ("POM Products"). (PX0364-0002, Answer ¶ 6; CX1426_0003, Compl. ¶ 6).

Response to Finding No. 122:

Respondents object to the term "manufactured" as vague and ambiguous. POM Juice is produced by pressing whole pomegranates, including the arils and peels. (CX0967_0014, *in camera*).

123. POM manufactures, advertises, and sells other products containing pomegranate, including various POM Juice blends, Lite POM Juice, POMx bars, POMx iced tea and iced coffee, and a POMx sports recovery beverage. (JX0003 ¶ B.8).

Response to Finding No. 123:

Respondents have no specific response.

124. (CX0967_0014, *in camera*). The subsequent cloudy juice is filtered and/or enzyme treated before concentrating. (CX0537_0003). The concentrate is stored in 52-gallon drums. (CX1369 (Tupper, Welch Dep. at 22)).

Response to Finding No. 124:

Respondents have no specific response.

125. To make it ready for sale, the concentrate is reconstituted with water to make "100 percent pomegranate juice," pasteurized, and bottled for sale. (JX0003 ¶ B.9; CX1369 (Tupper, Welch Dep. at 19-23)). The final juice product contains "85.4% water, 10.6% total sugars, 1.4% pectin, 0.2-1.0% polyphenols, and organic acids." (CX0537_0003).

Response to Finding No. 125:

Respondents have no specific response.

126. POM Juice does not contain dietary fiber or vitamin C. (CX0537_0014; CX0716_0041). It contains a variety of polyphenols, including 80-90% ellagitannins and gallotannins, 8-15% anthocyanins and 2-5% ellagic acid. (CX0163_0007).

Response to Finding No. 126:

Irrelevant. POM does not make any claims on basis of having dietary fiber or vitamin C.

127. (CX1379_0008, *in camera*). A serving of POM Juice provides 140 calories and 34 grams of sugar. (CX1306 (Weidner, Decl. at 0020)).

Response to Finding No. 127:

Complaint Counsel failed to state that the second finding of fact in Finding No. 127 cannot be logically related to the first finding of fact since the first finding of fact related

to a "single" serving, whereas the second finding of fact to Finding No. 127 relates to a "serving", and not a "single" serving. In fact, the serving size referred to in CX1306 (Weidner Decl. at 0020) is 240ml, which is more than the eight ounces referred to in CX1379_0008. Since the serving size referred to in CX1306 (Weidner Decl. at 0020) is more than eight ounces, the evidence cited does not support the proposition that a single serving of POM Juice provides 140 calories and 34 grams of sugar as Complaint Counsel alleges.

128. According to Respondents,

(CX1379_0008, *in camera*).

Response to Finding No. 128:

Complaint Counsel fails to acknowledge the general objections to the Requests raised by Respondents, which Respondents incorporate herein, including but not limited to, Respondents' objection that the Request did not contain a reasonable temporal limitation (CX1379_004), Respondents' objection that the Requests were overbroad (CX1379_002), and Respondents' objection that the Request was vague and/or ambiguous (CX1379_004).

129. One eight-ounce glass of POM Juice equals roughly two and a half pomegranates, and thus has the sugar content of two and a half pomegranates. (S. Resnick, Tr. 1633-34).

Response to Finding No. 129:

Vague and Ambiguous. Complaint Counsel mischaracterizes Mr. Resnick's statements regarding the number of pomegranates and amount of sugar contained in an eight-once glass of POM Juice. Mr. Resnick was expressing his personal opinion, as a layman, and his best estimate of the number of pomegranates and resultant quantity of sugar in an eight-ounce glass of POM Juice. Mr. Resnick in no way voiced the actual quantity of pomegrantaes and sugar in POM Juice, and has no actual knowledge of whether the entire amout of sugar contained in a pomegranate is transferred into the finished POM

Juice product after blending and pasteurization and Complaint Counsel pointed to no other record evidence in support.

130. POMx was created to use up the "tens of thousands of tons of discarded, mashed-up pomegranates left over from the juicing process." (CX0001_0013; CX0967_0014). Pomegranate extracts, because of the production process, contain no anthocyanins. (CX1352 (Heber, Dep. at 358); *see also* CX1258_0003 (POMx has only "trace" anthocyanins)).

Response to Finding No. 130:

Respondents object to the proposed finding to the extent that Complaint seek to imply that POMx and POM Juice are not bioequivalent. (RFF 915-925). Complaint Counsel have presented no evidence refuting this very point.

131. Mrs. Resnick stated "[m]y marketing team and I were eager to learn if we could produce a pomegranate extract that could deliver the power of eight ounces of POM juice in a capsule. . . . [P]roduction of a pomegranate extract would necessitate a whole new round of science to determine whether it was safe and effective." (CX0001_00013).

Response to Finding No. 131:

Respondents object to the proposed finding to the extent Complaint Counsel seek to imply that POMx and POM Juice are not bioequivalent or that that research studying POM Juice is not applicable to POMx. (RFF 915-925).

132.

(CX0967_0014, *in camera*).

Response to Finding No. 132:

Respondents have no specific response.

133.

(CX1379_0008-09, *in camera*).

Response to Finding No. 133:

Complaint Counsel has mischaracterized Respondents' response to the Request for Admission in Finding 133. Respondents do not "instruct" consumers to take one teaspoon of POMx Liquid daily, but rather the website recommends that consumers take one teaspoon of POMx Liquid daily. (CX1379_008, *in camera*).

134.

(CX0967_0014, *in camera*).

Response to Finding No. 134:

Respondents have no specific response.

135.

(CX1379_0008, *in camera*).

Response to Finding No. 135:

Complaint Counsel has mischaracterized Respondents' response to the Request for Admission in Finding 135. Respondents do not "instruct" consumers to take one POMx Pill daily, but rather the website states "our recommended daily serving is one pill.". (CX1379_009, *in camera*)

B. Respondents' Sales in Commerce

136.

(CX0967_0014, *in camera*).

Response to Finding No. 136:

Respondents have no specific response.

137. In four years, POM went "from zero to $165 million in sales." (CX0001_00012).

Response to Finding No. 137:

Respondents object to this finding as the cited quotation is not contained within the referenced page.

138. According to Mrs. Resnick, the "lion's share of the business is a hundred percent pomegranate juice." (L. Resnick, Tr. IX.B.6.278-79).

Response to Finding No. 138:

Respondents have no specific response.

139. POM's U.S. Sales of 100% Juice, from September 2002 to November 2010, totaled approximately $247,739,776. (JX0001 ¶ 15).

Response to Finding No. 139:

Respondents have no specific response.

140. For the 52 weeks ending July 20, 2008, the weighted average base price per unit for POM Juice was $2.93 for an 8-ounce bottle or $4.29 for a 16-ounce bottle. (CX0221_0007).

Response to Finding No. 140:

Respondents have no specific response.

141. In 2007, POM began selling POMx Pills and Liquid. (CX1347 (Glovsky, Dep. at 29)).

Response to Finding No. 141:

Respondents have no specific response.

142. Consumers can purchase POMx Pills and POMx Liquid via the company website or through a telephone call center. POMx Pills also are available through a few U.S. Retail outlets that sell dietary supplement products. (JX0003 ¶ B.14).

Response to Finding No. 142:

Respondents have no specific response.

143. POM's Total POMx Pill Gross Revenue, from May 2007 to November 2010, totaled approximately $4,017,681. (JX0001 ¶ 16).

Response to Finding No. 143:

Respondents have no specific response.

144. POM's Total POMx Liquid Gross Revenue, from May 2007 to November 2010, totaled approximately $209,820. (JX0001 ¶ 17).

Response to Finding No. 144:

Respondents have no specific response.

145.

(CX1379_0009-10, *in camera*).

Response to Finding No. 145:

Respondents have no specific response.

146.

(CX1379_0010-11, *in camera*).

Response to Finding No. 146:

Respondents have no specific response.

IV. HISTORY OF POM AND FORAY INTO SCIENTIFIC RESEARCH

147. In 1987, Stewart and Lynda Resnick acquired farmland containing over 100 acres of mature pomegranate trees. (CX0105_0002).

Response to Finding No. 147:

Respondents have no specific response.

148. Over the next decade, their company, Paramount Farming, vastly expanded the pomegranate plantings, surmising that the return on pomegranates could eclipse that of their citrus and almond plantings "so long as the market [was] receptive to the crop." (CX0105_0002).

Response to Finding No. 148:

The proposed finding misstates the evidence. Between 1989 and 2001, Paramount Farming continued to acquire and plant additional pomegranate acreage, bringing the total to 6,000 acres by 2001. (CX0105_0002-0008).

149. In 2000, the Resnicks formed Paramount Juice Company and, shortly thereafter, in 2001, changed the name to POM Wonderful LLC. (CX1418_0001-03).

Response to Finding No. 149:

Respondents have no specific response.

150. By Spring 2001, the yield from the Resnicks' 6,000 acres of pomegranates "ha[d] progressed exponentially . . . making it essential to immediately begin a marketing program for the POM Juice product." (CX0004_0001).

Response to Finding No. 150:

The proposed finding only partially quotes the cited exhibit. The full citation should include the following: "It has always been management's intention to sell POM Juice as well as fresh product to the consumers. However, the yield from the acreage has progressed exponentially with each passing year, making it essential to immediately begin a marketing program for the Pom Juice product. (CX0004_0001).

151. POM began bottling, selling, and marketing POM Juice on a regional basis in Fall 2002, and in national markets in 2003. (CX1353 (Tupper, Dep. at 41-42); CX1395_0003).

Response to Finding No. 151:

The evidence cited by Complaint Counsel does not support the proposition that POM began bottling, selling, and marketing POM Juice in national markets in 2003. Mr. Tupper's cited testimony shows that POM could have began bottling, selling, and marketing POM Juice in national markets not until 2004. (Tupper, Tr. 42). Mr. Tupper's testimony reads as follows:

"Q. And when did you start selling Pom juice nationally?

"A. Well, let's see, I think we began that process of growing our geographical distribution the following year in 2003. But I'm trying to remember when we reached, you know national distribution. It might – *might not have been until 2004*."

(Tupper, Tr. 41-42 emphasis added).

152. According to Mrs. Resnick, when Respondents went about creating a market for pomegranate juice, "only about one in ten Americans said they were familiar with pomegranates, and fewer than half of that group said they had eaten one in the past year." (PX0370 at 2).

Response to Finding No. 152:

Respondents' Counsel object to this proposed finding, which purports to suggest that Respondents created the market for pomegranate juice. Pomegranates and pomegranate juice have been safely consumed by many different cultures throughout the world and for thousands of years. (PX0192-0013, 0018, 0042; See generally 32 U.S.C. § 231(s); 21 C.F.R. § 182.20).

153.

(CX0967_0009, *in camera*).

Response to Finding No. 153:

Respondents object to this proposed finding as vague and ambiguous as to "premised its business plan."

Respondents also object to this proposed finding, which purports to argue that Respondents' research endeavors were motivated exclusively to generate financial and marketing value or that Mr. and Mrs. Resnick did not sponsor research on the Challenged Products prior to instituting a research program. Stewart and Lynda Resnick were, indeed, intrigued with the folklore and history surrounding the health giving properties of pomegranate and, in 1998, nearly four years prior to the launch of POM Juice, began collaborating with researchers to verify whether, and to what extent, there was any truth

underlying the fruit's history as a powerful contributor to human health. (L. Resnick, Tr. 150; CX1363 (S. Resnick, Coke Dep. at 61-63, 65-66); CX0105_0003; CX1362 (L. Resnick, Coke Dep. at 71-72); S. Resnick, Tr. 1855-56); CX1359 (L. Resnick, Dep. at 82); CX1360 (S. Resnick, Dep. at 84-85); CX1372 (S. Resnick, Tropicana Dep. at 32; CX1374 (Tupper, Ocean Spray Dep. at 87); CX1358 (Aviram, Dep. at 4); CX1367 (S. Resnick, Welch's Dep. at 15); CX0001_0010-0011; PX0004).

154. According to Mr. Resnick, a primary part of POM's messaging to consumers is about the health benefits of its products. (S. Resnick, Tr. 1653; CX1372 (S. Resnick, Trop. Dep. at 31-32)). Indeed, he testified that Respondents publicized the results of their research because of a belief "that people should try to both prevent and cure diseases as naturally as they can." (CX1372 (S. Resnick, Trop. Dep. at 43)).

Response to Finding No. 154:

Respondents object to the phrase "primary part" as vague and ambiguous.

Mr. Resnick testified at trial that his motivation in sponsoring the research and sharing the findings was to "do well by doing good" or in other words to "help society" by exploring where the Challenged products "can do the most good." (S. Resnick, Tr. 1862-63).

Respondents object to the proposed finding to the extent that Complaint Counsel construe Mr. Resnick's statements to bolster their argument that Respondents intended to convey to consumers that the Challenged Products are "clinically proven" to treat, prevent or reduce the risk of disease or that they intended to do so in the same sense that a drug prevents, treats, or reduces the risk of disease. Although Respondents genuinely believe in the health benefits of the Challenged products and in the scientific integrity of POM's sponsored research (CX1406 (Tupper, Tropicana Tr.182-83); CX1363 (S. Resnick, Coke Dep. at 83; CX1360 (S. Resnick, Dep. at 200, 229, 246); PX1372 (S. Resnick, Tropicana Dep. at 42-43); CX1371 (Tupper, Tropicana Dep. at 171); CX1362 (L. Resnick, Coke Dep. at 51, 80); CX1375 (L. Resnick, Dep. at 8, 209)), Stewart Resnick, Lynda Resnick,

and Matt Tupper testified specifically that POM never intended to convey the claim that the Challenged Products are "clinically proven" to treat, prevent, or reduce the risk of disease, and certainly not in the same sense as a drug treats, prevents, or reduces the risk of disease. (Tupper, Tr. 992, 3008; L. Resnick, Tr. 194, 196-97, 217-19; CX1363 (S. Resnick, Coke Dep. at 81); CX1376 (S. Resnick, Ocean Spray Dep. at 135); CX1372 (S. Resnick, Tropicana Dep. at 52, 56-59); CX1364 (Tupper, Coke Dep. at 297, 299); CX1374 (Tupper, Ocean Spray Dep. at 7); CX1362 (L. Resnick, Dep. at 283-84)). Moreover, POM never states, expressly or by implication, conspicuously on the face of any of the Challenged Ads that scientific tests "prove" that the Challenged Products "prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction," or even that they "prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction." (Appendix of Advertisements). Throughout its advertising, POM highlights that POM Juice is a 100% juice product wholly-derived from the pomegranate fruit, and that POMx has the same content as the pomegranate fruit itself and is 100% derived from the exact same fruit. (*See* RFF 494). Indeed, Respondents have never advertised their products as a pharmaceutical drug, nor intended to advertise their products as drugs. (RFF 495-96). Rather, Respondents have always marketed the Challenged Products for what they intrinsically are: whole-food products. (RFF 497-99). Accordingly, it is far more logical (and the evidence demonstrates) that reasonable consumers would view the Challenged Products the way they perceive any other extremely healthy whole foods, like broccoli, blueberries, grapes or tomatoes, which may help prevent or improve your odds against disease, but which are not a drug with a single target of action against a particular disease or condition.

155. Mrs. Resnick stated, "[p]ure and unadulterated, this juice was not only delicious; it had the power to help heal people. It was health in a bottle. People needed pomegranate juice in their lives (even if they didn't know it yet), and I knew they would pay what it was worth." (CX0001_0006).

Response to Finding No. 155:

Respondents object to the proposed finding to the extent that Complaint Counsel construe Mrs. Resnick's opinions as evidence to bolster their argument Respondents intended to convey to consumers that the Challenged Products are "clinically proven" to treat, prevent or reduce the risk of disease in the same sense that a drug prevents, treats, or reduces the risk of disease. Respondents genuinely believe in the health benefits of the Challenged products, as indicated by Mrs. Resnick's statement that "it had the power to help heal people," and in the scientific integrity of POM's sponsored research. (CX1406 (Tupper, Tropicana Tr.182-83); CX1363 (S. Resnick, Coke Dep. at 83; CX1360 (S. Resnick, Dep. at 200, 229, 246); PX1372 (S. Resnick, Tropicana Dep. at 42-43); CX1371 (Tupper, Tropicana Dep. at 171); CX1362 (L. Resnick, Coke Dep. at 51, 80); CX1375 (L. Resnick, Dep. at 8, 209)). Specifically, Mrs. Resnick considers POM juice to be "health in a bottle" because of the medical benefits of the juice revealed by both Respondents' research and the 8,000 year history of pomegranates. (L. Resnick, Tr. 78; CX1362 (L. Resnick, Dep. at 50-51); (CX1375 (L. Resnick, Tropicana Dep. at 110)). Rather, Respondents have always marketed the Challenged Products for what they intrinsically are: whole-food products. (RFF 497-99). Accordingly, it is far more logical (and the evidence demonstrates) that reasonable consumers would view the Challenged Products the way they perceive any other extremely healthy whole foods, like broccoli, blueberries, grapes or tomatoes, which may help prevent or improve your odds against disease, but which are not a drug with a single target of action against a particular disease or condition. However, Stewart Resnick, Lynda Resnick, and Matt Tupper testified specifically that POM never intended to convey the claim that the Challenged Products treat, prevent, or reduce the risk of disease in the same sense as a drug treats, prevents, or reduces the risk of disease. (Tupper, Tr. 992, 3008; L. Resnick, Tr. 194, 196-97, 217-19; CX1363 (S. Resnick, Coke Dep. at 81); CX1376 (S. Resnick, Ocean Spray Dep. at 135);

CX1372 (S. Resnick, Tropicana Dep. at 52, 56-59); CX1364 (Tupper, Coke Dep. at 297, 299); CX1374 (Tupper, Ocean Spray Dep. at 7); CX1362 (L. Resnick, Dep. at 283-84)).

156. Mrs. Resnick also testified that POM uses the studies it has sponsored as a source of marketing, as this research is "[POM's] unique selling proposition." (CX1375 (L. Resnick, Trop. Dep. at 87)).

Response to Finding No. 156:

Respondents object to this finding to the extent Complaint Counsel the cited evidence to infer that the marketing or the ability to make health benefit claims was the sole force driving the Resnicks in their decisions to sponsor scientific research on the Challenged Products. In fact, the record reflects that this is not the case. The evidence shows that the Resnicks were driven by the desire to uncover, whether and to what extent, the consumption of the Challenged Product conferred a benefit to human health. (S. Resnick, Tr. 1752-53, 1861-63; CX1363 (S. Resnick, Coke Dep. at 59; Tupper, Tr. 3001; CX1360 (S. Resnick, Dep. at 145-46)).

POM's unique selling proposition is that, unlike its competitors, it only advertises a health benefit with much deliberation and thought. It does not prematurely share the findings of *every* newly uncovered health benefit even if the research shows that the benefit does in fact exist. (Tupper, Tr. 2979-81; S. Resnick, Tr. 1860). In fact, Mrs. Resnick testified to this very proposition on the same page of the deposition cited by Complaint Counsel:

"And we conduct the studies. They take a long time to conduct and a long time to be written up. Then it has to go and be published in a peer reviewed journal of great quality. It is only then that any announcement is ever made."

(CX1375 (L. Resnick, Tropicana Dep. at 87)). Thus, POM's unique selling proposition with respect to its use of POM's sponsored research in the advertising is POM does not share the findings of its research without the support of competent and reliable science.

157. Mr. Resnick admitted that the medical research sponsored by Respondents was for "Marketing/PR/Medical Outreach purposes." (CX1372 (S. Resnick, Trop. Dep. at 74-75); CX1029_0003).

Response to Finding No. 157:

Respondents object to the proposed finding of fact to the extent that Complaint Counsel cherry-pick Mr. Resnick's statement from this deposition to change the meaning of his statement. The relevant question and answer given by Mr. Resnick is as follows: "In your opinion, is that a fair description of *at least part of the reasons* why POM does medical research?" (CX1372 (S. Resnick, Trop. Dep. at 74-75, emphasis added)).

Respondents also object to this finding to the extent Complaint Counsel use this proposed finding to infer that the marketing or the ability to make health benefit claims was the sole force driving the Resnicks in their decisions to sponsor scientific research on the Challenged Products. The record reflects that this is not the case. The evidence shows that the Resnicks were driven by the desire to uncover, whether and to what extent, the consumption of the Challenged Product conferred a benefit to human health. (S. Resnick, Tr. 1752-53, 1861-63; CX1363 (S. Resnick, Coke Dep. at 59; Tupper, Tr. 3001; CX1360 (S. Resnick, Dep. at 145-46)).

158. POM began its pomegranate research under the direction of POM's former medical director, Dr. Leslie Dornfeld, a professor at the University of California, Los Angeles (UCLA) and the Resnicks' family physician. (L. Resnick, Tr. 150; CX1350 (Liker, Dep. at 29)).

Response to Finding No. 158:

Respondents object to this proposed finding to the extent that it is an incomplete description of Dr. Dornfeld's professorship at UCLA. Dr. Dornfeld was a professor of Internal Medicine at the University of California, Los Angeles. (CX105_0003).

159. In notes about a March 2001 meeting with Mrs. Resnick, Dr. Dornfeld described POM's "scope of research" as having "two directions. (A) for use in marketing (primarily circulation) and (B) 'home run' cure for cancer, etc." (CX0003_0001).

Response to Finding No. 159:

Respondents object to the proposed finding to the extent that Complaint Counsel construe Dr. Dornfeld's quote to mean that Respondents were driven by the desire to market the results of POM's sponsored research. In fact, the record shows the exact opposite. The Resnicks, years before ever selling POM juice, began collaborating with scientists to determine what benefits could be derived from the consumption of the juice. (CX1374 (Tupper, Ocean Spray Dep. at 87); CX1358 (Aviram Dep. at 4); CX1363 (S. Resnick, Coke Dep. at 61-63, 65-66); CX1367 (S. Resnick, Welch Dep. at 15); CX0001_0010-0011; L. Resnick, Tr. 150; PX0004). In fact, as early as 1998, nearly three years before this memo was written, POM had begun collaborating with Dr. Michael Aviram to determine the antioxidant and/or cardiovascular benefit properties of the fruit. (RFF 257) Indeed, Mr. Resnick testified at trial that his motivation in sponsoring the research was to "do well by doing good" or in other words to "help society" by exploring where the Challenged products "can do the most good." (S. Resnick, Tr. 1862-63). Moreover, the phrase, "(A) for use in marketing (primary circulation)" refers specifically to POM's intention to share the remarkable results of Dr. Aviram's published study on the anti-atherosclerotic benefits of the juice as shown in both humans and animals. (CX0003_0001).

Moreover, Respondents object to the proposed finding to the extent Complaint Counsel construe from the statement "(B) "home run" cure for cancer" to bolster their argument that Respondents intended to convey to consumers that the Challenged Products are "clinically proven" to treat, prevent or reduce the risk of disease or that they intended to do so in the same sense that a drug prevents, treats, or reduces the risk of disease. In fact, the following page of the cited exhibit explains a desire on the part of the Respondents to further develop POM's research to see whether and to what extent pomegranate has any anti-cancer benefits. "The work on cancers has really been to see if we can develop substances that might be synthesized as an adjunct or single substance cure for cancer. This is a much longer project and the UCLA project is just finishing the first of a 3-year plan." (CX0003_0002). Indeed, this statement conveys that the Resnicks desire to sponsor and develop a research program exploring the full spectrum of benefits of the Challenged Products. (S. Resnick, Tr. 1752, 1861-63). Moreover, Stewart Resnick, Lynda Resnick, and Matt Tupper testified specifically that POM never intended to convey the claim that the Challenged Products are "clinically proven" to treat, prevent, or reduce the risk of disease, and certainly not in the same sense as a drug treats, prevents, or reduces the risk of disease. (Tupper, Tr. 992, 3008; L. Resnick, Tr. 194, 196-97, 217-19; CX1363 (S. Resnick, Coke Dep. at 81); CX1376 (S. Resnick, Ocean Spray Dep. at 135); CX1372 (S. Resnick, Tropicana Dep. at 52, 56-59); CX1364 (Tupper, Coke Dep. at 297, 299); CX1374 (Tupper, Ocean Spray Dep. at 7); CX1362 (L. Resnick, Dep. at 283-84)). Additionally, POM never states, expressly or by implication, conspicuously on the face of any of the Challenged Ads that scientific tests "prove" that the Challenged Products "prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction," or even that they "prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction." (Respondents' Appendix of Advertisements). Throughout its advertising, POM highlights that POM Juice is a 100% juice product wholly-derived from the pomegranate fruit, and that POMx has the same content as the

pomegranate fruit itself and is 100% derived from the exact same fruit. (*See* RFF 494). Indeed, Respondents have never advertised their products as a pharmaceutical drug, nor intended to advertise their products as drugs. (RFF 495-96). Rather, Respondents have always marketed the Challenged Products for what they intrinsically are: whole-food products. (RFF 497-99). Accordingly, it is far more logical (and the evidence demonstrates) that reasonable consumers would view the Challenged Products the way they perceive any other extremely healthy whole food, like broccoli, blueberries, grapes or tomatoes, which may help prevent or improve your odds against disease, but which would not "stop" anything, like a drug with a single target of action against a particular disease or condition.

160. In a 2001 memorandum on the juice project, Mrs. Resnick noted several "proven health benefits associated with consumption of POM Juice that we can currently 'talk about' at scientific meetings, public relations campaigns and consumer promotions." These benefits included, among others: 1) effective antioxidant properties; 2) lowering LDL cholesterol that can adhere to the arteries; and 3) guarding against heart disease. Mrs. Resnick also noted preliminary evidence that POM Juice inhibits prostate cancer and tumor growth, but acknowledged that this information was not ready for public exposure. (CX0004_0012). Mrs. Resnick also saw value to ensuring "that the science is made public when the supply is available" and "want[ed] to publish the findings in stages to keep the news new." (CX0004_0004).

Response to Finding No. 160:

Respondents object to the proposed finding to the extent that Complaint Counsel construe Mrs. Resnick's statements to bolster their argument that Respondents intended to convey to consumers that the Challenged Products are "clinically proven" to treat, prevent or reduce the risk of disease or that they intended to do so in the same sense that a drug prevents, treats, or reduces the risk of disease.

Although Respondents genuinely believe in the health benefits of the Challenged products and in the scientific integrity of POM's sponsored research (CX1406 (Tupper, Tropicana Tr.182-83); CX1363 (S. Resnick, Coke Dep. at 83; CX1360 (S. Resnick, Dep. at 200, 229, 246); PX1372 (S. Resnick, Tropicana Dep. at 42-43); CX1371 (Tupper,

Tropicana Dep. at 171); CX1362 (L. Resnick, Coke Dep. at 51, 80); CX1375 (L. Resnick, Dep. at 8, 209)), Stewart Resnick, Lynda Resnick, and Matt Tupper testified specifically that POM never intended *to convey the claim* that the Challenged Products are "clinically proven" to treat, prevent, or reduce the risk of disease, and certainly not in the same sense as a drug treats, prevents, or reduces the risk of disease. (Tupper, Tr. 992, 3008; L. Resnick, Tr. 194, 196-97, 217-19; CX1363 (S. Resnick, Coke Dep. at 81); CX1376 (S. Resnick, Ocean Spray Dep. at 135); CX1372 (S. Resnick, Tropicana Dep. at 52, 56-59); CX1364 (Tupper, Coke Dep. at 297, 299); CX1374 (Tupper, Ocean Spray Dep. at 7); CX1362 (L. Resnick, Dep. at 283-84)). Moreover, POM never states, expressly or by implication, conspicuously on the face of any of the Challenged Ads that scientific tests "prove" that the Challenged Products "prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction," or even that they "prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction." (Respondents' Appendix of Advertisements). Throughout its advertising, POM highlights that POM Juice is a 100% juice product wholly-derived from the pomegranate fruit, and that POMx has the same content as the pomegranate fruit itself and is 100% derived from the exact same fruit. (See RFF 494). Indeed, Respondents have never advertised their products as a pharmaceutical drug, nor intended to advertise their products as drugs. (RFF 495-96). Rather, Respondents have always marketed the Challenged Products for what they intrinsically are: whole-food products. (RFF 497-99). Accordingly, it is far more logical (and the evidence demonstrates) that reasonable consumers would view the Challenged Products the way they perceive any other extremely healthy whole food, like broccoli, blueberries, grapes or tomatoes, which may help prevent or improve your odds against disease, but which would not "stop" anything, like a drug with a single target of action against a particular disease or condition.

161. In 2001, Respondents hired Dr. Liker, a physician at UCLA, to assist Dr. Dornfeld. (Liker, Tr. 1873, 1877; CX1350 (Liker, Dep. at 27-28)). Dr. Liker also became the Resnicks' personal physician and company wellness coordinator and wellness director in

2001. (Liker, Tr. 1876-77). Dr. Liker became POM's medical director in 2002. (Liker, Tr. 1877). He has been paid approximately for his work. (CX1379_0037, *in camera*).

Response to Finding No. 161:

As a consultant, Dr. Liker has been paid approximately for the many and varied duties he has performed as Medical Director over the course of more than a decade. (CX1379_0037, *in camera*).

162. Dr. Liker was responsible for "core research" relating to cardiovascular, prostate, and erectile dysfunction. (Dreher, Tr. 529).

Response to Finding No. 162:

Respondents object to the term phrase "was responsible for" as vague and ambiguous. Specifically, Dr. Liker testified at trial that, as Medical Director at POM, he is responsible for overseeing POM's medical research program and to "make sure that we're getting good science done by the top people in the most rigorous manner." (Liker, Tr. 1878). Dr. Liker went about this by looking at the body of research that had been done in a particular area of health and reviewing the literature in that field before seeking out the "most published authors in the leading journals and the most reputable institutions to conduct POM's research." (Liker, Tr. 1879-1880). Additionally, Respondents object to Complaint Counsel's use of the term "core research" to the extent that they intend to construe its meaning to be anything other than these were "primary areas of research" that Respondents have been interested in exploring. (Dreher, Tr. 529).

163. Respondents also hired Risa Schulman, who was POM's Director of Research & Development from approximately 2002-2005. (CX0105_0016). POM subsequently hired Dr. Dreher in 2005 as Vice President of Scientific and Regulatory Affairs. (Dreher, Tr. 527).

Response to Finding No. 163:

Respondents have no specific response.

164. Dr. Dreher's duties primarily entailed exploratory research, which was looking at new products such as POMx and developing clinical and basic science for new applications for POM products. "Basic science" refers to test-tube, animal studies, and preclinical research. Dr. Dreher also arranged for contracts and funding of research with universities and contract research organizations, provided the materials for testing, and helped to organize the objectives for the studies and for carrying out the studies. (Dreher, Tr. 528).

Response to Finding No. 164:

Respondents object to the term "exploratory" as vague and ambiguous.

165. Dr. Dreher reported to Mr. Tupper. He would also report to a certain extent to Dr. Liker, to help him manage the logistics associated with some of the larger studies. (Dreher, Tr. 529). Dr. Dreher and Dr. Liker met weekly for the first two-and-a-half to three years at POM, and then less frequently in the last year of his employment. (Dreher, Tr. 530).

Response to Finding No. 165:

Respondents have no specific response.

166. After Dr. Dreher left, POM hired Dr. Bradley Gillespie in 2009 as its Vice President of Clinical Development. (CX1349 (Gillespie, Dep. at 10-11); CX1353 (Tupper, Dep. at 28)).

Response to Finding No. 166:

Respondents have no specific response.

167. POM has also hired scientific consultants, including Dr. Aviram and Dr. David Heber. (CX1380_0005; CX1349 (Gillespie, Dep. at 264-65); Heber, Tr. 1941; S. Resnick, Tr. 1637).

Response to Finding No. 167:

Respondents have no specific response.

168. POM's consumer advertising frequently featured results from five POM-sponsored studies: two heart disease studies by Dr. Aviram; a study on blood flow in the heart by Dr. Dean Ornish; a prostate cancer study by Dr. Allan Pantuck; and an erectile dysfunction study by Mr. Christopher Forest and Dr. Harin Padma-Nathan. (*See, e.g.*, CCFF ¶¶ 336, 415, 425, 450-51, 455). The combined cost of these studies was no more than $2.49 million. (*See* CCFF ¶¶ 790, 823, 987, 1063).

Response to Finding No. 168:

Respondents object to Complaint Counsel's proposed finding as argumentative and vague. POM's body of research is interrelated, and studies, whether or not they are ever published or reach statistical significance, add to Respondents understanding of all of POM's science and benefits of the Challenged Products. (Tupper, Tr. 3000-02). The studies conducted concerning one disease or condition, such as the effect of antioxidants or nitric oxide, are sufficiently interrelated to other disease and conditions. (Tupper, Tr. 3000-01). In fact, Mr. Tupper testified that Respondents learned a great deal even from the unsuccessful studies and, in a very real way, all of Respondents' studies were important sources of knowledge that allowed them to make informed decisions. (Tupper, Tr. 3000-30001).

Respondents also object to Complaint Counsel's proposed finding to the extent that the $2.49 million tally understates the dollars spent on the research due to the exclusion of any overhead items, such as rent and salaries. (Tupper, Tr. 2999-3000).

169. The first Aviram study, published in 2001, was *Pomegranate Juice Consumption Inhibits Serum Angiotensin Converting Enzyme Activity and Reduces Systolic Blood Pressure* ("**Aviram ACE/BP Study (2001)**"). (CX0542). The Aviram ACE/BP Study (2001), conducted on ten patients, examined the effect of POM Juice consumption on ACE, an atherosclerosis-associated enzyme, and blood pressure. (CX0542).

Response to Finding No. 169:

Respondents object to the proposed finding as vague and ambiguous to the extent that it refers to ACE as "an atherosclerosis-associated enzyme". Specifically, ACE stands for "angiotensin converting enzyme" and is a protein that causes blood vessels to constrict. (CX0542_0001). Also, Respondents object to the term "first" as vague and ambiguous. Dr. Aviram published a study sponsored by Respondents in 2000. (PX0004).

170. The second Aviram study, published in 2004, was *Pomegranate Juice Consumption for 3 Years by Patients with Carotid Artery Stenosis Reduces Common Carotid Intima-Media Thickness, Blood Pressure and LDL Oxidation* ("**Aviram CIMT/BP Study (2004)**").

(CX0611). The Aviram CIMT/BP Study (2004), conducted on 19 patients, examined the effect of POM Juice consumption on carotid intima-media thickness ("CIMT"), which is an indirect measure of arterial plaque, and blood pressure. (CX0611).

Response to Finding No. 170:

Respondents object to the term "second" as vague and ambiguous.

Respondents object to the proposed finding as vague and ambiguous to the extent that it states that CIMT "is an indirect measure of arterial plaque, and blood pressure." Such statement is also unsupported by the cited evidence.

Complaint Counsel cite to Dr. Aviram's study generally for the proposition that CIMT is "an indirect measure of arterial plaque, and blood pressure." While Dr. Aviram's 2004 study did show a 12% reduction in systolic blood pressure after one year of pomegranate juice consumption and concluded that "pomegranate juice consumption (by patients with carotid artery stenosis) possess anti-atherosclerotic properties" and "reduced common carotid intima-media thickness" the authors of the study never made the connection or stated that CIMT is an indirect measure of arterial plaque and blood pressure, although such relationship may in fact exist. (CX0611_0005, 0031).

171. Dr. Ornish's study, published in 2005, was *Effects of Pomegranate Juice Consumption on Myocardial Perfusion in Patients with Coronary Heart Disease* ("**Ornish MP Study (2005)**"). (CX1198). The Ornish MP Study (2005) examined the effect of POM Juice consumption on 45 patients with coronary heart disease. (CX1198).

Response to Finding No. 171:

Respondents have no specific response.

172. Dr. Pantuck's study, published in 2006, was *Phase II Study of Pomegranate Juice for Men with Rising Prostate-Specific Antigen Following Surgery or Radiation for Prostate Cancer*, ("**Pantuck Phase II Prostate Cancer Study (2006)**"). (CX0815). The Pantuck Phase II Prostate Cancer Study (2006) examined the effect of POM Juice consumption on 46 men previously treated for prostate cancer by radiation therapy or surgery. (CX0815).

Response to Finding No. 172:

Respondents have no specific response.

173. Forest and Padma-Nathan's study on erectile dysfunction, published in 2007, was Efficacy and Safety of Pomegranate Juice on Improvement of Erectile Dysfunction in Male Patients with Mild to Moderate Erectile Dysfunction: A Randomized, Placebo-Controlled, Double-Blind, Crossover Study ("**Forest Erectile Dysfunction Study (2007)**"). (CX1193). The Forest Erectile Dysfunction Study (2007) examined the effect of POM Juice consumption on 53 men with mild to moderate erectile dysfunction. (CX1193).

Response to Finding No. 173:

Respondents have no specific response.

174. POM also sponsored a study by Dr. Michael Davidson, titled Effects of Consumption of Pomegranate Juice on Carotid Intima-Media Thickness in Men and Women at Moderate Risk for Coronary Heart Disease, published in 2009 ("**Davidson CIMT Study (2009)**"). (CX1065). The Davidson CIMT Study (2009) tested the effect of POM Juice on CIMT progression rates in 289 subjects at moderate coronary heart disease risk. (CX1065). This study, which had negative findings, was listed on POM's website in late 2009, but otherwise was not widely used in consumer advertising, even after POM knew of its results in 2006. (See, e.g., CCFF ¶ 415).

Response to Finding No. 174:

Respondents object to the last sentence of this proposed finding as argument and not averments of fact.

Respondents also object to the word "negative" as vague and ambiguous and argumentative.

The evidence does not support Complaint Counsel's argument that the results of Dr. Davidson's CIMT study are "negative." At 12 months, the data from Dr. Davidson's study showed a statistically significant reduction in CIMT in the group consuming pomegranate juice versus the placebo group in composite measurements, but statistical significance between the two groups was not demonstrated at 18 months. (CX1065; CX 1336 (Davidson, Dep. at 55)). However, in a post-hoc analysis of the study,

Dr. Davidson noted that patients with the highest risk factors of coronary heart disease, in fact, did experience a benefit as compared to the placebo group. (CX1065). Indeed, this analysis showed that the higher risk patients in the pomegranate juice group had significantly less anterior wall and/or composite CIMT progression versus control subjects. (CX1065). Thus, the evidence does not support Complaint Counsel's argument that the results of Dr. Davidson's CIMT study are "negative."

Additionally, Respondents object to the term "not otherwise widely used" as vague, ambiguous, argumentative and unsupported by the record. Complaint Counsel cite no evidence in the record supporting their argument that Dr. Davidson's CIMT study was "not otherwise widely" used in consumer advertising.

Complaint Counsel attempt to twist the facts of the publication of Dr. Davidson's CIMT study to imply that Respondents did not use its results in advertising the Challenged Products for nearly three years after receiving them because they were either trying to hide those results or because they believed the results were "negative." Indeed, this proposition is unsupported by the record.

POM did not use the results of the Davidson study in its advertising until 2009 because of the *delay in its publication*. Respondents received the results of Dr. Davidson's CIMT study in 2006, but Dr. Davidson and the Respondents decided to have the data re-read by a blinded independent group because both Dr. Davidson and POM's internal science team were confused by the results. (Liker, Tr. 1895-96; CX1350 (Liker, Dep. at 146, 149-50, 163-64)). Mr. Resnick also wanted to make sure that if POM's advertising shared the study's results that it, in fact, accurately reflected the true benefit from the Challenged Products. (Liker, Tr. 1895-96; CX1350 (Liker, Dep. at 146, 149-50, 163-64)). Furthermore, POM did not advertise the unpublished results between 2006 and 2009 because doing so would have interfered with Dr. Davidson's ability to get the

results published in a scientific journal. (CX1065). The re-reading of the results caused a delay in the publication of Dr. Davidson's study until 2009. Upon publication of Dr. Davidson's study in the American Journal of Cardiology, POM did share Dr. Davidson's published work.

V. RESPONDENTS' MARKETING AND ADVERTISING OF THE POM PRODUCTS

A. Overview of Marketing Techniques

175. Mrs. Resnick testified that she considered marketing to be like a wheel with many spokes, and for POM's business the marketing "spokes" included advertising, public relations, Internet marketing, event sponsorship, and product placement. (L. Resnick, Tr. 82-83).

Response to Finding No. 175:

Respondents have no specific response. [michelle]

176. Mrs. Resnick believes she created a market for pomegranate juice through "public relations, advertising events, product placement, et cetera, all the arms of marketing." POM itself stated that the millions of dollars it has spent promoting pomegranate juice for health in fact created the market for the juice: "Through its investment of millions of dollars to research and promote the nutritional qualities and health benefits associated with pomegranate juice, [POM] largely created the burgeoning market for genuine pomegranate juice that exists today." (CX1362 (L. Resnick, TCCC Dep. at 120); CX1395_0004; CX1396_0004; CX1397_0004; CX1398_0004;CX1399_0004).

Response to Finding No. 176:

Complaint Counsel have mischaracterized Mrs. Resnick's testimony. Mrs. Resnick testified that she created the "U.S. consumer market" "to some extent" for pomegranate juice. (L. Resnick, Tr. 81) Mrs. Resnick further testified that she did not utilize all the arms of marketing. (L. Resnick, Tr. 81). [michelle]

177. Information about the POM Products has been disseminated to the public through a variety of media, including print advertisements in magazines, freestanding inserts ("FSIs") in newspapers, out of home media such as billboards and bus shelters, posters in health clubs and doctors' offices, advertising on prescription drug bags, Internet websites, online banner advertisements, medical outreach, radio, television, press releases and press

interviews. (L. Resnick, Tr. 81-82 (radio), 186 (FSIs); Leow, Tr. 426-428, 457 (out of home, health clubs, banner ads, television); Perdigao, Tr. 597-98 (press releases), 608 (prescription drug bags); Tupper, Tr. 927 (magazine wraps); CX1375 (L. Resnick, Trop. Dep. at 167) (medical outreach); CX1357 (Kuyoomjian, Dep. at 85-86 (posters in doctors' offices), 122 (radio); PX0364-0002, Answer ¶¶ 9-10 (press interviews); *see also* CX1426_0002, Compl. ¶¶ 9-10; PX0364-0002, Answer ¶¶ 9-10 (admitting advertising and promotional materials attached to Complaint were disseminated)).

Response to Finding No. 177:

The cited testimony does not support Finding No. 1896 that "Information about POM Products" were disseminated but only that advertisements were disseminated in the manners alleged in Finding No. 1896. (L. Resnick, Tr. 81-82 (radio), 186 (FSIs); Leow, Tr. 426-428, 457 (out of home, health clubs, banner ads, television); Perdigao, Tr. 597-98 (press releases), 608 (prescription drug bags); Tupper, Tr. 927 (magazine wraps); CX1375 (L. Resnick, Trop. Dep. at 167) (medical outreach); CX1357 (Kuyoomjian, Dep. at 85-86 (posters in doctors' offices), 122 (radio); PX0364-0002, Answer ¶¶ 9-10 (press interviews); *see also* CX1426_0002, Compl. ¶¶ 9-10; PX0364-0002, Answer ¶¶ 9-10 (admitting advertising and promotional materials attached to Complaint were disseminated)). [Michelle]

178. POM's advertising campaigns have included "Superhero," "Dress[ed] Bottle," "Trust in POM," and "History." (JX0003 ¶ B.10).

Response to Finding No. 178:

Respondents have no specific response.

179. POM's North America consumer marketing expenses for juice, from April 2002 to November 2010, totaled approximately $53,194,735. (JX0001, ¶ 13).

Response to Finding No. 179:

Respondents have no specific response.

180. POM's consumer marketing expenses for POMx Pills and Liquid, from April 2007 to November 2010, totaled approximately $3,634,247. (JX0001, ¶ 14).

Response to Finding No. 180:

Respondents have no specific response.

B. Process of Creating and Disseminating POM Product Advertising

181. The creation of POM marketing and advertising was a collaborative effort that entailed coming up with ideas for print, outdoor, or television campaigns, as well as writing copy, creating graphics, and putting the ideas together for a final execution. (Leow, Tr. 420-21; Tupper, Tr. 920).

Response to Finding No. 181:

Although the creation of POM marketing and advertising was a collaborative effort, it should be noted that it was a collaborative effort between Fire Station Agency and POM Wonderful. (Tupper, Tr. 920).

182. The position of head of POM Marketing has been filled by numerous people over the past eight years. Starting in mid-2003 to June 2011, the heads of marketing have included: Tony Chang, Rina Calderon, John Regal, Jennifer Stein, Mark Cregar, Grant Beggs, Diane Kuyoomjian, Paul Coletta, and Jan Hall. (CX1353 (Tupper, Dep. at 22-26); CX1351 (McLaws, Dep. at 17); CX1357 (Kuyoomjian, Dep. at 21); CX1356 (Leow, Dep. at 25-26); CX1348 (Perdigao, Dep. at 31-32); Tupper, Tr. 889).

Response to Finding No. 182:

Respondents have no specific response

183. Mr. Perdigao started in an advertising position with Teleflora, a Roll company, in the summer of 2007. In January 2008, he became Roll's President of Advertising and Corporate Communications, and the head of the Fire Station in-house advertising agency. (Perdigao, Tr. 590-92, 595).

Response to Finding No. 183:

Respondents have no specific response.

184. Ms. Leow has been a creative director at Roll since 2005, with POM as one of her clients. She has continued to work on POM's advertising. (Leow, Tr. 415; CX1356 (Leow, Dep. at 16-18, 22)).

Response to Finding No. 184:

Ms. Leow is currently the creative director for Fire Station, one of Roll's companies.

(CX1356 (Leow, Dep. at 17-18)).

185. Monique McLaws was the brand manager for POM Juice from 2005 to 2006. (CX1351 (McLaws, Dep. at 13-14)).

Response to Finding No. 185:

Respondents have no specific response.

186. Staci Glovsky started as an independent consultant working for POM in March 2006 and was later the full-time brand manager for POMx from June 2006 to June 2007. She became the team leader from a marketing perspective and worked on the launch of POMx in 2007. (CX1347 (Glovsky, Dep. at 20, 23, 25, 39); CX1351 (McLaws, Dep. at 21)).

Response to Finding No. 186:

Respondents have no specific response.

1. "LRR Meetings"

187. Mrs. Resnick routinely held creative meetings with the senior in-house representatives of POM and Roll, including representatives of POM Marketing, Roll's public relations department and Roll's advertising agency, Fire Station. (L. Resnick, Tr. 87-88, 92).

Response to Finding No. 187:

Lynda Resnick did not testify that she "routinely" held creative meetings. (Entire record)

188. Staff members at POM and Roll informally refer to these meetings with Lynda Resnick as "LRR Meetings." (JX0003 ¶ A.12). In addition to Mrs. Resnick, Mr. Tupper and employees from POM's marketing and scientific departments, Fire Station employees and someone from Roll's Corporate Communications department regularly attend LRR meetings. (Rushton, Tr. 1366; Perdigao, Tr. 624-25; Tupper, Tr. 929-30, L. Resnick, Tr. 249 (Dr. Dreher attended marketing meetings); CX1351 (McLaws, Dep. at 33-34) (Mrs. Resnick, Mr. Tupper, Head of Marketing, brand managers, public relations, and sometimes Dr. Dreher attended meetings)).

Response to Finding No. 188:

Mr. Tupper testified that Dr. Dreher attended the LRR Meetings only infrequently and for a short amount of time. (Perdigao, Tr. 625).

189. It has been a typical business practice for the staff to prepare LRR Meeting agendas and post-meeting recaps. (L. Resnick, Tr. 106; CX1375 (L. Resnick, Trop. Dep. at 127); *see also* CX0410; CX0411 [compilations of meeting minutes]).

Response to Finding No. 189:

Respondents have no specific response.

190. The purpose of the LRR Meetings, and notes and recaps following the meetings, was to aid staff in following through on the next steps of the creative projects. (L. Resnick, Tr. 106).

Response to Finding No. 190:

Lynda Resnick did not testify about the purpose of recaps following the meetings.

(Entire record)

191. Mrs. Resnick testified that notes of an LRR meeting would memorialize a discussion held in her presence, and that notes of LRR meetings were sent to her. (L. Resnick, Tr. 112; CX1368 (L. Resnick, Welch Dep. at 29)).

Response to Finding No. 191:

Lynda Resnick testified that she never looked the notes of an LRR meeting. She further testified that the notes reflected the note taker's view or interpretation of the meeting discussion and not necessarily words she stated. (L. Resnick, Tr. 112)

2. Creative Briefs and Advertising Concepts

192. To start the creative process, POM Marketing would provide Fire Station with a "creative brief," which gave an overview of the assignment. The creative brief would include information such as: the target audience, advertising concept, benefits or health benefits, "reasons to believe," and tonality, among other things. (Leow, Tr. 451-452, 483-85; Tupper, Tr. 921; CX0409_0010, 0053, 0091, 0119).

Response to Finding No. 192:

Ms. Leow testified that the creative brief helped to inform Fire Station of the requested concept on the assignment, but it did not mean that Fire Station would ultimately go in that direction or even that it would focus on that particular concept. (Leow, Tr. 484). Professor Stewart testified that he did not know if any of the creative briefs had any effect on any advertisements and there was not any other evidence of any such effect. (Stewart, Tr. 3235).

193. In some cases, the creative briefs would contain information regarding POM's scientific studies. (CX1348 (Perdigao Dep. at 138)).

Response to Finding No. 193:

The creative briefs would provide only general, not specific, information about scientific studies. (CX1348 (Perdigao Dep. at 138)). Professor Stewart testified that he did not know if any of the creative briefs had any effect on any advertisements and there was not any other evidence of any such effect. (Stewart, Tr. 3235).

194. According to Mrs. Resnick, the purpose of creative briefs were "to brief the advertising agency on some of the key elements that should appear in the advertising." Creative briefs are "an understood part of the assignment" and "just part of . . . the way we do business." (L. Resnick, Tr. 123; *see also* CX1368 (L. Resnick, Welch Dep. at 94-96)).

Response to Finding No. 194:

Ms. Leow testified that the creative brief helped to inform Fire Station of the requested concept on the assignment, but it did not mean that Fire Station would ultimately go in that direction or even that it would focus on that particular concept. (Leow, Tr. 484). Professor Stewart testified that he did not know if any of the creative briefs had any effect on any advertisements and there was not any other evidence of any such effect. (Stewart, Tr. 3235).

195. Creative briefs are "fundamental planning tool[s] that advertising agencies and marketing departments use." (Stewart, Tr. 3185). Creative briefs are "very standard tool[s]" and are "regularly employed" in the advertising industry. (Stewart, Tr. 3185).

Response to Finding No. 195:

Professor Stewart testified that he did not know if any of the creative briefs had any effect on any advertisements and there was not any other evidence of any such effect. (Stewart, Tr. 3235).

196. POM Marketing maintains an archive of creative briefs from past campaigns. (Tupper, Tr. 922; *see also* CX0129-CX0131 (2007 creative briefs for POMx print advertisements); CX0409 (creative briefs ranging from January 2004 to October 2009)). Respondents generated creative briefs for a variety of POM campaigns, products, and promotional items between January 2004 and October 2009. Examples of the wide variety of marketing projects covered by the creative briefs include:

- Fresh juice (CX0409_0123-33, 0142-43, 0172; PX0520);
- POMx Pills (CX0409_0015-21, 0023-25, 0027-34, 0044-50, 0055-66, 0073-74, 0088-89, 0091-92, 0095-102, 0147; CX0129-0131);
- POMx Liquid (CX0409_0038-43, 0051-54, 0067-72, 0075-76; PX0516);
- Internet sites and emails (CX0409_0085-87, 0110-113, 0117-120, 0122, 0134-41, 0148-51; PX0517; PX0519; PX0521);
- Package inserts and newsletters (CX0409_0079-84, 0121);
- Postcards and direct mail (CX0409_090, 0105-09);
- Physical promotions like shelf banners, hang tags (CX0409_0001-09, 0022, 0026, 0144-46, 0156, 0164-67);
- Concepts like "Women's Lifestyle Print/Outdoor," and "Bikini" (CX0409_0010-11, 0014);
- Commuter train posters (CX0409_0103-04);
- Retail packaging (CX0409_0093-94, 0115-16);
- POM Tea (CX0409_0035-37, 0173-76);
- New York marketing campaign (CX0409_0153-55);

- Television (CX0409_0157-58; PX0522);
- Trade or trade show materials (CX0409_0012-13, 0159-60, 0168-70; PX0523); and
- Recipe cards or booklets (CX0409_0152, 0161-63, 0171).

Response to Finding No. 196:

Professor Stewart testified that he did not know if any of the creative briefs had any effect on any advertisements and there was not any other evidence of any such effect. (Stewart, Tr. 3235).

197. Mrs. Resnick has reviewed or provided input on creative briefs. (CX0409_0092 (stating that some copy, headlines, and images were "per LRR"); CX0084_0001 (stating that Mrs. Resnick had "real problems with the [creative briefs]" drafted by Ms. Glovsky, a former POM Marketing employee)).

Response to Finding No. 197:

Lynda Resnick testified that she has never written or read a creative brief. (CX1368 (L. Resnick, Welch Dep. at 96)). Professor Stewart testified that he did not know if any of the creative briefs had any effect on any advertisements and there was not any other evidence of any such effect. (Stewart, Tr. 3235).

198. Mr. Tupper has reviewed and given direction to POM's marketing staff on parts or elements of creative briefs. (Tupper, Tr. 924).

Response to Finding No. 198:

Mr. Tupper may have had discussions with the marketing department about individual parts or elements of marketing briefs, but he never reviewed creative briefs in their entirety. (Tupper, Tr. 924). Professor Stewart testified that he did not know if any of the creative briefs had any effect on any advertisements and there was not any other evidence of any such effect. (Stewart, Tr. 3235).

199. Mrs. Resnick stated that a "product is only as good as the [creative] brief that goes into it" and that she required creative briefs to be detailed enough for anyone to use to guide a project: "*I always say I want a marketing brief so tight that if the author were run over by a bus, anyone could pick up the project and complete it.*" (L. Resnick, Tr. 122-23; CX0001_0011) (emphasis added)).

Response to Finding No. 199:

Lynda Resnick testified that she has never written or read a creative brief. (CX1368 (L. Resnick, Welch Dep. at 96)). Ms. Leow testified that the creative brief helped to inform Fire Station of the requested concept on the assignment, but it did not mean that Fire Station would ultimately go in that direction or even that it would focus on that particular concept. (Leow, Tr. 484). Professor Stewart testified that he did not know if any of the creative briefs had any effect on any advertisements and there was not any other evidence of any such effect. (Stewart, Tr. 3235).

200. The creative brief would first be sent to the traffic department at Fire Station, and would then be assigned to appropriate personnel at the agency, depending on the project. (Leow, Tr. 452-53).

Response to Finding No. 200:

Ms. Leow testified that the creative brief helped to inform Fire Station of the requested concept on the assignment, but it did not mean that Fire Station would ultimately go in that direction or even that it would focus on that particular concept. (Leow, Tr. 484). Professor Stewart testified that he did not know if any of the creative briefs had any effect on any advertisements and there was not any other evidence of any such effect. (Stewart, Tr. 3235).

201. The creative team(s) at Fire Station would then come up with advertising concepts, which would be reviewed by Ms. Leow, then by Mr. Perdigao, and finally POM Marketing. Depending on the assignment, the concepts were sometimes also reviewed by Mr. Tupper. These reviews at the concept stage involved the general creative direction, look, tone, and idea of the advertising, rather than body copy. (Leow, Tr. 457-60; CX0265_0002).

Response to Finding No. 201:

Ms. Leow testified that the creative brief helped to inform Fire Station of the requested concept on the assignment, but it did not mean that Fire Station would ultimately go in that direction or even that it would focus on that particular concept. (Leow, Tr. 484). Professor Stewart testified that he did not know if any of the creative briefs had any effect on any advertisements and there was not any other evidence of any such effect. (Stewart, Tr. 3235).

202. Advertising concepts include the graphics and headlines. A headline is the main message of an advertisement and usually appears in larger type. Body copy is the smaller print usually appearing at the bottom of an advertisement. (Leow, Tr. 462-63, 467).

Response to Finding No. 202:

Respondents have no specific response.

203. The process of creating advertising was a fluid one, with Fire Station seeking input from POM Marketing at any step along the way if needed. (Leow, Tr. 458-59).

Response to Finding No. 203:

Respondents have no specific response.

204. Once the concepts for a big campaign were approved, they would ultimately go to Mrs. Resnick for approval. Fire Station presented advertising concepts to Mrs. Resnick during LRR Meetings. (Leow, Tr. 461; Perdigao, Tr. 623-25; Rushton, Tr. 1358).

Response to Finding No. 204:

Respondents have no specific response.

205. Mrs. Resnick's participation in the creative process included briefing POM Marketing, as well as meeting with POM and Fire Station personnel to review proposed creative pieces developed by Fire Station. (CX1368 (L. Resnick, Welch Dep. at 9-10)).

Response to Finding No. 205:

Respondents have no specific response.

206. At LRR Meetings and during other interactions with POM Marketing and Fire Station, Mrs. Resnick would approve a general direction for POM's advertising and also approved the lion's share of POM's advertising concepts. (CX1362 (L. Resnick, TCCC Dep. at 30-31); *see also* Perdigao, Tr. 604, 628 (agreeing that it is fair to say that Mrs. Resnick has final authority on advertising campaigns); Rushton, Tr. 1369-71 (stating that Mrs. Resnick requested and approved changes to POM's website and that when Mrs. Resnick did not like an online advertising concept, he would "go back to the drawing board" with Fire Station); L. Resnick, Tr. 99-100, 186-87; Leow, Tr. 470, 502; CX0023_0001 (stating that "LRR is going to take a more active role in writing copy[]" and that "[i]f [Mrs. Resnick] writes it, it will be approved"); CX1351 (McLaws, Dep. at 23) (stating that the "decision to either move forward or make adjustments [on marketing on advertising] came from Lynda")).

Response to Finding No. 206:

Respondents have no specific response.

207. For example, Mrs. Resnick has reviewed and provided detailed edits and suggestions for POMx Pill advertisements (CX0126_0002) and the POM Wonderful website (CX0024_0009-38); approved designs and headlines for advertisements in various media (CX0247_0002; CX0248_0002); and suggested and reviewed concepts for new advertisements (CX0266_0002-03; CX0320_0002).

Response to Finding No. 207:

Respondents have no specific response.

208. Examples of advertising headlines Mrs. Resnick approved included:

- "Wanna give prostate cancer the finger?"
- "Want to avoid the cardiologist? Gulp."
- "I'm off to save prostates"
- "Up, up and away with erectile dysfunction"
- "Uh Oh! That heart is under attack"

- "Holy Health! $25 million in medical research"
- "Risk your health in this economy? Never."

(CX1357 (Kuyoomjian, Dep. at 110, 148); *see also* L. Resnick, Tr. 117; CX0217_0002; CX0247_0002).

Response to Finding No. 208:

Lynda Resnick testified that she does not remember approving the headlines "Up, up and away with erectile dysfunction", "Uh-oh! That heart is under attack", "Holy Health! $25 million in medical research" and Risk your health in this economy? Never."

(L. Resnick, Tr. 117-118).

209. Disagreements about creative concepts would regularly occur at LRR meetings when Mrs. Resnick believed that someone was deviating from her brand or creative vision. (Rushton, Tr. 1368; CX1346 (Rushton, Dep. at 108-09)).

Response to Finding No. 209:

Mr. Rushton testified that the "disagreements" were really discussions where Mrs. Resnick "would debate something that was presented or somebody would debate her opinion." (Rushton, Tr. 1367).

3. Body Copy and Advertising Executions

210. After the creative concepts were approved, the creative team at Fire Station would draft body copy with direction from POM Marketing, based on the creative brief. (Leow, Tr. 462-63).

Response to Finding No. 210:

Fire Station would draft the body copy using the creative brief as an outline, not as a basis for the body copy. (Leow, Tr. 464).

211. POM Marketing would sometimes have input during the process of writing the copy. After the copy was drafted, it would go to POM Marketing and sometimes, depending on the project, to Mr. Tupper and Mrs. Resnick for approval. (Leow, Tr. 463-64; L. Resnick, Tr. 187).

Response to Finding No. 211:

Sometimes the body copy would go to the chief marketing officer for approval, rather than Mr. Tupper or Mrs. Resnick. (L. Resnick, Tr. 187).

212. There are no scientists or technical writers on Fire Station's staff. (Leow, Tr. 464-65). Therefore, if the body copy had a medical component, and POM Marketing wanted specific wording in the body copy of an advertisement, it would draft and provide this copy to Fire Station. For example, Ms. Leow of Fire Station testified that she would not have been involved in drafting the body copy for the "Decompress" print advertisement. (Leow, Tr. 464-65, 495-96).

Response to Finding No. 212:

Respondents object to the second sentence of this finding in that it is not clear which version of the "Decompress" advertisement is being discussed. Indeed, some versions of the "Decompress" advertisement did not even have body copy.

213. If the body copy came directly from POM Marketing, Fire Station personnel would not rewrite it. POM Marketing would also provide final review of any body copy drafted; depending on the project, Mr. Tupper might approve it as well. (Leow, Tr. 464-66).

Response to Finding No. 213:

Sometimes the body copy would go to the chief marketing officer or Mrs. Resnick for approval, rather than Mr. Tupper. (L. Resnick, Tr. 187).

214. POM Marketing personnel rarely, if ever, read or reviewed POM's studies, nor were they expected to. (CX1357 (Kuyoomjian, Dep. at 94, 162); CX1347 (Glovsky, Dep. at 186); CX1351 (McLaws, Dep. at 75-76)).

Response to Finding No. 214:

Contrary to Complaint Counsel's finding, Ms. Kuyoomjian testified that at various times she reviewed the scientific research. (CX1378 (Kuyoomjian, OS Dep. at 70)).

Moreover, one of Mr. Tupper's job duties is to ensure that POM's marketers correctly portray and interpret the science in the advertisements and that POM's advertisements are vetted by the legal department. Mr. Tupper is the connecting piece between the science and POM marketing. (Tupper Tr. 2975-2976).

Mr. Tupper also testified at trial that the process POM has used to connect the science to the advertising includes a "checklist of individuals who need to review and sign off on those ads, ultimately culminating in a legal review." (Tupper, Tr. 2977-78). Additionally, Mr. Resnick's stated policy as to the necessary relationship between the science advertising representations concerning specific health conditions requires that the advertising accurately represent the scientific conclusions, and the supporting science must include published clinical research. (CX1353 (Tupper, Dep. at 134); Tupper, Tr. 2979). This more formalized process involving many different individuals also acts as a guard against the occurrence of any inadvertent mistakes in all parts of the advertising. Indeed, POM's intended goal by this process is to "ensure that nothing falls through the cracks." (Tupper, Tr. 2977-78).

215. Ms. Kuyoomjian testified that in terms of the relationship between POM advertisements and the scientific support for these advertisements, she would primarily rely on conversations with Mr. Tupper to understand content in POM's advertising and if people felt that it was generally accurate in terms of representing what POM intended to say and what POM could say. She relied on Mr. Tupper to be the "arbiter" of whether people felt POM's advertising was accurate. (CX1378 (Kuyoomjian, OS Dep. at 71-72)).

Response to Finding No. 215:

One of Mr. Tupper's job duties is to ensure that POM's marketers correctly portray and interpret the science in the advertisements and that POM's advertisements are vetted by the legal department. Mr. Tupper is the connecting piece between the science and POM marketing. (Tupper Tr. 2975-2976).

Mr. Tupper also testified at trial that the process POM has used to connect the science to the advertising includes a "checklist of individuals who need to review and sign off on those ads, ultimately culminating in a legal review." (Tupper, Tr. 2977-78). Additionally, Mr. Resnick's stated policy as to the necessary relationship between the science advertising representations concerning specific health conditions requires that the advertising accurately represent the scientific conclusions, and the supporting science must include published clinical research. (CX1353 (Tupper, Dep. at 134); Tupper, Tr. 2979). This more formalized process involving many different individuals also acts as a guard against the occurrence of any inadvertent mistakes in all parts of the advertising. Indeed, POM's intended goal by this process is to "ensure that nothing falls through the cracks." (Tupper, Tr. 2977-78).

216. Ms. Kuyoomjian testified that she did not believe she ever talked with Dr. Dreher about advertising. (CX1378 (Kuyoomjian, OS Dep. at 43-44)).

Response to Finding No. 216:

Ms. Kuyoomjian did not talk with Dr. Dreher about advertising because, as Dr. Dreher testified, his duties as vice president of scientific and regulatory affairs did not include reviewing and approving advertising copy. (Dreher, Tr. 530).

Mr. Tupper testified at trial that the process POM has used to connect the science to the advertising includes a "checklist of individuals who need to review and sign off on those ads, ultimately culminating in a legal review." (Tupper, Tr. 2977-78). Additionally, Mr. Resnick's stated policy as to the necessary relationship between the science advertising representations concerning specific health conditions requires that the advertising accurately represent the scientific conclusions, and the supporting science must include published clinical research. (CX1353 (Tupper, Dep. at 134); Tupper, Tr. 2979). This more formalized process involving many different individuals also acts as a guard against

the occurrence of any inadvertent mistakes in all parts of the advertising. Indeed, POM's intended goal by this process is to "ensure that nothing falls through the cracks." (Tupper, Tr. 2977-78).

217. Mr. Tupper led meetings to review advertising copy from a scientific perspective prior to its dissemination. (Dreher, Tr. 530).

Response to Finding No. 217:

One of Mr. Tupper's job duties is to ensure that POM's marketers correctly portray and interpret the science in the advertisements and that POM's advertisements are vetted by the legal department. Mr. Tupper is the connecting piece between the science and POM marketing. (Tupper Tr. 2975-2976).

218. Dr. Dreher was not involved in such reviews; indeed he testified that he "[a]bsolutely [did] not" review or approve advertising copy, nor did he review creative briefs. (Dr. Dreher, Tr. 530, 532). Dr. Dreher, however, was the key spokesperson in the challenged newsletters for POMx. (*See* CCFF ¶¶ D.4.g.436, D.4.g.439).

Response to Finding No. 218:

With regard to the challenged newsletters, Dr. Dreher does not believe that there is anything false or misleading about those newsletters. (Dreher, Tr. 588). Dr. Dreher believes in the science supporting the health benefits of pomegranates despite the FTC's accusations against him. (Dreher, Tr. 588).

219. Dr. Dreher also testified that he did not have a formal or significant role in advising POM that they could only make structure function claims for POM Juice. Nor did he review with POM personnel what he understood the scientific substantiation requirements to be for making claims about prostate cancer or heart disease. (Dreher, Tr. 533-34).

Response to Finding No. 219:

Mr. Tupper testified at trial that the process POM has used to connect the science to the advertising includes a "checklist of individuals who need to review and sign off on those

ads, ultimately culminating in a legal review." (Tupper, Tr. 2977-78). Additionally, Mr. Resnick's stated policy as to the necessary relationship between the science advertising representations concerning specific health conditions requires that the advertising accurately represent the scientific conclusions, and the supporting science must include published clinical research. (CX1353 (Tupper, Dep. at 134); Tupper, Tr. 2979). This more formalized process involving many different individuals also acts as a guard against the occurrence of any inadvertent mistakes in all parts of the advertising. Indeed, POM's intended goal by this process is to "ensure that nothing falls through the cracks." (Tupper, Tr. 2977-78).

220. Likewise, Dr. Liker's role in marketing has been minimal, and he did not regularly review advertising disseminated by POM. (Liker, Tr. 1906-08).

Response to Finding No. 220:

Mr. Tupper testified at trial that the process POM has used to connect the science to the advertising includes a "checklist of individuals who need to review and sign off on those ads, ultimately culminating in a legal review." (Tupper, Tr. 2977-78). Additionally, Mr. Resnick's stated policy as to the necessary relationship between the science advertising representations concerning specific health conditions requires that the advertising accurately represent the scientific conclusions, and the supporting science must include published clinical research. (CX1353 (Tupper, Dep. at 134); Tupper, Tr. 2979). This more formalized process involving many different individuals also acts as a guard against the occurrence of any inadvertent mistakes in all parts of the advertising. Indeed, POM's intended goal by this process is to "ensure that nothing falls through the cracks." (Tupper, Tr. 2977-78).

221. After proofreading by Fire Station personnel, POM's advertisement would be sent to Fire Station's production department to create the "mechanical" – the completed advertisement in final electronic form that's ready to be sent to publications. (Leow, Tr. 466-67).

Response to Finding No. 221:

Ms. Leow testified that sometimes Mr. Tupper would review a final ad. (Leow, Tr. 466).

222. POM approves final executions of advertisements created by Fire Station before dissemination. (Leow, Tr. 466; Perdigao, Tr. 637). Mrs. Resnick would sometimes review finished advertisements. (Leow, Tr. 466).

Response to Finding No. 222:

Respondents have no specific response.

223. POM Marketing approves the media plan developed by Fire Station. (Perdigao, Tr. 639).

Response to Finding No. 223:

Respondents have no specific response.

224. Fire Station's traffic department transmits the final advertisements to media companies for dissemination. (Perdigao, Tr. 637-38, 640).

Response to Finding No. 224:

Respondents have no specific response.

4. Dissemination of Print Advertising

225. POM Juice print advertisements were disseminated in a wide variety of locally and nationally distributed publications, including but not limited to: the *Chicago Tribune* (CX0016), *Prevention* (CX0029, CX0034, CX0260), *Details* (CX0031), *Rolling Stone* (CX0036), *Health* (CX0103; CX0251), I*nStyle* (CX0109), *Men's Health* (CX0192, CX0260), and *Men's Fitness* (CX0274). *See also* CX0474; CX0371 (declarations describing capture of print advertisements and dissemination information).

Response to Finding No. 225:

Respondents have no specific response.

226. POM also disseminated a "magazine wrap" or "cover wrap" advertisement, which was placed around issues of *Time* magazine distributed in urologists' offices. (CX0314; Leow, Tr. 426; Tupper, Tr. 927; L. Resnick, Tr. 122). A "cover wrap" is a type of

advertisement that covers the actual magazine cover, essentially replacing it. (CX1357 (Kuyoomjian, Dep. at 86)).

Response to Finding No. 226:

Mrs. Resnick testified that the magazine wrap only ran once. (L. Resnick, Tr. 122).

227. POMx Pills print advertisements were disseminated in a wide variety of locally and nationally distributed publications, including but not limited to: *Fortune* (CX0120), the *New York Times* (CX0169, CX0337), *Discover* (CX0122), *Men's Health* (CX0348), *Popular Science* (CX0348), *Time* (CX0350) and *Playboy* (CX0355, CX0470_0001; Leow Tr. 496). (Leow, Tr. 425).

Response to Finding No. 227:

Respondents have no specific response.

228. Mrs. Resnick testified that POM used media tracking services to ensure that advertisements ran in the media for which they were purchased. (L. Resnick, Tr. 131-33; *see also* CX1368 (L. Resnick, Welch Dep. at 135-37)).

Response to Finding No. 228:

Respondents have no specific response.

229. In order to confirm that POM's print advertisements ran as ordered, Fire Station keeps a copy of the print publication in which every advertisement appeared. (Leow, Tr. 479-80; Perdigao, Tr. 641, 647).

Response to Finding No. 229:

Mr. Perdigao testified that Fire Station keeps "the lion's share" of print publications in which POM's ads have run, not all of them as the finding suggests. (Perdigao, Tr. 647)

230. POM also disseminated package inserts or brochures with direct mail shipments of POMx (CX1426_00010-11, 38-42 [Compl. 10.A and Ex. I]; L. Resnick, Tr. 245), and direct mail newsletters to POMx customers (CX1426_00015-17, 00046-51 [Compl. ¶¶10.H-I and Exs. M, N]). These print materials contained various scientific claims about the benefits of POM Juice and POMx often describing studies in detail and providing statistics on the incidence of diseases. (L. Resnick, Tr. 177-78, 246-47).

Response to Finding No. 230:

Respondents object to the second sentence of this finding of fact on the basis that it misstates the evidence and the print materials speak for themselves.

231. A version of the POMx brochure also was available as point-of-purchase material at GNC stores where POMx was sold. (L. Resnick, Tr. 245-46).

Response to Finding No. 231:

Respondents have no specific response.

5. Strategy for Internet Advertising

232. POM has maintained the pomwonderful.com website since at least January 2003. (CX0013_0004). It has maintained the pomegranatetruth.com website since at least January 2008. (CX0170_0002). POM launched pompills.com in early 2007. (CX1347 (Glovsky, Dep. at 134-35)).

Response to Finding No. 232:

Respondents have no specific response.

233. Mrs. Resnick stated that "[e]ver since we first introduced POM, we have put our Web address on every product we sell. Putting your URL on your products is the cheapest and most effective ad spend you can make – because it's free." (CX0001_0027).

Response to Finding No. 233:

Respondents have no specific response to the extent this is a verbatim quote from the source, but object to the extent Complaint Counsel has presented no evidence that either statement is true. For example, there has been no expert or otherwise evidence or testimony that "putting your URL on your products is the cheapest and most effective ad spend you can make…".

234. Since at least September 2007, POM has had an online department. (Rushton, Tr. 1353). The online department is part of POM's marketing department and handles anything related to the Internet, including marketing, engagement, interaction, and development. (Rushton, Tr. 1353-54).

Response to Finding No. 234:

Respondents have no specific response other than to object to the extent Complaint Counsel insinuates that the online department was responsible for the noted responsibilities without oversight, input or control from other people above the department.

235. Jeffrey Rushton was the Director of Marketing for Online from September 2007 through March 2010. (Rushton, Tr. 1353).

Response to Finding No. 235:

Respondents have no specific response.

236. POM Marketing prepares creative briefs for online components of POM's marketing initiatives. (Rushton, Tr. 1391). Such briefs are then submitted to Fire Station. (Rushton, Tr. 1392).

Response to Finding No. 236:

Respondents have no specific response.

237. Mrs. Resnick was very involved in the conception of the POM Wonderful website. (L. Resnick, Tr. 94).

Response to Finding No. 237:

Mischaracterizes Mrs. Resnick's testimony. She stated she was not very involved in the website or the Internet except at the inception of the website. (L. Resnick, Tr. 94).

238. Mrs. Resnick provided written comments on the POM Wonderful website draft, called a "wireframe," in May 2004. (CX0024_0009; L. Resnick, Tr. 98-100).

Response to Finding No. 238:

Mrs. Resnick is "not positive" she made these comments. In fact, other people may have written as well. (L. Resnick, Tr. 104).

239. In June 2004, after a meeting with Mrs. Resnick, then Vice President of Marketing, John Regal, transmitted Mrs. Resnick's written comments and advised POM staff that glossary terms on the website were to be rewritten to provide "simple baby talk definition[s]" that would be "quickly tie[d] into [the] pomegranate juice benefit." (CX0024_0001). These glossary terms included "Alzheimer's," "atherosclerosis," "carotid artery stenosis," "cancer," "plaque," and "stroke." (CX0024_0003). Mrs. Resnick testified that "baby talk" meant simplifying the text so that a layperson could understand it. (CX1359 (L. Resnick, Dep. at 173-74).

Response to Finding No. 239:

Mischaracterizes the document. John Regal did not say all the terms needed to re-written to be "quickly tie[d] into [the] pomegranate juice benefit". He simply stated that the terms needed to be defined in line with the example he provided which was on nitric oxide. Complaint Counsel is impermissibly trying to tie all the terms to "pomegranate benefit" or related concepts and that simply was not the point or impetus of the email from John Regal. (CX0024_0001-3).

240. Mrs. Resnick testified that on the "POM Glossary" page of the POM Wonderful website wireframe, after the definition of the term "atherosclerosis," she added the written comment, "I AM LOOKING FOR MORE EXPLANATION HERE. EXPLAIN HOW THE ARTERIES HARDEN AND HOW POM SOFTENS THE PLAQUE AND HELPS THE BODY ELIMINATE IT." (CX0024_0027; CX1359 (L. Resnick, Dep. at 175-76)).

Response to Finding No. 240:

Respondents have no specific response other than this says nothing about whether this or any other version was actually placed on the website. In fact, other people may have written comments as well. (L. Resnick, Tr. 104).

241. The website wireframe also included a page on "Health Benefits" of POM Juice. (CX0024_0009, 16). A comment on this page identified the "Net Takeaway" as "Drinking 8oz of POM Wonderful a day guards against heart disease, stroke, erectile dysfunction, premature aging, Alzheimer's, even cancer." (CX0024_0016).

Response to Finding No. 241

Respondents have no specific response other than this says nothing about whether this or any other version was actually placed on the website. Similarly, this says nothing about what an actual consumer takes away from the message. Indeed, Complaint Counsel does not present any evidence that this version or any other version was ever published.

242. In approximately 2008, POM converted pomwonderful.com from a traditional static format to more of a dynamic, blog format that has sought engagement from external sources. (Rushton, Tr. 1354). POM launched this "Community" version of pomwonderful.com in approximately December 2009. (CX0473 (Dec. 2009, pomwonderful.com)).

Response to Finding No. 242:

Respondents have no specific response.

243. In October 2009, one of the rotating frames on the pomwonderful.com homepage welcomed consumers to its "new community site." (CX0473 (Oct. 2009, pomwonderful.com at 00:25)). The "community" design encouraged website visitors to "participate," including by "Tell[ing] Us Your Health Story." Consumers posted testimonials about medical phenomena from drinking pomegranate juice. (L. Resnick, Tr. 134; CX1362 (L. Resnick, TCCC Dep. at 15)).

Response to Finding No. 243:

Respondents have no specific response other than to note that "medical phenomena" is undefined and vague and is simply the opinion of Mrs. Resnick. Additionally, the testimonials were on the website much less than a year. (L. Resnick, Tr. 134).

244. The "Community" section of the site also featured blog posts and videos by "POM Experts" like Dr. Aviram, Dr. Heber, and Susan Bowerman, Assistant Director at the UCLA Center for Human Nutrition. (CX0473 (Oct. 2009, pomwonderful.com at 06:52)). POM paid Susan Bowerman to write blog posts for pomwonderful.com. (CX0203_0001; CX1346 (Rushton, Dep. at 145)).

Response to Finding No. 244:

Respondents have no specific response other than to note Ms. Bowerman was also used to assist in rewriting or reworking sections on the website.

245. To direct traffic to its website, POM used keyword advertising with search engines. (Rushton, Tr. 1357). With keyword advertising, marketers can pay for their advertisements to appear on the search results pages of search engines such as Google, Yahoo, Bing, among others, by purchasing keywords that consumers may search for. (Rushton, Tr. 1357-58).

Response to Finding No. 245:

Respondents have no specific response other than to note search engine optimization is commonly used by most advertisers and in fact Google and others provide a list of words that should be used in order to optimize the search engine traffic.

246. Examples of keywords POM has used in its search engine advertising include: "prostate cancer prevention," "prostate cancer info," "prostate cancer research," and "cancer prostate." (Rushton, Tr. 1389; CX0427).

Response to Finding No. 246:

Respondents dispute this proposed finding as contrary to the evidence in the record as the testimony cited and document noted show that although the quoted language was considered by Mr. Rushton and/or suggested by the automated Google Analysis, it appears it was ultimately not run pursuant to POM marketing veto. Even the testimony cited shows that Mr. Rushton was unaware if the terms were actually made active on the search engine: Q. And then on column D, which was under the heading of Keyword, "prostate cancer prevention" would have been a keyword that was being used in the Google search engine at that time; correct? A. This doesn't show whether it was being used, this chart doesn't show. But it does show it was in the system. This doesn't show whether it was active or not, so I can't answer that definitively. (Rushton, Tr. 1385-90)

247. To direct traffic to its website, POM also has used meta information and meta tags to target consumers. (Rushton, Tr. 1356-57). Meta information does not show up visually on web pages, but it is used by search engines to help define or better understand the content on web pages. POM used meta tags to optimize its websites in an attempt to obtain higher placement in search engine results. (Rushton, Tr. 1356-58).

Response to Finding No. 247:

Respondents have no specific response.

248. POM used, or planned to use, the meta keywords "cancer fighting buy" on its "Buy Pills" web page. (Rushton, Tr. 1381; CX0419).

Response to Finding No. 248:

Respondents dispute this proposed finding as contrary to the evidence in the record as the testimony cited and document noted show that although the quoted language was considered by Mr. Rushton and/or suggested by the automated Google Analysis, it appears it was ultimately not run pursuant to POM marketing veto. (Rushton, Tr. 1385-90)

249. CX0419 is an example of a document that defines all of the meta information on a page, including the page name, the title of the page, the meta description, the keywords, and any "alt information." (Rushton, Tr. 1380). "Alt information," or "alternative information," appears when one places a mouse over an image, page, or flash file. (Rushton, Tr. 1380).

Response to Finding No. 249:

Respondents have no specific response.

250. POM used, or planned to use, the following meta information for the "health prostate" page of the pompills.com website: 1) a meta description of "Prostate Cancer and general prostate health studies from POM Wonderful. Get the antioxidant power of POM Wonderful 100% Pomegranate Juice in a calorie-free supplement"; 2) meta keywords like "prostate health," "extend PSA doubling time," "PSA doubling," "prostate cancer," and "prostate cancer prevention"; and 3) "alt information" like "POMx and POM Wonderful ongoing prostate cancer research." (Rushton, Tr. 1382; CX0419_0001).

Response to Finding No. 250:

Respondents dispute this proposed finding as contrary to the evidence in the record as the testimony cited and document noted show that although the quoted language was considered by Mr. Rushton and/or suggested by the automated Google Analysis, it appears ultimately it was never run pursuant to POM marketing veto. (Rushton, Tr. 1385-90).

251. POM used, or planned to use, the following meta description for the "health research" page of the pompills.com website: "POM Wonderful's scientific research on the health benefits of pomegranate juice, such as cardiovascular disease, prostate cancer, and antioxidant activity . . . ." "Cardiovascular disease" and "prostate cancer" were also identified as "meta keywords" for the "health research" page. (CX0419_0001).

Response to Finding No. 251:

[Respondents dispute this proposed finding as contrary to the evidence in the record as the testimony cited and document noted show that although the quoted language was considered by Mr. Rushton and/or suggested by the automated Google Analysis, it appears ultimately it was never run pursuant to POM marketing veto. (Rushton, Tr. 1385-90)].

252. Mrs. Resnick has stated that "organic search, paid search, and e-mail blasts" are the "three forms of advertising on the Web that [she] find[s] the most effective." (CX0001_00036).

Response to Finding No. 252:

Respondents have no specific response to the extent this is a verbatim quote from the source, but object to the extent Complaint Counsel has presented no evidence that the statement is fact and not merely the opinion of Mrs. Resnick. Complaint Counsel failed to present evidence that POM utilized all the forms of advertising quoted.

253. POM has purchased online banner advertisements on websites, including specific websites with audiences interested in personal health, fitness, and physical well-being

such as *Men's Health*, *ESPN*, *Livestrong*, and *WebMD*. (Rushton, Tr. 1397-98; CX0463; CX0466; CX0468; Leow, Tr. 428-29).

Response to Finding No. 253:

Respondents have no specific response.

254. For its banner advertising, POM has used rich media, which is any type of flash media, such as an animated movie or flash banner advertisement that appears on a website. (Rushton, Tr. 1358, 1374).

Response to Finding No. 254:

Respondents have no specific response.

255. Mrs. Resnick has stated that "[POM has] steadily increased [its] ad buying online, and [online ads] now represent[] 12 percent of [POM's] total ad budget." (CX0001_00028).

Response to Finding No. 255:

This quote says nothing about POM's current online advertising budget.

256. POM has advertised its products through online social media such as Twitter, Facebook, and blogs. (Tupper, Tr. 928, 1359).

Response to Finding No. 256:

Respondents have no specific response.]

257. Mrs. Resnick has stated that "keeping close tabs on Twitter allows [Respondents] to engage in conversations that are meaningful to [their] brands. When [they] see a discussion under way on antioxidants, for example, [they] sometimes join right in, sharing [their] latest research or providing other relevant information." (CX0001_00031).

Response to Finding No. 257:

Complaint Counsel's cite is incorrect. POM has only made truthful claims regarding the state of the science on antioxidants and free radicals or to accurately describe the

encouraging results of preliminary research regarding the impact antioxidants may have on heart health, prostate health or other possible health benefits (RRFF 670).

258. As part of its blogger initiative, POM prepared a blogger package to get bloggers to try POM Juice. It sent the package to as many bloggers as possible who had a health, fitness, or healthy consumption message. (Rushton, Tr. 1398-99; CX0209). The blogger package was a four-page letter along with pomegranate juice samples. (Rushton, Tr. 1399). POM distributed well over a thousand blogger packages. (Rushton, Tr. 1399).

Response to Finding No. 258:

Respondents have no specific response other than to note that just because blogger packages went out that does not mean they were either received or resulted in actual blogging about POM.

259. CX0209 is an example of the letter contained in the blogger package. It includes a "backed by science" section stating that "POM Wonderful 100% Pomegranate Juice is the only juice whose health benefits are backed by $25 million in medical research" and "[b]enefits include improved heart and prostate health and better erectile function." (Rushton, Tr. 1399-1400; CX0209). The letter also includes a page of "Clinical Research Highlights" in the areas of "Cardiovascular Health," "Prostate Cancer Health," and "E.D. Health." (CX0209).

Response to Finding No. 259:

The message that the "backed by science" section actually conveys is that Respondents are committed to the science, and learning the truth about pomegranates. POM Wonderful 100% Pomegranate Juice is supported by $25 million of initial scientific research from leading universities, which has uncovered encouraging results in prostate and cardiovascular health. As Mrs. Resnick testified, the purpose of including the amount of money related to medical research in the advertising was to convey a message about the company, and its level of dedication to learning the truth about pomegranates. Mrs. Resnick testified, "[Respondents wanted] a very direct of communicating to the consumer that here was a natural food that had gone through rigorous scientific testing and that we cared enough to do this and we wanted to tell

people that we had and continue to do scientific research." (L. Resnick, Tr. 251; see also CCFF 309, 311).

260. In a January 2009 email to POM Marketing employees titled "FW: THE DELICIOUS JUICE THAT ACTUALLY CLEARS YOUR ARTERIES!," Mr. Tupper forwarded the text of what he described as a "good blog." (CX0271). The blog post attached stated that pomegranate juice could "help curb prostate cancer . . . [and] prevent[] the oxidation of LDL cholesterol, thus preventing arterial plaque." The blog also stated that "pomegranate juice does more than just prevent arterial plaque. It actually gets rid of existing plaque! And this was proven in a well-designed placebo controlled study." (CX0271 (summarizing the Aviram CIMT/BP Study (2004) and reporting an [arterial] plaque reduction of "a whopping 35%")).

Response to Finding No. 260:

Mr. Tupper testified that the reference to bood blog was that "it was good to see people getting the word out about the science behind POM." (Tupper, Tr. 1045).

6. Strategy for Public Relations Communications

261. Mrs. Resnick testified that public relations is the "unsung hero of marketing." In her view, "there is nothing as effective in the entire world as getting someone else to say something good about your product or services, what we call a third-party endorsement." (CX0001_00025; L. Resnick, Tr. 139).

Response to Finding No. 261:

Respondents object to the extent Complaint Counsel has presented no evidence that the statement is fact and not merely the opinion of Mrs. Resnick.

262. Public relations includes media relations, which is outreach to the media, including publications and print media, as well as broadcast media like radio and television. Public relations is a component of corporate communications. Corporate communications is the function within businesses that protects, enhances, and preserves a reputation for a business or a brand. (Posell, Tr. 301-02).

Response to Finding No. 262:

Respondents have no specific response.

263. Fiona Posell was Vice President of Corporate Communications at POM, which she identified as "a subsidiary of Roll," from approximately October 2002 to February 2006, and Vice President of Corporate Communications and Public Relations at Roll from approximately March 2006 to February 2008. (CX1436_0002; Posell, Tr. 298-99).

Response to Finding No. 263:

Respondents have no specific response other than to note that POM was not a subsidiary of Roll Global LLC or under Roll's corporate structure until January 1, 2011.

264. For POM, Ms. Posell was responsible for the strategic and tactical execution of all activities pertaining to corporate relations, public relations, crisis management, reputation management, customer service, and celebrity outreach. At POM, Ms. Posell reported to Mrs. Resnick and Mr. Tupper. (Posell, Tr. 325; CX1436_0002).

Response to Finding No. 264:

Complaint Counsel has mischaracterized the evidence to the extent the finding of fact suggests. Ms. Posell was singularly responsible for all the job duties listed, and was not subject to input, oversight or control from those above her.

265. One of the strategies for POM's public relations program was to "augment and enhance marketing function via focused and collaborative efforts." Marketing-driven public relations was a component of POM's public relations. (CX0011_0002; Posell, Tr. 330).

Response to Finding No. 265:

Respondents have no specific response.

266. POM issued press releases regarding its products and the studies it sponsored. The press releases supported POM's marketing efforts and communicated consumer messages. (CX0013_0001). Mr. Perdigao confirmed that press releases are one way of marketing POM's products. (Perdigao, Tr. 597-98).

Response to Finding No. 266

Respondents have no specific response.

267. Respondents' public relations staff would also pitch to the media information about company-sponsored scientific studies of pomegranate. (CX1375 (L. Resnick, Trop. Dep.

at 145-46); *see also* CX1375 (L. Resnick, Trop. Dep. at 161) (acknowledging reference to "needing a PR push promoting the results" of two studies)).

Response to Finding No. 267:

Respondents have no specific response other than to object to the term "pitch"—a more appropriate term would be inform. (CX1375 (L. Resnick, Trop. Dep. at 145-46)

268. An element of POM's marketing-driven public relations was to "[c]oordinate press activities to coincide with advertising campaigns." For example, one of the "[k]ey messages" that was part of POM's public relations plan was that POM "helps reduce the risk of heart disease." (CX0011_0004-05).

Response to Finding No. 268:

Respondents object to the extent Complaint Counsel is attempting to infer from one document prepared by Ms. Posell that a key message of POM's public relations was POM "helps reduce the risk of heart disease." First, one document cannot and does not explain or otherwise represent the entirety of POM's advertising or marketing strategy over many years. Second, at best, POM's actual adverting as to heart disease is that POM may help reduce the risk and instead usually focused and highlighted the findings of this promising research. (See Section V + VIIC).

269. Staci Glovsky, a former POM Marketing employee, noted that public relations could be used to help communicate a story where POM could not make certain disease or testimonial claims via advertising, the website, or the product label. (CX0054_0001).

Response to Finding No. 269:

Mischaracterizes the evidence. The email cited recognizes and states that the key issue that needs to be vetted is the message and not the medium and that advertising that touches on disease or related claims needed to be vetted by legal first. (CX0054_0001).

270. Corporate Communications worked with Roll and POM personnel (*e.g.,* Mrs. Resnick, Mr. Tupper, POM Marketing, POM scientific affairs, Fire Station, and Roll Consulting) on the press releases, interactions with media regarding the health benefits of POM

products, and website content, among other things. (CX0012; CX0013; CX0024; CX0028; CX0038; CX0041; CX0043; CX0044; CX0127; CX0238_0001).

Response to Finding No. 270:

Respondents object that the proposed finding is ambiguous as to which company Corporate Communications was a part of, which companies the listed individuals worked for and to the extent the proposed finding suggests that POM was making disease claims as opposed to general health benefit claims.

271. For example, Respondents have included a "fact sheet" on the "Health Benefits of [POM Juice]" in POM's press kits. (*See, e.g.,* CX0219_0001-02). A fact sheet from August 2008 described the "specific health benefits . . . associated with [POM Juice]," including:

- Under the heading "**Cardiovascular Health**," the fact sheet described various medical studies and highlighted results such as: "**[a]fter only three months, blood flow to the heart improved approximately 17% in the 100% pomegranate juice group**"; "**decrease in plaque of up to 30%**"; "**100% pomegranate juice inhibited ACE (angiotensin converting enzyme) by 36% after two weeks of daily consumption**"; "**drinking 8 oz. of 100% pomegranate juice per day for two weeks lowered the susceptibility of LDL oxidation**, a key factor in the build-up of plaque in the arteries . . . ." (CX0219_0002-03).

- Under the heading "**Prostate Cancer**," the fact sheet highlighted that "**[c]onsuming 100% pomegranate juice prolonged [study subjects'] post-prostate surgery PSA doubling time from 15 to 54 months**." (CX0219_0004).

- Under the heading "**Erectile Dysfunction**," the fact sheet highlighted that "**men drinking 8 oz. of 100% pomegranate juice daily for four weeks were 50% more likely to experience improved erections**." (CX0219_0004).

Response to Finding No. 271:

Respondents have no specific response to the extent the language as quoted is accurate but object to the extent Complaint Counsel is suggesting that POM is somehow making implicit or explicit establishment claims via broad general statements of general heath by discussing the results of research performed.

272. A February 2008 document of "proposed responses" to a journalist writing about "superfruits" for the *Los Angeles Times* included bullet points such as:

- "[Pomegranate juice is] [b]eneficial for heart disease, prostate cancer and erectile dysfunction. -- these benefits are based on clinical (i.e., human) research, not just test tube theories." (CX0182_0001).
- "Compared to other 'superfruits,' the pomegranate is the only one that has medically proven health benefits in the human body. -- This is a key point. Everybody else can brag about how great their product 'scores' in a test tube (and we of course can brag louder than anyone else!), but it really comes down to what happens in the human body." (CX0182_0001).
- "And, not all pomegranate juices are created equal. Of the other pomegranate juices, POM is the only one guaranteed to be 100% authentic, and the only one with proven health benefits." (CX0182_0001).
- "POM is the only pomegranate juice – and any other commercially available beverage, for that matter – backed by $23 million in medical research. Actually, POM is the only pomegranate juice backed by any medical research at all." (CX0182_0002).

Response to Finding No. 272:

Respondents have no specific response to the extent these are verbatim quotes from the source, but object to the extent Complaint Counsel is attempting to take these quotes out of context and out of the qualified arena where the statements made were done in the context of explaining the research done on pomegranate juice and to the extent Complaint Counsel insinuates that these bullet points implicate implicit or explicit establishment claims.

273. In "talking points" for Dr. Heber or Dr. Liker's use in an interview with a journalist in 2003, two of these points were:

Positive effects on heart health that have been seen in humans include protection against LDL oxidation, a key factor in the build-up of plaque in the arteries. Pomegranate juice also blocked the ACE enzyme. Blocking ACE has been shown to lead to fewer heart attacks in patients with heart disease. In addition, drinking [POM Juice] lowered systolic blood pressure in people with high blood pressure. High blood pressure is a known risk factor for atherosclerosis.

Additionally, studies in mice have revealed exciting results. In mice, P♥M Wonderful pomegranate juice was shown to prevent the formation of plaque in the arteries. In a

subsequent study it was shown that pomegranate juice could actually halt the build-up of plaque even in advanced disease after two months of pomegranate juice consumption. (CX0605_0002).

Response to Finding No. 273:

Respondents have no specific response to the extent these are verbatim quotes from the source, but object to the extent Complaint Counsel is attempting to take these quotes out of context and out of the qualified arena where the statements made were done in the context of explaining the research done on pomegranate juice and to the extent Complaint Counsel insinuates that these bullet points implicate implicit or explicit establishment claims.

274. The value of public relations activities is quantified by a metric known as "advertising equivalency," the amount it would have cost to buy an advertisement in a print publication equivalent to the coverage from the editorial or article that appeared in that publication due to the public relations activities. (Posell, Tr. 338; L. Resnick, Tr. 140; *see also* CX1375 (L. Resnick, Trop. Dep. at 116-17)).

Response to Finding No. 274:

Mischaracterizes the evidence. As discussed during the trial and briefing, "advertising equivalency" has largely been discredited as not actually representative of actual advertising. And Ms. Posell admitted that the dollar amount of alleged equivalent advertising for a PR or editorial piece is "very arbitrary". (Posell, Tr. 338-40).

275. POM tracked the advertising equivalency of its public relations activities on a regular basis. (Posell, Tr. 339-40).

Response to Finding No. 275:

Respondents have no specific response except to note that as discussed during the trial and briefing, "advertising equivalency" has largely been discredited as not actually representative of actual advertising. And Ms. Posell admitted that the dollar amount of

alleged equivalent advertising for a PR or editorial piece is "very arbitrary". (Posell, Tr. 338-40).

276. In 2003, the advertising equivalency for the articles that mentioned pomegranate juice (including POM brand) or pomegranates was $2.6 million. This included 234 articles with a circulation of 199 million people. (CX0430_0002).

Response to Finding No. 276:

Mischaracterizes the evidence. As discussed during the trial and briefing, "advertising equivalency" has largely been discredited as not actually representative of actual advertising. And Ms. Posell admitted that the dollar amount of alleged equivalent advertising for a PR or editorial piece is " very arbitrary". (Posell, Tr. 338-40).

277. In 2004, the advertising equivalency for the articles that mentioned pomegranate juice (including POM brand) or pomegranates was $3.16 million. This included 517 articles with a circulation of 302 million people. (CX0431_0002).

Response to Finding No. 277:

Mischaracterizes the evidence. As discussed during the trial and briefing, "advertising equivalency" has largely been discredited as not actually representative of actual advertising. And Ms. Posell admitted that the dollar amount of alleged equivalent advertising for a PR or editorial piece is "very arbitrary". (Posell, Tr. 338-40).

278. In 2005, the advertising equivalency for the articles that mentioned pomegranate juice (including POM brand) or pomegranates was $6.3 million. This included 1021 articles with a circulation of 566 million people. (CX0432_0002).

Response to Finding No. 278:

Mischaracterizes the evidence. As discussed during the trial and briefing, "advertising equivalency" has largely been discredited as not actually representative of actual advertising. And Ms. Posell admitted that the dollar amount of alleged equivalent advertising for a PR or editorial piece is "very arbitrary". (Posell, Tr. 338-40).

279. In 2006, the advertising equivalency for the articles that mentioned pomegranate juice (including POM brand), pomegranates, or POM Tea was $4.63 million, with the vast majority attributable to pomegranate juice (including POM brand) and pomegranates. This included 1074 articles with a circulation of 516 million people. (CX0433_0002).

Response to Finding No. 279:

Mischaracterizes the evidence. As discussed during the trial and briefing, "advertising equivalency" has largely been discredited as not actually representative of actual advertising. And Ms. Posell admitted that the dollar amount of alleged equivalent advertising for a PR or editorial piece is "very arbitrary". (Posell, Tr. 338-40).

280. Mrs. Resnick has noted that media coverage, such as newspaper and magazine articles about pomegranates and POM, amounts to "the kind of third-party endorsements that money can't buy" and that "[a]ll of that priceless, positive buzz helped increase revenue and significantly enhanced our brand equity." (CX0001_0019).

Response to Finding No. 280:

Respondents have no specific response to the extent this is a verbatim quote from the source, but object to the extent Complaint Counsel has presented no evidence that the statement is fact and not merely the opinion of Mrs. Resnick.

C. Respondents' Intent to Advertise Health Claims

1. Health Claims Were POM's "Unique Selling Proposition"

281. Mrs. Resnick's marketing philosophy is to look at the intrinsic value of a product, and to employ a "unique selling proposition" to communicate the product's intrinsic value to consumers. She defines "unique selling proposition" as "what is it about your product or service that sets you apart from the competition." (L. Resnick, Tr. 74-77).

Response to Finding No. 281:

Complaint Counsel presented no evidence that Respondents believe the "intrinsic value" or "unique selling proposition" of the Challenged Products is their ability to treat, prevent or reduce the risk of heart disease, prostate cancer and erectile dysfunction. Respondents genuinely believe in the integrity of POM's research program and the health benefits of

the Challenged Products. (RFF 502-520). For example, Mrs. Resnick believes pomegranates and pomegranate juice have unique health-giving properties. (RFF 516). She considers POM Juice to be "health in a bottle" because of the medical benefits of the juice revealed by both POM's research and the 8,000 year history of pomegranates. (RFF 517). Mrs. Resnick believes "with all her heart" that if you lead a healthy lifestyle and consume pomegranate juice, you will be healthier. (RFF 518). Respondents' belief in the science is justified by the high level of scientific integrity in POM's science program and in the studies themselves. (RFF 269, 333-45, 393-94, 436-39, 521-523, 959-86, 1066-68, 1086, 1147-1174, 1683-93, 1702-17). Given the "entire body of evidence, not only the research that [Respondents have] done and others have done, but also the history of [pomegranates] being consumed by millions of people over thousands of years" (L. Resnick, Tr. 78), Respondents do not dispute that part of the Challenged Products' intrinsic value are the health benefits of pomegranates. Thus, it is not surprising that POM's ads summarize some of Respondents' scientific research on the Challenged Products in the areas of cardiovascular, prostate and erectile health and talk about the healthful properties of the Challenged Products, including that the Challenged Products contain abundant antioxidants and that they are wholly derived from pomegranate fruit. (RFF 493-99, 2478-2505, 2518-44). However, Respondents dispute that they ever intended to convey or that the Challenged Ads do convey the claim that the Challenged Products treat, prevent or reduce the risk of heart disease, prostate cancer and erectile dysfunction or that they are "clinically proven" to do so. (RFF 496, 535, 538, 540, 545-50, 2209-11, 2280; CX1375 (L. Resnick, Trop., Dep. at 79-81).

282. According to Mr. Resnick, it has been important for POM to distinguish itself from competitors because POM was "doing all the advertising and creating demand for everyone" so he "was trying to figure out, if there's some way to more push our product than pomegranate juice in general . . . ." (CX1376 (S. Resnick, OS Dep. at 142-43)).

Response to Finding No. 282:

Complaint Counsel mischaracterizes Mr. Resnick's testimony to the extent they imply he was referring to advertising the healthy benefits of the Challenged Products. POM Juice is a 100% juice product wholly-derived from the pomegranate fruit. (RFF 493). However, in or about 2008, despite POM's attempts to clean up the industry through its lawsuit against Purely Juice, some of POM's competitors were still selling a juice product advertised as 100% pomegranate juice but which was, in fact, adulterated. (CX1376 (S. Resnick, OS Dep. at 142)). Mr. Resnick described this as "pomegranate fraud" because often the "pomegranate" juice included only 3% pomegranate juice. (CX1376 (S. Resnick, OS Dep. at 142-43)). Given the relative high cost of pomegranates, this enabled these competitors undercut POM in price. (CX1376 (S. Resnick, OS Dep. at 142)). Because Mr. Resnick wanted to distinguish POM from competitors selling adulterated pomegranate juice, he was interested in "trying to figure out, if there's some way to more push our product than pomegranate juice in general, since there was so much other false juices around." (CX1376 (S. Resnick, OS Dep. at 142-43). To that end, he testified that what distinguished POM from competitors selling "false juice" included: "that we[']re a hundred percent California, most of the juice was imported because there was very little in California; that we grew the product, processed the product, sold the product. Those were the things that, you know, people could be more dependent upon our product than other products." (CX1376 (S. Resnick, OS Dep. at 143)). Mr. Resnick was therefore focused on many factors that distinguished POM from its competitors.

283. Mrs. Resnick believes that, for marketing purposes, part of the intrinsic value of POM Juice was its power to heal people; that it was shown to reduce arterial plaque and factors leading to atherosclerosis; and that it was shown to have a powerful effect against prostate cancer. (L. Resnick, Tr. 75-76; *see also* CX1359 (L. Resnick, Dep. at 16, 18); CX0001_0005, 0011).

Response to Finding No. 283:

Complaint Counsel presented no evidence that Respondents believe the "intrinsic value" of POM Juice is its ability to treat, prevent or reduce the risk of heart disease, prostate cancer and erectile dysfunction. Rather, as Complaint Counsel concedes in this proposed finding, Mrs. Resnick expressly stated that in her personal opinion the "intrinsic value" of POM Juice is limited to being shown to reduce arterial plaque and factors leading to atherosclerosis as well as being beneficial against prostate cancer. (L. Resnick, Tr. 75-76; *see also* CX1359 (L. Resnick, Dep. at 16, 18); CX0001_0005, 0011). Moreover, Competent and reliable scientific evidence exists supporting the conclusion that the consumption of the Challenged Products (1) help reduce arterial plaque and factors leading to atherosclerosis; (2) support prostate health, including by prolonging PSA doubling time in men with rising PSA after primary treatment for prostate cancer; and (3) inhibit the clinical development of prostate cancer cells in men who have not been diagnosed. (RFF 1077, 1087-88, 1099, 1101-06, 1209-10, 1297, 1577-78, 1612-1783).

Respondents object to the proposed finding to the extent that Complaint Counsel construe Mrs. Resnick's testimony to bolster their argument that Respondents intended to convey to consumers that the Challenged Products treat, prevent or reduce the risk of disease. Although Respondents genuinely believe in the health benefits of the Challenged Products and in the scientific integrity of POM's research (RFF 502-20), they dispute that Respondents ever intended to convey or that the Challenged Ads do convey the claim that the Challenged Products treat, prevent or reduce the risk of heart disease, prostate cancer and erectile dysfunction or that they are "clinically proven" to do so. (RFF 496, 535, 538, 540, 545-50, 2209-11, 2280; CX1375 (L. Resnick, Trop., Dep. at 79-81).

284. Mr. Resnick also testified that POM communicates to consumers the "[company's] belief that pomegranate juice is beneficial in treating some causes of impotence, for the purpose of promoting sales of its product." (CX1372 (S. Resnick, Trop. Dep. at 45)).

Response to Finding No. 284:

Respondents object to the proposed finding to the extent that Complaint Counsel construe Mr. Resnick's testimony to bolster their argument that Respondents intended to convey to consumers that the Challenged Products treat, prevent or reduce the risk of disease. Although Mr. Resnick personally believes that consuming pomegranate juice helps with erectile dysfunction and that POM's research supports his believe (RFF 505), Respondents dispute that they ever intended to convey or that the Challenged Ads do convey the claim that the Challenged Products treat, prevent or reduce the risk of heart disease, prostate cancer and erectile dysfunction or that they are "clinically proven" to do so. (RFF 496, 535, 538, 540, 545-50, 2209-11, 2280; CX1375 (L. Resnick, Trop., Dep. at 79-81). Indeed, Mr. Resnick testified that "we're very careful about our [erectile health] claims" and base them, in part, on Nobel Laureate Dr. Louis Ignarro's research on the mechanism by which pomegranate juice promotes erectile health and function via its antioxidant components and its impact on nitric oxide (CX1372 (S. Resnick, Trop. Dep. at 45)), which is of "paramount importance" to good erectile health and function and is the key molecule that governs penile erections. (RFF 1924, 1936-91, 2065-79; RRFF 1087). Thus, POM only believes that pomegranate juice is beneficial to treating "impotence" in "the same way that these difference nitric oxide-producing pills work, such as Viagra." (CX1372 (S. Resnick, Trop. Dep. at 44-45)). But Mr. Resnick never testified that POM Juice is equivalent to Viagra-type drugs or was ever advertised as such. Also, as explained by Respondents' expert, Dr. Goldstein, the terms "impotence" and "erectile dysfunction" are interchangeable. (PX0352 (Goldstein, Dep at. 16)).

Moreover, Respondents dispute Complaint Counsels' assertion that the eight so-called "erectile dysfunction" advertisements identified in Appendix A suggest that the Challenged Products can "treat," "prevent," or "reduce the risk of" erectile dysfunction. Instead, Respondents' advertisements only promote the message of "erectile health" or

"erectile function." (RFF 2047-50). To the extent POM's ads even mentioned "erectile dysfunction," as when quoting from the published *Forest/Padma-Nathan RCT Study*, the statements were highly qualified with language like, "emerging science suggests," "help protect," and "in a preliminary study on erectile function," all of which contradict any impression that these ads are clinically proven to treat, prevent or reduce the risk of erectile dysfunction. (Reply Ad Appendix). In any event, POM possesses competent and reliable scientific evidence, confirmed by Respondents' erectile experts, that the Challenged Products may help or ameliorate symptoms of an existing condition and improve erectile function—and not serve as substitute or replacement for conventional medical treatment. (RRFF 764, 1085, 1088; Burnett, Tr. 2255-56, 2272-73, 2301, 2312); PX0349 (Burnett, Dep. at 60); PX0352 (Goldstein, Dep. at 44, 46-47, 157)).

285. Mrs. Resnick testified that she believes POM Juice can ward off prostate cancer, but concedes there is no study that proves that POM Juice can prevent cancer. (CX1362 (L. Resnick, TCCC Dep. at 38); CX1375 (L. Resnick, Trop. Dep. at 102-03)).

Response to Finding No. 285:

Respondents object to the proposed finding to the extent that Complaint Counsel construe Mrs. Resnick's testimony to bolster their argument that Respondents intended to convey to consumers that the Challenged Products treat, prevent or reduce the risk of disease. Although Mrs. Resnick personally believes that consuming pomegranate juice has a powerful affect against prostate cancer (RFF 519; CX1375 (L. Resnick, Trop. Dep. at 102); CX1362 (L. Resnick, TCCC Dep. at 38)), Respondents dispute that they ever intended to convey or that the Challenged Ads do convey the claim that the Challenged Products treat, prevent or reduce the risk of heart disease, prostate cancer and erectile dysfunction or that they are "clinically proven" to do so. (RFF 496, 535, 538, 540, 545-50, 2209-11, 2280; CX1375 (L. Resnick, Trop., Dep. at 79-81)). More specifically, Lynda Resnick testified that the headline, "I'm off to save PROSTATES!" was absolutely not intended to mean that POM Juice would prevent prostate cancer. (RFF

531). Mrs. Resnick further testified that the intent of the ad was not to communicate to consumers that POM would treat prostate cancer; it was meant to communicate that POM Juice is good for your prostate or at most improves prostate health. (L. Resnick, Tr. 217-19). Nor did Mrs. Resnick intend to use Dr. Pantuck's prostate cancer study to communicate to consumers that POM Juice would treat prostate cancer. (RFF 537).

286. Mr. Resnick testified that the reason Respondents sponsor research is because they "believe that pomegranate can be very helpful as a natural disease prevention and curative and very healthy." (CX1363 (S. Resnick, TCCC Dep. at 84-85); *see also* CX1372 (S. Resnick, Trop. Dep. at 42-43)).

Response to Finding No. 286:

Complaint Counsel mischaracterizes Mr. Resnick's testimony to the extent they imply he testified that Respondents conveyed the claim that the Challenged Products prevent, treat or reduce the risk of disease. Although Respondents genuinely believe in the healthful benefits of the Challenged Products and in the integrity of POM's research program (RFF 502-20), they dispute that Respondents ever intended to convey or that the Challenged Ads do convey the claim that the Challenged Products treat, prevent or reduce the risk of heart disease, prostate cancer and erectile dysfunction or that they are "clinically proven" to do so. (RFF 496, 535, 538, 540, 545-50, 2209-11, 2280; CX1375 (L. Resnick, Trop., Dep. at 79-81)). Moreover, Mr. Resnick testified specifically that POM is not attempting to influence consumers to believe that pomegranate juice prevents, treats or reduces the risk of disease, but rather letting them make their own decisions. (RFF 542-43, 545). Indeed, Mr. Resnick categorically denied that the purpose of POM's research was so Respondents could tell the public about the research and then influence consumers to buy pomegranate juice to prevent disease. (CX1363 (S. Resnick, TCCC Dep. at 84-85)).

The goal of Respondents' research program is to uncover the truth behind the health benefits of the pomegranate–not to make health benefit claims. (RFF 271). Indeed, Respondents did not design their research solely to market the results but ultimately to

understand how the consumption of pomegranate works in the human body. (RFF 312-13). Accordingly, Mr. Resnick told the scientists conducting Respondents' research that his primary interest in sponsoring research is to establish the truth. (RFF 273).

287. According to Mr. Resnick, the company believes pomegranate juice is beneficial for preventing and treating coronary heart disease and prostate cancer. (CX1372 (S. Resnick, Trop. Dep. at 42, 48)).

Response to Finding No. 287:

Respondents object to the proposed finding to the extent that Complaint Counsel construe Mr. Resnick's testimony to bolster their argument that Respondents intended to convey to consumers that the Challenged Products prevent and treat coronary heart disease and prostate cancer. Although Respondents believe that pomegranate juice is beneficial to cardiovascular and prostate health and that POM's research supports this belief (RFF 503-04, 506, 510, 519, 520), they dispute that Respondents ever intended to convey or that the Challenged Ads do convey the claim that the Challenged Products treat, prevent or reduce the risk of heart disease, prostate cancer and erectile dysfunction or that they are "clinically proven" to do so. (RFF 496, 535, 538, 540, 545-50, 2209-11, 2280; CX1375 (L. Resnick, Trop., Dep. at 79-81). More specifically, in regard to POM Juice, Mr. Resnick testified "We certainly don't say it's going to prevent coronary heart disease. That would be a drug claim, and we don't make any drug claims." (CX1372 (S. Resnick, Trop. Dep. at 59)). In regard to whether POM Juice is beneficial in treating coronary heart disease, Mr. Resnick testified "I don't think we make those claims. Again, I think what we're talking about broadly as heart healthy, and antioxidants. People are strong believers that antioxidant[s] are healthy for your heart. And that's generally what all these benefits come from." (CX1372 (S. Resnick, Trop. Dep. at 59)). As for prostate cancer, Mr. Resnick testified specifically "we're not making a claim it prevents," rather we believe pomegranate juice prolongs the PSA doubling time, which has a beneficial effect on prostate cancer. (CX1372 (S. Resnick, Trop. Dep. at 56-57)). Moreover,

competent and reliable scientific evidence exists supporting the conclusion that the consumption of the Challenged Products have beneficial effects cardiovascular and prostate health. (RFF 1077, 1087-88, 1099-1106, 1209-10, 1297, 1577-78, 1612-1783).

288. Mr. Resnick also testified that both POM and consumers believe "that we've proven that . . . [POM Juice] really does prolong people's lives if they are getting the onset of prostate cancer." (CX1376 (S. Resnick, OS Dep. at 218-19)).

Response to Finding No. 288:

Respondents object to the proposed finding to the extent that Complaint Counsel construe Mr. Resnick's testimony to bolster their argument that Respondents intended to convey to consumers that the Challenged Products prevent and treat coronary heart disease and prostate cancer. Although Respondents believe that pomegranate juice is beneficial to prostate health and that POM's research supports this belief (RFF 503-04, 510, 519-20), they dispute that Respondents ever intended to convey or that the Challenged Ads do convey the claim that the Challenged Products treat, prevent or reduce the risk of heart disease, prostate cancer and erectile dysfunction or that they are "clinically proven" to do so. (RFF 496, 535, 538, 540, 545-50, 2209-11, 2280; CX1375 (L. Resnick, Trop., Dep. at 79-81). Complaint Counsel has also failed to show that Mr. Resnick is qualified to testify as to what consumers "believe" on any subject, including the Challenged Products, prolonging their lives and prostate cancer. Moreover, competent and reliable scientific evidence exists supporting the conclusion that the consumption of the Challenged Products have beneficial effects on prostate health. (RFF 1577-78, 1612-1783).

Even if POM and consumers believe "that [POM has] proven that . . . [POM Juice] really does prolong people's lives if they are getting the onset of prostate cancer," Mr. Resnick never testified that any buyer of POM Juice purchased the product to treat, prevent or reduce the risk of heart disease, prostate cancer or erectile dysfunction. (CX1376

(S. Resnick, OS Dep. at 1-336)). Nor did he testify that consumers buy POM Juice because of any claim in the Challenged Ads. (CX1376 (S. Resnick, OS Dep. at 1-336)).

289. Mrs. Resnick considers "health in a bottle" to be POM Juice's unique selling proposition. (L. Resnick, Tr. 77-78; CX1375 (L. Resnick, Trop. Dep. at 41-42)).

Response to Finding No. 289:

Complaint Counsel presented no evidence that Respondents believe the "unique selling proposition" of the Challenged Products is their ability to treat, prevent or reduce the risk of heart disease, prostate cancer and erectile dysfunction. Respondents genuinely believe in the integrity of POM's research program and the health benefits of the Challenged Products. (RFF 502-520). For example, Mrs. Resnick believes pomegranates and pomegranate juice have unique health-giving properties. (RFF 516). She considers POM Juice to be "health in a bottle" because of the medical benefits of the juice revealed by both POM's research and the 8,000 year history of pomegranates. (RFF 517). Mrs. Resnick believes "with all her heart" that if you lead a healthy lifestyle and consume pomegranate juice, you will be healthier. (RFF 518). Respondents' belief in the science is justified by the high level of scientific integrity in POM's science program and in the studies themselves. (RFF 269, 333-45, 393-94, 436-39, 521-523, 959-86, 1066-68, 1086, 1147-1174, 1683-93, 1702-17). Accordingly, given the "entire body of evidence, not only the research that [Respondents have] done and others have done, but also the history of [pomegranates] being consumed by millions of people over thousands of years" (L. Resnick, Tr. 78), Respondents do not dispute that part of the Challenged Products' unique selling proposition are the health benefits of pomegranates.

Therefore, certain of POM's ads summarize some of Respondents' scientific research on the Challenged Products in the areas of cardiovascular, prostate and erectile health and talk about the healthful properties of the Challenged Products, including that the Challenged Products contain abundant antioxidants and that they are wholly derived from

pomegranate fruit. (RFF 493-99, 2478-2505, 2518-44). However, Respondents dispute that they ever intended to convey or that the Challenged Ads do convey the claim that the Challenged Products treat, prevent or reduce the risk of heart disease, prostate cancer and erectile dysfunction or that they are "clinically proven" to do so. (RFF 496, 535, 538, 540, 545-50, 2209-11, 2280; CX1375 (L. Resnick, Trop., Dep. at 79-81).

Moreover, POM never states, expressly or by implication, conspicuously on the face of any of the Challenged Ads that scientific tests "prove" that the Challenged Products "prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction," or even that they "prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction." (RFF 2209-11, 2467-68, 2506, 2517; Reply Ad Appendix; Appendix of Advertisements). Even where medical research was referenced in advertising, the ads conveyed qualified messages about the health benefits of the Challenged Products, not definitive claims that the products will treat, prevent or reduce the risk of heart disease, prostate cancer or erectile dysfunction. (RFF 2517). Throughout its advertising, POM highlights that POM Juice is a 100% juice product wholly-derived from the pomegranate fruit, and that POMx has the same content as the pomegranate fruit itself and is 100% derived from the exact same fruit. (RFF 493-94, 2518-44; Reply Ad Appendix). Indeed, Respondents have never advertised their products as a pharmaceutical drug, nor intended to advertise their products as drugs. (RFF 495-96, 524-30). Rather, Respondents have always marketed the Challenged Products for what they intrinsically are: whole-food products. (RFF 497-99).

290. Mrs. Resnick testified that she developed the logo P♥M, with a heart in place of the "O," in order to immediately tell consumers that the juice is heart healthy or good for one's heart. (L. Resnick, Tr. 146-47; CX1375 (L. Resnick, Trop. Dep. at 33-34)).

Response to Finding No. 290:

Respondents do not disagree that Mrs. Resnick's development of the logo P♥M, with a heart in place of the "O," was intended by her to tell consumers that the POM Juice is generally heart healthy. Respondents, however, object to the proposed finding to the extent that Complaint Counsel construe Mr. Resnick's testimony to bolster their argument that Respondents intended to convey to consumers that the Challenged Products prevent, treat or reduce the risk of heart disease. Although Respondents believe that pomegranate juice is beneficial to heart health and that POM's research supports this belief (RFF 506, 510, 515-20), they dispute that Respondents ever intended to convey or that the Challenged Ads do convey the claim that the Challenged Products treat, prevent or reduce the risk of heart disease, prostate cancer and erectile dysfunction or that they are "clinically proven" to do so. (RFF 496, 535, 538, 540, 545-50, 2209-11, 2280; CX1375 (L. Resnick, Trop., Dep. at 79-81). Moreover, Complaint Counsel presented no evidence that Mrs. Resnick or any Respondent intended the logo P♥M to convey the message that the Challenged Products treat, prevent, or reduce the risk of any disease.

291. Mrs. Resnick considers the product package at the point of sale to be a "minibillboard" for the brand. (CX0001_0017). The POM Juice bottle or POMx Pill package, including the POM logo with a heart in place of the "O," appeared in all of POM's advertising. POMx Pill advertisements frequently displayed a bottle of POM Juice as well. (*See e.g.*, CCFF ¶¶ D.4.a.400, D.4.c.415).

Response to Finding No. 291:

Respondents do not disagree that Mrs. Resnick's development of the logo P♥M, with a heart in place of the "O," was intended by her to tell consumers that the POM Juice is generally heart healthy. Respondents, however, object to the proposed finding to the extent that Complaint Counsel construe Mr. Resnick's testimony to bolster their argument that Respondents intended to convey to consumers that the Challenged Products prevent, treat or reduce the risk of heart disease. Although Respondents believe

that pomegranate juice is beneficial to heart health and that POM's research supports this belief (RFF 506, 510, 515-20), they dispute that Respondents ever intended to convey or that the Challenged Ads do convey the claim that the Challenged Products treat, prevent or reduce the risk of heart disease, prostate cancer and erectile dysfunction or that they are "clinically proven" to do so. (RFF 496, 535, 538, 540, 545-50, 2209-11, 2280; CX1375 (L. Resnick, Trop., Dep. at 79-81). Moreover, Complaint Counsel presented no evidence that Mrs. Resnick or any Respondent intended the logo P♥M to convey the message that the Challenged Products treat, prevent, or reduce the risk of any disease.

292. Ms. Leow testified that "POM is unique" compared to other Roll brands in terms of advertising design, because they have a "medical component." (Leow, Tr. 494-495).

Response to Finding No. 292:

Respondents object to the proposed finding to the extent that Complaint Counsel construe Ms. Leow's testimony to bolster their argument that Respondents intended to convey to consumers that the Challenged Products prevent and treat coronary heart disease, prostate cancer and erectile dysfunction. Respondents have developed a truly unprecedented amount of scientific research on the Challenged Products. (RFF 451). Moreover, Respondents believe that pomegranate juice is beneficial to prostate health and that POM's research supports this belief (RFF 503-04, 510, 519-20). Thus, some of POM's ads summarize Respondents' research on the Challenged Products in the areas of cardiovascular, prostate and erectile health and talk about the healthful properties of the Challenged Products. (Respondents' Reply Ad Appendix). However, Respondents dispute that they ever intended to convey or that the Challenged Ads do convey the claim that the Challenged Products treat, prevent or reduce the risk of heart disease, prostate cancer and erectile dysfunction or that they are "clinically proven" to do so. (RFF 496, 535, 538, 540, 545-50, 2209-11, 2280; CX1375 (L. Resnick, Trop., Dep. at 79-81).

Additionally, the cited evidence does not support the propositions that POM's ads (1) all include a "medical component"; (2) convey establishment or efficacy claims; (3) convey the claim that the Challenged Products are "clinically proven" to prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction; or (4) convey the claim that the Challenged Products prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction. (Appendix of Advertisements; Reply Ad Appendix; RFF 496, 531, 535, 537-38, 540, 545-50, 2280; CX1375 (L. Resnick, Trop., Dep. at 79-81)). Also, Respondents object that the term "medical component" is vague and ambiguous and that Complaint Counsel presented no evidence equating that term to treat, prevent, or reduce the risk of heart disease, prostate cancer and erectile dysfunction.

293. In a May 2003 issue of *Business Journal*, Ms. Posell was quoted as stating, "POM Wonderful is a product that carries a very strong health and medical message." (CX0430_0003).

Response to Finding No. 293:

Respondents do not dispute that the above-quoted statement by Ms. Posell appeared in a May 2003 issue of *Business Journal*. Respondents, however, contend that Ms. Posell's statement was specifically directed at POM's products (*e.g.*, "Pom Wonderful is a product that carries a very strong health and medical message."), not the Challenged Ads. (CX0430_0003). Nowhere in the *Business Journal* article does Ms. Posell speak about POM's advertising. (CX0430_0003). Therefore, the evidence cited does not support the propositions that POM's ads (1) include a "health and medical message"; (2) convey establishment or efficacy claims; (3) convey the claim that the Challenged Products are "clinically proven" to prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction; or (4) convey the claim that the Challenged Products prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction. (CX0430_0003; Appendix of Advertisements; Reply Ad Appendix; RFF 496, 531, 535, 537-38, 540, 545-50, 2280; CX1375 (L. Resnick, Trop., Dep. at 79-81)). Moreover, to

the extent POM's products carry any "health and medical message" as perceived by Ms. Posell, they are limited to those specifically referenced by her in the article, including the "high concentration of a type of antioxidant called polyphenols." (CX0430_0003).

Also, Respondents object that the term "health and medical message" is vague and ambiguous and that Complaint Counsel presented no evidence equating that term to treat, prevent, or reduce the risk of heart disease, prostate cancer and erectile dysfunction.

294. Meeting notes from June 2006 described some of the "Unique Properties of POM" as "Anti-aging," and "Heart disease – aging of heart muscles, joints, etc [*sic*] heart plaque." One of POM's objectives at the time was to "ensure that all POM products stand for building your immune system and keeping you healthy." Moreover, under a heading, "Who Are We??" the minutes stated, "Convince people of preventative medicine & effects," "Antioxidants [*sic*] → Healthy buzz word (people accepted and believed)," and "PILLS – POMx – health – not about taste." (CX0058_0001, 0003, 0004).

Response to Finding No. 294:

Respondents object to this finding as irrelevant and not probative of Respondents' intent to convey the Challenged Claims. Complaint Counsel presented no evidence showing who drafted the "meeting notes," why they were drafted, or whether they were ever distributed to others. Lynda Resnick testified that she did not draft the meeting notes, doesn't remember ever seeing the meeting notes, and doesn't remember any June 2006 meeting referenced in the meeting notes. (CX1375 (L. Resnick, Trop., Dep. at 105-06)). In regard to the information under the heading "Who Are We??," Mrs. Resnick testified: "I don't even know what this is. It doesn't make any sense to me. I didn't write it, and I don't know what it means." (CX1375 (L. Resnick, Trop., Dep. at 109)). Likewise, with respect to the phrase "Convince people of preventative medicine & effects" under the heading "Who Are We??," Mrs. Resnick testified: "I didn't write that. I don't know what it means. It certainly is not who we are." (CX1375 (L. Resnick, Trop., Dep. at 109)). Based on the fact that the meeting notes, including portions cited by Complaint Counsel did not reflect either her or POM's position on POM's products or advertising,

Mrs. Resnick testified "I'm not sure who created it, nor do I believe that they know what they're talking about." CX1375 (L. Resnick, Trop., Dep. at 110)).

Additionally, Respondents object to the proposed finding to the extent that Complaint Counsel construe the "meeting notes" to bolster their argument that Respondents intended to convey to consumers that the Challenged Products prevent, treat or reduce the risk of heart disease, prostate cancer and erectile dysfunction. Although Respondents believe that pomegranate juice is beneficial to prostate health and that POM's research supports this belief (RFF 503-04, 510, 519-20), they dispute that Respondents ever intended to convey or that the Challenged Ads do convey the claim that the Challenged Products treat, prevent or reduce the risk of heart disease, prostate cancer and erectile dysfunction or that they are "clinically proven" to do so. (RFF 496, 535, 538, 540, 545-50, 2209-11, 2280; CX1375 (L. Resnick, Trop., Dep. at 79-81)).

Moreover, POM never states, expressly or by implication, conspicuously on the face of any of the Challenged Ads that scientific tests "prove" that the Challenged Products "prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction," or even that they "prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction." (RFF 2209-11, 2467-68, 2506, 2517; Reply Ad Appendix; Appendix of Advertisements). Even where medical research was referenced in advertising, the ads conveyed qualified messages about the health benefits of the Challenged Products, not definitive claims that the products will treat, prevent or reduce the risk of heart disease, prostate cancer or erectile dysfunction. (RFF 2517). Throughout its advertising, POM highlights that POM Juice is a 100% juice product wholly-derived from the pomegranate fruit, and that POMx has the same content as the pomegranate fruit itself and is 100% derived from the exact same fruit. (RFF 493-94, 2518-44; Reply Ad Appendix). Indeed, Respondents have never advertised their products as a pharmaceutical drug, nor intended to advertise their products as drugs.

(RFF 495-96, 524-30). Rather, Respondents have always marketed the Challenged Products for what they intrinsically are: whole-food products. (RFF 497-99).

295. Mr. Tupper testified that in POM's advertising the imagery and the headlines are irreverent and grab attention, but the body copy is factual and conveys a serious health benefits message. (Tupper, Tr. 1066).

Response to Finding No. 295:

Complaint Counsel mischaracterize Mr. Tupper's testimony to the extent they imply he testified that in the Challenged Ads the imagery and the headlines are irreverent and grab attention, but the body copy is factual and conveys a serious health benefits message. Instead, Mr. Tupper merely answered questions about the imagery, headlines and body copy of two specific POM advertisements (CX0003, CX0192) as opposed to making generalized statements applicable to the Challenged Ads. (Tupper, Tr. 1065-66). Moreover, Mr. Tupper never testified that Respondents wanted consumers to take the health benefits message conveyed in the "What gets your heart pumping?" and "Life support" ads seriously. He testified: "We believe it's a serious message. It's up to the consumer to decide, but we certainly believe it's important." (Tupper, Tr. 1066). In regard to the "serious message" discussed in the "What gets your heart pumping?" and "Life support" ads, Mr. Tupper stated that the message concerned the "health benefits of the product, the research, our commitment to the research." (Tupper, Tr. 1066).

Additionally, Dr. Butters testified that the use of humor blocks any communication to reasonable consumers that drinking POM Juice treats, prevents, or reduces the risk of heart disease, prostate cancer or erectile dysfunction. (Butters, Tr. 2864).

296. Mrs. Resnick stated in her book that "[i]f we can make you chuckle, we have an opportunity to connect with a more serious message grounded in our brand's identity and extrinsic value." (CX0001_0020).

Response to Finding No. 296:

Respondents do not dispute that the passage "[i]f we can make you chuckle, we have an opportunity to connect with a more serious message grounded in our brand's identity and intrinsic value" appears on page 112 of Mrs. Resnick's book *Rubies in the Orchard*. (CX0001_0019). However, Complaint Counsel presented no evidence and the cited evidence does not support the assertion that the Challenged Ads (1) convey either a "serious" or humorous message; or (2) elicited any emotion from consumers, including making them "chuckle." Complaint Counsel presented no extrinsic evidence or expert opinion on the Challenged Ads' meaning, consumer perceptions of the Challenged Ads, or consumer interpretations regarding the Challenged Ads. (Reply Ad Appendix; Appendix of Advertisements). The term "serious message" is vague and ambiguous.

Moreover, Respondents object to the proposed finding to the extent that Complaint Counsel construe Mrs. Resnick's statement in her book to bolster their argument that Respondents intended to convey to consumers that the Challenged Products prevent, treat or reduce the risk of heart disease, prostate cancer and erectile dysfunction. Although Respondents believe that pomegranate juice is beneficial to prostate health and that POM's research supports this belief (RFF 503-04, 510, 519-20), they dispute that Respondents ever intended to convey or that the Challenged Ads do convey the claim that the Challenged Products treat, prevent or reduce the risk of heart disease, prostate cancer and erectile dysfunction or that they are "clinically proven" to do so. (RFF 496, 535, 538, 540, 545-50, 2209-11, 2280; CX1375 (L. Resnick, Trop., Dep. at 79-81).

Additionally, Dr. Butters testified that the use of humor blocks any communication to reasonable consumers that drinking POM Juice treats, prevents, or reduces the risk of heart disease, prostate cancer or erectile dysfunction. (Butters, Tr. 2864).

297. Mrs. Resnick elaborated that "if you make someone laugh or cry . . . if you can elicit an emotion from someone, their guard goes down a little and they listen to you . . . . [I]f you

can be charming and funny or sad then your message will come through." (CX1359 (L. Resnick, Dep. at 242-43)).

Response to Finding No. 297:

Complaint Counsel presented no evidence and the cited evidence does not support the assertion that (1) the Challenged Ads elicited any emotion from consumers, including making them "laugh or cry"; (2) the Challenged Ads were "charming and funny"; or (3) the Challenged Ads caused consumers to let their guard down or listen to the ads. Complaint Counsel presented no extrinsic evidence or expert opinion on the Challenged Ads' meaning, consumer perceptions of the Challenged Ads, or consumer interpretations regarding the Challenged Ads. (Reply Ad Appendix; Appendix of Advertisements).

Moreover, Respondents object to the proposed finding to the extent that Complaint Counsel construe Mrs. Resnick's testimony to bolster their argument that Respondents intended to convey to consumers that the Challenged Products prevent, treat or reduce the risk of heart disease, prostate cancer and erectile dysfunction. Although Respondents believe that pomegranate juice is beneficial to prostate health and that POM's research supports this belief (RFF 503-04, 510, 519-20), they dispute that Respondents ever intended to convey or that the Challenged Ads do convey the claim that the Challenged Products treat, prevent or reduce the risk of heart disease, prostate cancer and erectile dysfunction or that they are "clinically proven" to do so. (RFF 496, 535, 538, 540, 545-50, 2209-11, 2280; CX1375 (L. Resnick, Trop., Dep. at 79-81)).

Additionally, Dr. Butters testified that the use of humor blocks any communication to reasonable consumers that drinking POM Juice treats, prevents, or reduces the risk of heart disease, prostate cancer or erectile dysfunction. (Butters, Tr. 2864).

298. Dr. Butters, whom Respondents offered as an expert in linguistics, confirmed that the use of parody, exaggeration, and humor is part of the process that can bring health messages in POM's advertisements to the potential purchaser. One of the effects of the humor is to capture the attention of the viewer and help them connect with a more serious message grounded in the advertisements. (Butters, Tr. 2853-54, 2865-66).

Response to Finding No. 298:

Respondents object that the term "bring health messages" is a vague paraphrase of Dr. Butters' actual testimony. Dr. Butters testified that the use of humor blocks any communication to reasonable consumers that drinking POM Juice treats, prevents, or reduces the risk of heart disease, prostate cancer or erectile dysfunction. (Butters, Tr. 2864). Dr. Butters further testified that one of the effects of the humor is to help the viewer connect with the more serious message stated in the body text. (Butters, Tr. 2866).

2. POM Targeted Health-Conscious Consumers Concerned About Illness

299. POM ran print advertisements in certain consumer magazines, including *Health Magazine*, *Men's Health*, and *Men's Fitness*, because these publications were geared toward the health-conscious consumer. (Leow, Tr. 425-26).

Response to Finding No. 299:

Although Respondents do not dispute that POM ran print advertisements in the above-referenced magazines, they dispute Complaint Counsels' implication that a focus on health health-conscious consumers, including those concerned about illness–the very type of consumers that would purchase *Health Magazine*, *Men's Health* and *Men's Fitness*–is evidence that Respondents intended to convey the claims that the Challenged Products treat, prevent or reduce the risk of heart disease, prostate cancer and erectile dysfunction. These magazines are replete with "superfood" suggestions, health tips, guides to healthy living, effective exercise tips and techniques, and any number of articles to assist those focused on proactively maintaining their health and, therefore, reducing the risk of disease - - but not like a drug does, with both its increased efficacy (*e.g.*, Lipitor and Prilosec) and safety risks. Instead, the typical article in these magazines may focus on, for example, "5 unexpected reasons to drink more water," the benefits of tomatoes, and why or why not "an apple a day may keep the doctor away." This month's *Men's*

Fitness, for example, discusses "Healthy Fried Food?" and asks "What Makes Red Wine Healthy?" Statements in this magazine (and others) that blueberries contain resveratrol, "a heart disease- and cancer-fighting antioxidant found in red grapes and red wine" (*see* http://findarticles.com/p/articles/mi_m1608/is_9_17/ai_80309781/?tag=content;col1) is not a statement that it will in fact prevent these diseases. The audience of *Health Magazine*, *Men's Health* and *Men's Fitness* (and target audience of POM's products as argued by Complaint Counsel) do not receive the message that blueberries (or pomegranates) "prevent" diseases like a drug prevents the buildup of bad cholesterol, or like foot powder prevents fungus with their single effective target of action. Instead, at most, they receive the message that consumption may reduce the risk of (or help prevent) disease like a healthy diet and exercise do. This is obvious from the magazine type itself.

Moreover, Complaint Counsel's fallacious argument that the medium in which POM advertised shows Respondents' intent to convey disease-claims is further belied by the fact that POM's advertisements were disseminated in a wide variety of nationally distributed publications devoted to fashion, beauty and lifestyle (*e.g.*, *Details*, *InStyle*, *Town and Country*), global business (*Fortune*), music and popular culture (*e.g.*, *Rolling Stone* and *Playboy*), science and technology (*e.g.*, *Popular Science*), gay and lesbian interests (*e.g.*, *Advocate*) as well as in local newspapers (*e.g.*, *LA Times* and *Chicago Tribune*). (CCFF 225, 227, 341, 349, 363, 372, 397). None of these publications focus on health-conscious consumers, including those concerned about illness. Nor is it reasonable to assume that readers of these publications - - with their articles about beauty, fashion, home, fitness, entertaining, general nutrition, business and celebrity lifestyles - - adopt Complaint Counsel's extremely aggressive view that POM's advertising actually convey the message that the Challenged Products are "clinically proven" to treat, prevent or reduce the risk of heart disease, prostate cancer and erectile dysfunction.

Also, although Respondents genuinely believe in the healthful benefits of the Challenged Products and in the integrity of POM's research program (RFF 50 2-20), they dispute that they ever intended to convey or that the Challenged Ads do convey the claim that the Challenged Products treat, prevent or reduce the risk of heart disease, prostate cancer and erectile dysfunction or that they are "clinically proven" to do so. (RFF 496, 535, 538, 540, 545-50, 2209-11, 2280; CX1375 (L. Resnick, Trop., Dep. at 79-81)).

300. With a median age around thirty, the early adopters of POM products were younger than the company expected, but over time the POM purchasers have "migrate[d] older to people that have heart disease or prostate cancer in their family, or have a fear of having it themselves." (CX1368 (L. Resnick, Welch Dep. at 63-64, 66-67)).

Response to Finding No. 300:

Respondents object to the proposed finding to the extent that Complaint Counsel construe Mrs. Resnick's testimony to bolster their argument that a focus on health health-conscious consumers, including those concerned about illness is evidence that Respondents intended to convey the claims that the Challenged Products treat, prevent or reduce the risk of heart disease, prostate cancer and erectile dysfunction. The record evidence proves just the opposite: Although Respondents genuinely believe in the healthful benefits of the Challenged Products and in the integrity of POM's research program (RFF 50 2-20), they dispute that they ever intended to convey or that the Challenged Ads do convey the claim that the Challenged Products treat, prevent or reduce the risk of heart disease, prostate cancer and erectile dysfunction or that they are "clinically proven" to do so. (RFF 496, 535, 538, 540, 545-50, 2209-11, 2280; CX1375 (L. Resnick, Trop., Dep. at 79-81)). Complaint Counsel presented no evidence directly contradicting the individual Respondents' testimony.

Complaint Counsel also misstate Mrs. Resnick's testimony. Mrs. Resnick testified that POM's consumers were generally people who "want a really healthy drink" and that POM was noticing that its consumers were "starting to migrate older, to people that have

heart disease or prostate cancer in their family, or have a fear of having it themselves." (CX1368 (L. Resnick, Welch Dep. at 67)). Even if there was an uptick in POM Juice buyers having "heart disease or prostate cancer in their family, or hav[ing] a fear of having it themselves," Mrs. Resnick never testified that these buyers bought POM Juice because of any claim in the Challenged Ads. (CX1368 (L. Resnick, Welch Dep. at 1-178)). Nor did Mrs. Resnick testify that any buyer of POM Juice purchased the product to treat, prevent or reduce the risk of heart disease, prostate cancer or erectile dysfunction. (CX1368 (L. Resnick, Welch Dep. at 1-178)). Indeed, Mrs. Resnick's cited testimony was not in response to a question about why people buy the Challenged Products or whether the Challenged Claims are material to consumers purchase decisions. (CX1368 (L. Resnick, Welch Dep. at 66-67)). Of course, as shown by the testimony and survey of Professor Reibstein, the Challenged Claims, in fact, are not material to consumers. (RFF 2219, 2613-46, 2678, 2696-2701). Complaint Counsel presented no evidence to rebut Professor Reibstein's testimony and survey. (RFF 2680-84).

301. Current POM Juice buyers tend to be in their forties, fifties, or older, and are sophisticated to some extent about their health. (L. Resnick, Tr. 127-28).

Response to Finding No. 301:

Complaint Counsel grossly mischaracterize Mrs. Resnick's testimony. Mrs. Resnick never testified that POM Juice buyers tend to be in their "fifties, or older." Rather, Mrs. Resnick testified that current POM Juice buyers "tend to be in their forties and maybe even into their fifties and onward." (L. Resnick, Tr. 128) (emphasis added). Mrs. Resnick's testimony at trial is consistent with her deposition testimony in the *POM Wonderful LL v. Welch's* case where in response to the question "Can you describe who POM's consumers are now," she answered: "So our ages migrated a little older. I think we're probably in the early 40s at this point." (CX1368 (L. Resnick, Welch Dep. at 1-178)). Therefore, the evidence cited by Complaint Counsel does not support their

proposition that Respondents were "targeting" older people (*e.g.*, buyers in their fifties or older) who might be more concerned about illness than younger consumers.

Moreover, Mrs. Resnick testimony was not in response to a question about why people buy the Challenged Products or whether the Challenged Claims are material to them. (. (L. Resnick, Tr. 127). Instead, she was simply asked to describe "generally" POM's target audience. (L. Resnick, Tr. 127). As shown by the testimony and survey of Professor Reibstein, the Challenged Claims, in fact, are not material to consumers. (RFF 2219, 2613-46, 2678, 2696-2701). Complaint Counsel presented no evidence to rebut Professor Reibstein's testimony and survey. (RFF 2680-84). Also, even if current POM Juice buyers are "sophisticated to some extent about their health," Mrs. Resnick never testified that they buy the Challenged Products to treat, prevent or reduce the risk of heart disease, prostate cancer or erectile dysfunction. (L. Resnick, Tr. 72-219).

Respondents also object to the proposed finding to the extent that Complaint Counsel construe Mrs. Resnick's testimony to bolster their argument that a focus on health health-conscious consumers, including those concerned about illness is evidence that Respondents intended to convey the claims that the Challenged Products treat, prevent or reduce the risk of heart disease, prostate cancer and erectile dysfunction. Although Respondents genuinely believe in the healthful benefits of the Challenged Products and in the integrity of POM's research program (RFF 50 2-20), they dispute that they ever intended to convey or that the Challenged Ads do convey the claim that the Challenged Products treat, prevent or reduce the risk of heart disease, prostate cancer and erectile dysfunction or that they are "clinically proven" to do so. (RFF 496, 535, 538, 540, 545-50, 2209-11, 2280; CX1375 (L. Resnick, Trop., Dep. at 79-81)).

302. Numerous creative briefs dating from January 2004 to at least July 2006 described the POM target audience as "likely to be affluent, professional, college grads who are very health-conscious (hypochondriacs) and live in urban areas." (CX409_0001; *see also* CX0409_0003, 0005-6, 0008, 0010, and 0022). Similarly, in 2008, POM and Roll noted

that the primary target consumer for a juice campaign "should be the 30-something health conscious (hypochondriac?) who is educated and affluent." (CX0211_0002).

Response to Finding No. 302:

Respondents object to the proposed finding to the extent that Complaint Counsel construe specific language in POM's creative briefs to bolster their argument that a focus on health health-conscious consumers, including those concerned about illness is evidence that Respondents intended to convey the claims that the Challenged Products treat, prevent or reduce the risk of heart disease, prostate cancer and erectile dysfunction. First, although Respondents genuinely believe in the healthful benefits of the Challenged Products and in the integrity of POM's research program (RFF 50 2-20), they dispute that they ever intended to convey or that the Challenged Ads do convey the claim that the Challenged Products treat, prevent or reduce the risk of heart disease, prostate cancer and erectile dysfunction or that they are "clinically proven" to do so. (RFF 496, 535, 538, 540, 545-50, 2209-11, 2280; CX1375 (L. Resnick, Trop., Dep. at 79-81)).

Second, specific language in POM's creative briefs do not counter the available evidence on Respondents' intent in POM's advertising. (RFF 496, 535, 538, 540, 545-50, 2209-11, 2280; CX1375 (L. Resnick, Trop., Dep. at 79-81)). Creative briefs were typically prepared by junior POM marketing employees. (Perdigao, Tr. 2790; Tupper, Tr. 921; CX1356 (Leow, Dep. 40)). Mrs. Resnick and Mr. Tupper seldom, if ever, saw, reviewed or provided feedback on creative briefs. (CX1359 (L. Resnick, Dep. 102-03, 109); Tupper, Tr. 923-24; CX1353 (Tupper, Dep. 224); Perdigao, Tr. 623-24, 2790-91; (CX1348 (Perdigao, Dep. 170, 268); Leow, Tr. 459-60; CX1356 (Leow, Dep. 54-55)). Mrs. Resnick testified that she typically did not discuss any particular creative brief with POM marketing employees. (CX01359 (L. Resnick, Dep. 109). There is no evidence that Mr. Resnick has ever seen a creative brief. (Perdigao, Tr. 2791). Indeed, the evidence shows that he had very little involvement in the marketing of POM's

products and no day-to-day involvement. (RFF 75-76; Perdigao, Tr. 604; Leow, Tr. 419, 465-66).

There is also only a tenuous relationship between creative briefs and final advertisement. The creative process is collaborative and fluid, with lots of people involved, which results in the final advertisement being vastly different than the rough idea initially discussed in the creative brief. (Perdigao, Tr. 609-14, 621-22, 2790-91; Leow, Tr. 458-59, 463-65; Tupper, Tr. 920, 929). Indeed, the ideas of the junior marketing staff expressed in creative briefs were frequently modified, altered and rejected. (Perdigao, Tr. 2790; Leow, Tr. 460). This is simply the nature of the creative process as implemented at Fire Station and POM. Creative briefs serve the administrative function of initiating a Fire Station work order. (Perdigao, Tr. 616-17, 2790). They also provided Fire Station a basic overview on a particular marketing project. (Tupper, Tr. 921; Perdigao, Tr. 622-23; Leow, Tr. 451). Because creative briefs were preliminary in nature, they were very general. (Rushton, Tr. 1396). Thus, the purpose of creative briefs was merely to generate creative ideas around a concept, not dictate specific wording, graphics or claims to be included in the advertisement. (Tupper, Tr. 921; Perdigao, Tr. 621-23).

Once a Fire Station received a creative brief, a creative team or teams was assigned to develop concepts for the proposed advertisement. (Perdigao, Tr. 619, 621-22; CX1348 (Perdigao, Dep. 54); Leow, Tr. 453). The concepts were then shown to Liz Leow, Fire Station's Creative Director, who might like them, dislike them, adjust them, or send them back to the drawing board. (Perdigao, Tr. 621-22; CX1348 (Perdigao, Dep. 55); Leow, Tr. 458-59). If Ms. Leow liked the concepts, they went to Mr. Perdigao, head of Firestation advertisement agency, for review and then to POM marketing for comment. (Perdigao, Tr. 615; CX1348 (Perdigao, Dep. 55); Leow, Tr. 459). There were often multiple rounds of revisions to the concepts at this stage of the creative

process. (Leow, Tr. 459). Sometimes the larger creative concepts were rejected by POM and Fire Station had to start the creative process from the beginning. (Leow, Tr. 460; CX1356 (Leow, Dep. 42-43)).

In sum, because the ad that actually ran typically did not reflect the creative brief prepared by the junior POM marketing employee, it is not accurate to describe creative briefs as reflective of the "intent" of an advertisement. (Perdigao, Tr. 2791). Mr. Michael Perdigao was asked several questions about the use of the "creative brief" at Firestation, in connection with POM:

> Q. All right. Are the creative briefs typically seen by Mrs. Resnick?
> A. No.
> Q. Are they typically seen by Mr. Resnick?
> A. No.
> Q. Are they typically seen by the legal department?
> A. No.
> Q. Do the ads that actually are run typically reflect the creative brief that started the process by this junior person writing a creative brief?
> A. Not generally with POM, no.
> Q. All right. If I wanted to determine the intention of the company or the people that run the company, would I look to the creative briefs to show that intention?
> A. No.

(Perdigao, Tr. 2790-2791). Accordingly, creative briefs provide no basis to infer Respondents' intent to convey the Challenged Claims.

303. Creative briefs dated June 28, 2006 and July 13, 2006, which stated they were to be used for all future POMx Pill projects, make clear that POM's marketing message was intended to reach consumers who were seeking cures or prevention for illnesses or disease. Specifically, the creative briefs identified the target audience for POMx Pills as a "[c]onsumer . . . who is seeking a natural cure for current ailments or to maintain health and prevent future ailments[.]" The briefs also note under "tonality" that "the pill formula is more medicinal by nature[.]" (CX0409_0016-19).

Response to Finding No. 303:

See Response to Finding No. 302.

304. Similarly, another creative brief for POMx Pills, dated September 1, 2006, shows that POM was targeting consumers who sought to prevent or reduce the risk of prostate cancer. It explicitly stated several times that the "[m]ain creative focus is prostate cancer." This creative brief identified the target consumer audience's age and gender as "**men 40+, HH $75K+, primarily men who are scared to get prostate cancer[.]**" (CX0409_0023).

Response to Finding No. 304:

See Response to Finding No. 302.

305. In a creative brief for the "Health Benefits" section of the POM Wonderful website, the "target audience" was described as including "[c]onsumers . . . with an ailment that pomegranates have been rumored to help" as well as "healthcare professionals [like] [p]rimary care physicians" and "[u]rologists." (CX0200_0002).

Response to Finding No. 305:

See Response to Finding No. 302.

306. POM included scientific information in advertising and marketing material to help sell its products, because the scientific information provided the consumer with a "reason to believe." (Leow, Tr. 512-13; CX0095_0002).

Response to Finding No. 306:

Respondents do not dispute that Liz Leow expressed her personal opinion that the specific "scientific" information referenced in her January 17, 2007 email to Robin Jones might help sell POM Juice. But the evidence cited does not support the proposition that Ms. Leow believes that any other scientific information would be helpful to POM's sales or that Respondents believe that any "scientific" information would be helpful to sales. Respondents also dispute that Ms. Leow, who is an employee of Roll (Leow, Tr. 414), has the authority to speak on behalf of POM, including stating why POM included "scientific information" in any of its advertising and marketing materials. The evidence

cited also does not support the proposition that any the scientific research referenced in the Challenged Ads was material to consumers' purchase decisions. As shown by the testimony and survey of Professor Reibstein, the Challenged Claims, in fact, are not material to consumers. (RFF 2219, 2613-46, 2678, 2696-2701). Complaint Counsel presented no evidence to rebut Professor Reibstein's testimony and survey. (RFF 2680-84).

Moreover, Respondents object to the proposed finding to the extent that Complaint Counsel construe the cited evidence to bolster their argument that Respondents intended to convey to consumers that the Challenged Products treat, prevent or reduce the risk of disease. Respondents genuinely believe in the health benefits of the Challenged Products and in the scientific integrity of POM's research (RFF 502-20). Thus, it is not surprising that POM's ads summarize some of Respondents' scientific research on the Challenged Products in the areas of cardiovascular, prostate and erectile health and talk about the healthful properties of the Challenged Products, including that the Challenged Products contain abundant antioxidants and that they are wholly derived from pomegranate fruit. (RFF 493-99, 2478-2505, 2518-44). However, the Respondents dispute that they ever intended to convey or that the Challenged Ads do convey the claim that the Challenged Products treat, prevent or reduce the risk of heart disease, prostate cancer and erectile dysfunction or that they are "clinically proven" to do so. (RFF 496, 535, 538, 540, 545-50, 2209-11, 2280; CX1375 (L. Resnick, Trop., Dep. at 79-81).

Additionally, POM never states, expressly or by implication, conspicuously on the face of any of the Challenged Ads that scientific tests "prove" that the Challenged Products "prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction," or even that they "prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction." (RFF 2209-11, 2467-68, 2506, 2517; Reply Ad Appendix; Appendix of Advertisements). Even where medical research was referenced in

advertising, the ads conveyed qualified messages about the health benefits of the Challenged Products, not definitive claims that the products will treat, prevent or reduce the risk of heart disease, prostate cancer or erectile dysfunction. (RFF 2517). Throughout its advertising, POM highlights that POM Juice is a 100% juice product wholly-derived from the pomegranate fruit, and that POMx has the same content as the pomegranate fruit itself and is 100% derived from the exact same fruit. (RFF 493-94, 2518-44; Reply Ad Appendix). Indeed, Respondents have never advertised their products as a pharmaceutical drug, nor intended to advertise their products as drugs. (RFF 495-96, 524-30). Rather, Respondents have always marketed the Challenged Products for what they intrinsically are: whole-food products. (RFF 497-99).

307. Under "Benefit," the creative brief for POMx Pills, dated September 1, 2006, emphasized "**Main creative focus for 1st round is prostate cancer. (The benefits are from the studies – which showed a decrease in the doubling time of PSA levels.)**" (CX0409_0024).

Response to Finding No. 307:

See Response to Finding No. 302.

308. POM's marketing materials also made claims for other diseases and conditions in addition to cardiovascular disease, prostate cancer and erectile function. For example, several print advertisements referred to premature aging and Alzheimer's disease, and Mrs. Resnick stated in a *Martha Stewart* television appearance in November 2008 that pomegranate juice "helps Alzheimer's." (CX0016; CX0033; CX0036; CX0473 (Compl. Ex. E-6)).

Response to Finding No. 308:

Respondents object to the proposed finding to the extent that Complaint Counsel construe the cited evidence to bolster their argument that Respondents intended to convey the claims that the Challenged Products treat, prevent or reduce the risk of heart disease, prostate cancer and erectile dysfunction. The record evidence proves just the opposite: Although Respondents genuinely believe in the healthful benefits of the Challenged Products and in the integrity of POM's research program (RFF 50 2-20), they dispute that

they ever intended to convey or that the Challenged Ads do convey the claim that the Challenged Products treat, prevent or reduce the risk of heart disease, prostate cancer and erectile dysfunction or that they are "clinically proven" to do so. (RFF 496, 535, 538, 540, 545-50, 2209-11, 2280; CX1375 (L. Resnick, Trop., Dep. at 79-81)). Complaint Counsel presented no evidence directly contradicting Respondents' testimony.

Respondents further object to the proposed finding because whether Respondents "made claims for other diseases and conditions," including for "premature aging and Alzheimer's disease" in addition to cardiovascular disease, prostate cancer and erectile function is irrelevant because Complaint Counsel has not alleged that Respondents have made any false or misleading claims in advertising concerning claims that the Challenged Products treat, prevent or reduce the risk of premature aging or Alzheimer's disease.

Additionally, the evidence is overwhelming that the use of humorously exaggerated headlines and imagery in the Cheat Death (CX0036) and Life Support (CX0033) ads was never intended to convey the message that the Challenged Products treat, prevent or reduce the risk of heart disease, prostate cancer or erectile dysfunction. For example, Michael Perdigao, head of Fire Station advertising agency, testified that the headline, graphics and line "Dying is so dead" in the "Cheat death" ad was meant to be humorous, hyperbole and puffery. (RFF 2278). He said "it's going to extreme puffery in terms of the fact that our product is so healthy that this bottle was able to cheat death." (RFF 2278). Mr. Tupper also testified that much of the "Cheat death" advertisement was not meant to be interpreted literally, but was an example of puffery. (RFF 2279). Mrs. Resnick agreed that much of the "Cheat death" ad is puffery and stated that the headline is meant to convey the fact that the product is good for you. (RFF 2280). She further testified that the idea of the ad is to make you laugh. "And what we're saying here essentially with puffery is that you'll live longer if you -- you can cheat death, which we all know you can't." (RFF 535, 2280). The intent of the "Cheat death" ad was to get the

attention of the reader, make the reader read the ad, remember the shape of the bottle and the fact that POM Juice is a healthy product. (Appendix of Advertisements ¶ 97). Moreover, Mr. Tupper testified that the meaning of the Life Support (CX0033) ad is that POM Juice is an incredibly healthful product that helps support a healthy life driven by the antioxidant content of the juice. (Appendix of Advertisements ¶ 272). Complaint Counsel presented no evidence contradicting Respondents' testimony.

Finally, Respondents contend that Mrs. Resnick's interview on *The Martha Stewart Show* (CX0473(Compl. Exh. E-6, November 2008) is not actionable under the FTCA, and therefore not at issue here, because it: (1) does not constitute "advertising"; (2) represents constitutionally protected speech; and (3) in any event, cannot be considered as material to the purchasing decision of any consumers. (RFF 2252-66).

3. POM Referenced Science and Research in Ads to Prove That Its Products Can Treat or Ward Off Specific Diseases

309. Mrs. Resnick testified that POM wanted consumers to know about the investment that it has made in science and emphasized the scientific research in its marketing. (L. Resnick, Tr. 78-79, 277). Thus, POM's advertisements in various media claimed that its products were "supported" or "backed" by tens of millions of dollars in medical and scientific research at the world's leading universities. The specific amounts ranged from $20 million to $34 million, depending on the time frame of the advertisement. (*See, e.g.*, CCFF ¶¶D.1.g.357, D.1.h.363, D.1.h.364, D.2.b.372, D.2.c.379, D.2.c.380, D.3.385, D.4.a.397, D.4.b.409, D.4.c.415, D.4.d.421, D.4.e.425, D.4.e.426, 444, 473, 508).

Response to Finding No. 309:

Respondents object to the proposed finding to the extent that Complaint Counsel construe the cited evidence to bolster their argument that Respondents intended to convey to consumers that the Challenged Products treat, prevent or reduce the risk of disease. Respondents genuinely believe in the health benefits of the Challenged Products and in the scientific integrity of POM's research (RFF 502-20). Thus, it is not surprising that POM's ads summarize some of Respondents' scientific research on the Challenged Products in the areas of cardiovascular, prostate and erectile health and talk about the

healthful properties of the Challenged Products, including that the Challenged Products contain abundant antioxidants and that they are wholly derived from pomegranate fruit. (RFF 493-99, 2478-2505, 2518-44). However, the Respondents dispute that they ever intended to convey or that the Challenged Ads do convey the claim that the Challenged Products treat, prevent or reduce the risk of heart disease, prostate cancer and erectile dysfunction or that they are "clinically proven" to do so. (RFF 496, 535, 538, 540, 545-50, 2209-11, 2280; CX1375 (L. Resnick, Trop., Dep. at 79-81).

Moreover, POM never states, expressly or by implication, conspicuously on the face of any of the Challenged Ads that scientific tests "prove" that the Challenged Products "prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction," or even that they "prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction." (RFF 2209-11, 2467-68, 2506, 2517; Reply Ad Appendix; Appendix of Advertisements). Even where medical research was referenced in advertising, the ads conveyed qualified messages about the health benefits of the Challenged Products, not definitive claims that the products will treat, prevent or reduce the risk of heart disease, prostate cancer or erectile dysfunction. (RFF 2517). Throughout its advertising, POM highlights that POM Juice is a 100% juice product wholly-derived from the pomegranate fruit, and that POMx has the same content as the pomegranate fruit itself and is 100% derived from the exact same fruit. (RFF 493-94, 2518-44; Reply Ad Appendix). Indeed, Respondents have never advertised their products as a pharmaceutical drug, nor intended to advertise their products as drugs. (RFF 495-96, 524-30). Rather, Respondents have always marketed the Challenged Products for what they intrinsically are: whole-food products. (RFF 497-99).

Additionally, Complaint Counsel mischaracterize Mrs. Resnick's testimony to the extent they imply that citing to money spent on research in POM's ads was meant to convey the claim that the Challenged Products treat, prevent or reduce the risk of disease. Rather,

Mrs. Resnick testified that the purpose of the "backed by" claims was to convey a message about the company, and its level of dedication to learning the truth about pomegranates. She said "[Respondents wanted in] a shorthand way, which you always look for in advertising, a very direct way of communicating to the consumer that here was a natural food that had gone through rigorous scientific testing and that we cared enough to do this and we wanted to tell people that we had and continue to do scientific research." (L. Resnick, Tr. 251). Mrs. Resnick's testimony is consistent with Mr. Resnick's who stated that the goal of the research program is to uncover the truth behind the health benefits of the pomegranate, not to make health claims. (RFF 271, 273-75). Simply put, Complaint Counsel presented no evidence that Mrs. Resnick intended reference to research in the Challenged Ads to convey the claims attributed to the Challenged Ads by Complaint Counsel. (L. Resnick, Tr. 72-219, 227-289).

310. POM's intention in disseminating the "backed by" advertisements was to convey its commitment to the science program, the seriousness, breadth, and depth of the science, and to distinguish itself from other food and supplement companies. (Tupper, Tr. 2997-98).

Response to Finding No. 310:

Respondents object to the proposed finding to the extent that Complaint Counsel construe the cited evidence to bolster their argument that Respondents intended to convey to consumers that the Challenged Products treat, prevent or reduce the risk of disease. Respondents genuinely believe in the health benefits of the Challenged Products and in the scientific integrity of POM's research (RFF 502-20). Thus, it is not surprising that POM's ads summarize some of Respondents' scientific research on the Challenged Products in the areas of cardiovascular, prostate and erectile health and talk about the healthful properties of the Challenged Products, including that the Challenged Products contain abundant antioxidants and that they are wholly derived from pomegranate fruit. (RFF 493-99, 2478-2505, 2518-44). However, the Respondents dispute that they ever

intended to convey or that the Challenged Ads do convey the claim that the Challenged Products treat, prevent or reduce the risk of heart disease, prostate cancer and erectile dysfunction or that they are "clinically proven" to do so. (RFF 496, 535, 538, 540, 545-50, 2209-11, 2280; CX1375 (L. Resnick, Trop., Dep. at 79-81).

Moreover, POM never states, expressly or by implication, conspicuously on the face of any of the Challenged Ads that scientific tests "prove" that the Challenged Products "prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction," or even that they "prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction." (RFF 2209-11, 2467-68, 2506, 2517; Reply Ad Appendix; Appendix of Advertisements). Even where medical research was referenced in advertising, the ads conveyed qualified messages about the health benefits of the Challenged Products, not definitive claims that the products will treat, prevent or reduce the risk of heart disease, prostate cancer or erectile dysfunction. (RFF 2517). Throughout its advertising, POM highlights that POM Juice is a 100% juice product wholly-derived from the pomegranate fruit, and that POMx has the same content as the pomegranate fruit itself and is 100% derived from the exact same fruit. (RFF 493-94, 2518-44; Reply Ad Appendix). Indeed, Respondents have never advertised their products as a pharmaceutical drug, nor intended to advertise their products as drugs. (RFF 495-96, 524-30). Rather, Respondents have always marketed the Challenged Products for what they intrinsically are: whole-food products. (RFF 497-99).

Additionally, Complaint Counsel mischaracterize Mr. Tupper's testimony to imply that the purpose of citing to money spent on research in POM's ads was to claim that the Challenged Products treat, prevent or reduce the risk of disease. Rather, Mr. Tupper testified that the purpose of including the amount of money related to medical research in the advertising was to convey a message about the company, and its level of dedication to learning the truth about pomegranates. He said "what our intention has always been is to

convey our commitment to the science program, the seriousness, the breadth, the depth of that science program, and to do so by illustrating that concept with the amount of funding that we've provided to the science ….And so in those ads, by citing the aggregate amount of funding, we're trying to communicate that, hey, this is a serious science program. We care about science. We're committed to science. That's a core part of what we do." (Tupper, Tr. 2997-98). Mr. Tupper's testimony is consistent with Mr. Resnick's who stated that the goal of the research program is to uncover the truth behind the health benefits of the pomegranate, not to make health claims. (RFF 271, 273-75). Simply put, Complaint Counsel presented no evidence that Mr. Tupper intended reference to research in the Challenged Ads to convey the claims attributed to the Challenged Ads by Complaint Counsel. (Tupper, Tr. 885-942, 950-1068, 2972-3039).

311. Mrs. Resnick also testified that the purpose of putting the amount of money spent on research in the advertising was to communicate to consumers in a "very direct way" that the product "had gone through rigorous scientific testing." (L. Resnick, Tr. 251). POM communicated the amount of money spent to communicate that POM does not "just say our product is great, we have clinical studies that prove its efficacy." (CX0409_0057).

Response to Finding No. 311:

Respondents object to the proposed finding to the extent that Complaint Counsel construe the cited evidence to bolster their argument that Respondents intended to convey to consumers that the Challenged Products treat, prevent or reduce the risk of disease. Respondents genuinely believe in the health benefits of the Challenged Products and in the scientific integrity of POM's research (RFF 502-20). Thus, it is not surprising that POM's ads summarize some of Respondents' scientific research on the Challenged Products in the areas of cardiovascular, prostate and erectile health and talk about the healthful properties of the Challenged Products, including that the Challenged Products contain abundant antioxidants and that they are wholly derived from pomegranate fruit. (RFF 493-99, 2478-2505, 2518-44). However, the Respondents dispute that they ever intended to convey or that the Challenged Ads do convey the claim that the Challenged

Products treat, prevent or reduce the risk of heart disease, prostate cancer and erectile dysfunction or that they are "clinically proven" to do so. (RFF 496, 535, 538, 540, 545-50, 2209-11, 2280; CX1375 (L. Resnick, Trop., Dep. at 79-81).

Moreover, POM never states, expressly or by implication, conspicuously on the face of any of the Challenged Ads that scientific tests "prove" that the Challenged Products "prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction," or even that they "prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction." (RFF 2209-11, 2467-68, 2506, 2517; Reply Ad Appendix; Appendix of Advertisements). Even where medical research was referenced in advertising, the ads conveyed qualified messages about the health benefits of the Challenged Products, not definitive claims that the products will treat, prevent or reduce the risk of heart disease, prostate cancer or erectile dysfunction. (RFF 2517). Throughout its advertising, POM highlights that POM Juice is a 100% juice product wholly-derived from the pomegranate fruit, and that POMx has the same content as the pomegranate fruit itself and is 100% derived from the exact same fruit. (RFF 493-94, 2518-44; Reply Ad Appendix). Indeed, Respondents have never advertised their products as a pharmaceutical drug, nor intended to advertise their products as drugs. (RFF 495-96, 524-30). Rather, Respondents have always marketed the Challenged Products for what they intrinsically are: whole-food products. (RFF 497-99).

Additionally, Complaint Counsel mischaracterize Mrs. Resnick's testimony to imply that the purpose of citing to money spent on research in POM's ads was to claim that the Challenged Products treat, prevent or reduce the risk of disease. Rather, Mrs. Resnick testified that the purpose of including the amount of money related to medical research in the advertising was to convey a message about the company, and its level of dedication to learning the truth about pomegranates. She said "[Respondents wanted in] a shorthand way, which you always look for in advertising, a very direct way of communicating to

the consumer that here was a natural food that had gone through rigorous scientific testing and that we cared enough to do this and we wanted to tell people that we had and continue to do scientific research." (L. Resnick, Tr. 251). Mrs. Resnick's testimony is consistent with Mr. Resnick's who stated that the goal of the research program is to uncover the truth behind the health benefits of the pomegranate, not to make health claims. (RFF 271, 273-75). Simply put, Complaint Counsel presented no evidence that Mrs. Resnick intended reference to research in the Challenged Ads to convey the claims attributed to the Challenged Ads by Complaint Counsel. (L. Resnick, Tr. 72-219, 227-289).

Finally, the snippet taken from a single "Concept" in a single creative brief does not support Complaint Counsel's proposition that POM referenced the amount of money spent on research to communicate that the Challenged Products are clinically proven to treat, prevent or reduce the risk of disease. First, the creative brief cited by Complaint Counsel is clearly identified as a "DRAFT" and Complaint Counsel have presented no evidence that this brief was ever finalized or acted upon. (CX0409_0057). Nor did Complaint Counsel to demonstrate who prepared the creative brief and why. Second, creative briefs were typically prepared by junior POM marketing employees, with Lynda Resnick and Matthew Tupper seldom if ever seeing, reviewing or providing feedback on creative briefs. (RRFF 302-05, 307). There is no evidence that Mr. Resnick has ever seen a creative brief. (RRFF 302-05, 307). Third, the creative process was collaborative and fluid, with lots of people involved, which resulted in the final advertisement being vastly different than the rough idea initially discussed in the creative brief. (RRFF 302-05, 307). Because the ad that actually ran typically did not reflect the creative brief prepared by the junior POM marketing employee, it is not accurate to describe creative briefs as reflective of the "intent" of an advertisement. (RRFF 302-05, 307).

312. Dr. Butters, Respondents' linguist, wrote in a previous article that the words "medical," "research," and "study" have highly positive connotations for consumers. He also wrote

that as a modifier, "medical" seems to be strongly associated with treatment. (Butters, Tr. 2879-81).

Response to Finding No. 312:

In 312 insert: "This proposed finding is a huge error. The cited article, CX2067, was not about consumers' connotations as Complaint Counsel falsely contends, but rather was a study on *medical research subjects* entitled "Semantic and Pragmatic Variability in Medical Research Terms: Implications for Obtaining Meaningful Informed Consent." (Butters, Tr. 2835-36) (discussing CX2067). The data was collected from structured interviews with the research subjects, designed to elicit their reaction to requests for consent to being part of medical research – there were no consumers involved, just medical research subjects. (Butters, Tr. 2836-37). In their questioning at trial, Complaint Counsel conceded that they had "slightly mischaracterized" the article (Butters, Tr. 2837), but in this proposed finding of fact they have mischaracterized it beyond recognition. The "highly positive connotations" were not from consumers, but rather an evaluation of terms used to describe potential medical research to potential research subjects. (Butters, Tr. 2837). The purpose of the study was "to find out what sorts of words were the most neutral and most ethically sound to use in informed consent documents." (Butters, Tr. 2837). Dr. Butters later agreed that the article stated in part as follows: " 'Second, medical research and medical studies carry favorable connotations that would predispose subjects towards research participation.' It then goes on to say, 'All three words -- medical, research, and study -- have highly positive connotations, and as a modifier, 'medical' especially seems to be strongly associated with treatment.' " (Butters, Tr. 2881). But as that quote explicitly states, this was just the research subjects' reaction to these terms in the context of assessing their reaction to the language of informed consents, specifically the effect on research participation. It is disingenuous for Complaint Counsel to mischaracterize this article as being about "consumer" reactions."

313. One of the reasons POM moved away from the "Dressed Bottle" campaign was that it feared the campaign was selling the overall benefits of pomegranate juice regardless of

brand, when only POM had conducted a significant amount of medical research to confirm the health benefits of its product. (CX0286_0002).

Response to Finding No. 313:

Respondents object to the proposed finding to the extent that Complaint Counsel construe the cited evidence to bolster their argument that Respondents intended to convey to consumers that the Challenged Products treat, prevent or reduce the risk of disease. Respondents genuinely believe in the health benefits of the Challenged Products and in the scientific integrity of POM's research (RFF 502-20). Thus, it is not surprising that POM's ads summarize some of Respondents' scientific research on the Challenged Products in the areas of cardiovascular, prostate and erectile health and talk about the healthful properties of the Challenged Products, including that the Challenged Products contain abundant antioxidants and that they are wholly derived from pomegranate fruit. (RFF 493-99, 2478-2505, 2518-44). However, the Respondents dispute that they ever intended to convey or that the Challenged Ads do convey the claim that the Challenged Products treat, prevent or reduce the risk of heart disease, prostate cancer and erectile dysfunction or that they are "clinically proven" to do so. (RFF 496, 535, 538, 540, 545-50, 2209-11, 2280; CX1375 (L. Resnick, Trop., Dep. at 79-81).

Moreover, POM never states, expressly or by implication, conspicuously on the face of any of the Challenged Ads that scientific tests "prove" that the Challenged Products "prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction," or even that they "prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction." (RFF 2209-11, 2467-68, 2506, 2517; Reply Ad Appendix; Appendix of Advertisements). Even where medical research was referenced in advertising, the ads conveyed qualified messages about the health benefits of the Challenged Products, not definitive claims that the products will treat, prevent or reduce the risk of heart disease, prostate cancer or erectile dysfunction. (RFF 2517).

Throughout its advertising, POM highlights that POM Juice is a 100% juice product wholly-derived from the pomegranate fruit, and that POMx has the same content as the pomegranate fruit itself and is 100% derived from the exact same fruit. (RFF 493-94, 2518-44; Reply Ad Appendix). Indeed, Respondents have never advertised their products as a pharmaceutical drug, nor intended to advertise their products as drugs. (RFF 495-96, 524-30). Rather, Respondents have always marketed the Challenged Products for what they intrinsically are: whole-food products. (RFF 497-99).

Additionally, Complaint Counsel mischaracterize the cited evidence to imply that the purpose of moving away from the "Dressed Bottle" campaign in POM's ads was to claim that the Challenged Products treat, prevent or reduce the risk of disease. Rather, as evident from Claire Nelson's email from which Complaint Counsel selectively quote, the purpose was purely a business decision in reaction to the unethical actions of competitors who were undercutting POM by selling cheaper and inferior "100%" pomegranate juice. More specifically, as explained by Ms. Nelson, after several years of POM running the "Dressed Bottle" campaign, "many competitive pomegranate juices have entered the market. Most of those are not pure pomegranate juice like POM, but instead include filler juices, sugar or other additives. Also, only POM has conducted a significant amount of medical research to confirm the specific health benefits of our product, and all those other brands are attempting to ride on our coattails. For all these reasons, the company became increasingly concerned that [the "Dressed Bottle"] campaign may not be sufficiently proprietary, but rather selling the overall benefits of pomegranate juice. The new "Comic Book" campaign was introduced in Q1 2009 to address the new business realties. It was intended to build on the Antioxidant Superpower equity, and reclaim/reinforce POM's superiority: POM is 100% pure pomegranate juice – no fillers, added sugar or other additives (i.e., beware of imposter juice!) (Only POM is backed by $25 million in medical research with specific health benefits (primarily for cardiovascular

and prostate health) At the same time, it is also important that we maintain our quirky and witty brand personality." (CX0286_0002). Nowhere does Ms. Nelson state that Respondents intended to convey any specific claim with either advertising campaign, much less the claims attributed to the Challenged Ads by Complaint Counsel.

314. The Comic Book campaign, introduced in the first quarter of 2009, was intended to "reclaim/reinforce POM's superiority," including that "[o]nly POM is backed by $25 million in medical research with specific health benefits (primarily for cardiovascular and prostate health)." (CX0286_0002).

Response to Finding No. 314:

See Response to Finding No. 313.

315. A creative brief for the "Health Benefits" section of the POM Wonderful website, from approximately June 2008, directed that "[t]here should be an undertone throughout all of these sections: 'backed by science!' Even on the more consumer-friendly pages we still need to show our authoritative status and passion for the investment/research in your health." These health benefits were to include "heart health," "prostate health," "E.D.," and "[d]iabetes." (CX0200_0002).

Response to Finding No. 315:

Respondents object to the proposed finding to the extent that Complaint Counsel construe the cited evidence to bolster their argument that Respondents intended to convey to consumers that the Challenged Products treat, prevent or reduce the risk of disease. Respondents genuinely believe in the health benefits of the Challenged Products and in the scientific integrity of POM's research (RFF 502-20). Thus, it is not surprising that POM's ads summarize some of Respondents' scientific research on the Challenged Products in the areas of cardiovascular, prostate and erectile health and talk about the healthful properties of the Challenged Products, including that the Challenged Products contain abundant antioxidants and that they are wholly derived from pomegranate fruit. (RFF 493-99, 2478-2505, 2518-44). However, the Respondents dispute that they ever intended to convey or that the Challenged Ads do convey the claim that the Challenged Products treat, prevent or reduce the risk of heart disease, prostate cancer and erectile

dysfunction or that they are "clinically proven" to do so. (RFF 496, 535, 538, 540, 545-50, 2209-11, 2280; CX1375 (L. Resnick, Trop., Dep. at 79-81).

Moreover, POM never states, expressly or by implication, conspicuously on the face of any of the Challenged Ads that scientific tests "prove" that the Challenged Products "prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction," or even that they "prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction." (RFF 2209-11, 2467-68, 2506, 2517; Reply Ad Appendix; Appendix of Advertisements). Even where medical research was referenced in advertising, the ads conveyed qualified messages about the health benefits of the Challenged Products, not definitive claims that the products will treat, prevent or reduce the risk of heart disease, prostate cancer or erectile dysfunction. (RFF 2517). Throughout its advertising, POM highlights that POM Juice is a 100% juice product wholly-derived from the pomegranate fruit, and that POMx has the same content as the pomegranate fruit itself and is 100% derived from the exact same fruit. (RFF 493-94, 2518-44; Reply Ad Appendix). Indeed, Respondents have never advertised their products as a pharmaceutical drug, nor intended to advertise their products as drugs. (RFF 495-96, 524-30). Rather, Respondents have always marketed the Challenged Products for what they intrinsically are: whole-food products. (RFF 497-99).

Additionally, the snippet taken from a single creative brief does not support Complaint Counsel's proposition that POM referenced science and research to communicate that the Challenged Products are clinically proven to treat, prevent or reduce the risk of disease. First, Complaint Counsel presented no evidence on who prepared the creative brief, why it was prepared, or its applicability to the Challenged Ads not on POM's website. Second, Complaint Counsel presented no evidence on what the unknown author of the creative brief meant by the phrase "an undertone throughout all of these sections: 'backed by science.'" Third, even Complaint Counsel concede that the health benefits to be

included on the website were simply "heart health," "prostate health" and "E.D," not the more aggressive health benefits that the Challenged Products "treat," "prevent" or "reduce the risk" of heart disease, prostate cancer or erectile dysfunction. (CX0200_0002). Fourth, creative briefs were typically prepared by junior POM marketing employees, with Lynda Resnick and Matthew Tupper seldom if ever seeing, reviewing or providing feedback on creative briefs. (RRFF 302-05, 307). There is no evidence that Mr. Resnick has ever seen a creative brief. (RRFF 302-05, 307). Fifth, the creative process was collaborative and fluid, with lots of people involved, which resulted in the final advertisement being vastly different than the rough idea initially discussed in the creative brief. (RRFF 302-05, 307). Because the ad that actually ran typically did not reflect the creative brief prepared by the junior POM marketing employee, it is not accurate to describe creative briefs as reflective of the "intent" of an advertisement. (RRFF 302-05, 307).

316. In March 2009, POM's consumer affairs representative, in response to an inquiry from a consumer about POM Juice's health properties, informed the consumer that "[u]nbiased clinical trials have proven that pomegranate juice is effective in the treatment of prostate cancer, arterial plaque, and many other health issues." (CX0455_0010).

Response to Finding No. 316:

Respondents object to the proposed finding to the extent that Complaint Counsel construe the consumer affairs representative's response to the consumer to bolster their argument that Respondents intended to convey to consumers that the Challenged Products treat, prevent or reduce the risk of disease. First, the representative's statement to the consumer was in violation of POM's policy regarding communicating with the public. As testified to by Matt Tupper, POM maintains written instructions called the Consumer Affairs Knowledge Base for employees on to how to answer certain categories of consumer questions relating to health-related issues. (Tupper, Tr. 3019-20; CX0308).

Those instructions state explicitly that in responding to a consumer's question about prostate cancer, the consumer affairs representative is to inform the consumer:

> Thank you for your inquiry and opportunity to answer your question. Beginning in 1998, a number of top scientists in their fields, including a Nobel Laureate, have conducted and are continuing to conduct research on Pomegranate juice and its effect on antioxidant activity. Since research began, multiple peer-reviewed studies have been published in leading scientific journals. The results have been promising and research is ongoing. In particular, a study recently published in the prestigious Clinical Cancer Research showed that drinking pomegranate juice may significantly slow the progression of prostate cancer….If you have any questions regarding cancer research, treatment or chemotherapy, we recommend you speak with your physician." (CX0308_0006) (emphasis added).

Thus, the manner in which the representative responded to the consumer's inquiry was in direct violation of POM's written instructions. Moreover, in responding to health-related inquiries or a question about a medical condition, Mr. Tupper testified that POM instructs its employees to tell consumers to consult with his or her physician and strongly encourages this recommendation. (RFF 530). Mr. Tupper further testified that it is absolutely against POM's policy for a POM employee to tell anyone that POM Juice is a substitute for proper medical treatment. (RFF 527-29). Indeed, Mr. Resnick further testified that if he found out that an employee was recommending that a consumer drink POM Juice instead of following his or her doctor's advice, he would first terminate the employee and second, he would make clear to the consumer that such information is not correct, and that the employee lacked the authority to make such a statement and should not have done so. (RFF 526). Given these facts, it is not surprising that Complaint

Counsel have presented no evidence that Respondents instructed the consumer affairs representative to respond in the erroneous manner in which she did. Simply put, there is absolutely no evidence that Respondents intended the representative to convey to the consumer that POM Juice is proven to be an effective in the treatment of any disease.

Second, although Respondents genuinely believe in the health benefits of the Challenged Products and in the scientific integrity of POM's research (RFF 502-20), Respondents dispute that they ever intended to convey or that the Challenged Ads do convey the claim that the Challenged Products treat, prevent or reduce the risk of heart disease, prostate cancer and erectile dysfunction or that they are "clinically proven" to do so. (RFF 496, 535, 538, 540, 545-50, 2209-11, 2280; CX1375 (L. Resnick, Trop., Dep. at 79-81).

Third, POM never states, expressly or by implication, conspicuously on the face of any of the Challenged Ads that scientific tests "prove" that the Challenged Products "prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction," or even that they "prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction." (RFF 2209-11, 2467-68, 2506, 2517; Reply Ad Appendix; Appendix of Advertisements). Even where medical research was referenced in advertising, the ads conveyed qualified messages about the health benefits of the Challenged Products, not definitive claims that the products will treat, prevent or reduce the risk of heart disease, prostate cancer or erectile dysfunction. (RFF 2517). Throughout its advertising, POM highlights that POM Juice is a 100% juice product wholly-derived from the pomegranate fruit, and that POMx has the same content as the pomegranate fruit itself and is 100% derived from the exact same fruit. (RFF 493-94, 2518-44; Reply Ad Appendix). Indeed, Respondents have never advertised their products as a pharmaceutical drug, nor intended to advertise their products as drugs. (RFF 495-96, 524-30). Rather, Respondents have always marketed the Challenged Products for what they intrinsically are: whole-food products. (RFF 497-99).

317. POM also cited Dr. Pantuck's study in an August 2008 response to a consumer inquiry, stating, "[A] study, published in the prestigious journal Clinical Cancer Research, showed that drinking Pomegranate juice (*may significantly slow the progression of prostate cancer in humans*.)" (CX0485_0776 (emphasis added)).

Response to Finding No. 317:

Respondents do not disagree that in response to a consumer inquiry, a consumer affairs representative informed the consumer about the promising results of Dr. Pantuck's 2006 study entitled "Phase II Study of Pomegranate Juice for Men with Rising Prostate-Specific Antigen Following Surgery or Radiation for Prostate Cancer," published in the prestigious Clinical Cancer Research Journal. (RFF 1661; CX0485_0776). In the study, Dr. Pantuck studied men that had undergone radical prostatectomy or radiotherapy and found that drinking 8 ounces of POM Juice daily materially lengthened PSADT in nearly 50% of men after 18 months. (RFF 1661-69). The study also found that when POM Juice was tested *in vitro* on prostate cell assays, it was found to both decrease prostate cancer cell proliferation by 12% (*i.e.*, slow its growth) and stimulate prostate cancer cell apoptosis (cell death) by 17%. (RFF 1670). Additionally, serum nitric oxide increased by 23% in men that consumed POM Juice. (RFF 1670). Nitric oxide is a molecule that has been found to inhibit inflammation, which is correlated with higher risk of cancer. (RFF 1661-64, 1670, 1965). Accordingly, competent and reliable evidence supports the statement made by the consumer affairs representative to the consumer about the affect of POM Juice on prostate cancer. (RFF 1660-81, 1690-93, 1695-1700, 1710-18, 1739-83).

Moreover, Respondents object to the proposed finding to the extent that Complaint Counsel construe the consumer affairs representative's response to the consumer to bolster their argument that Respondents intended to convey to consumers that the Challenged Products treat, prevent or reduce the risk of diseases. Although Respondents genuinely believe in the health benefits of the Challenged Products and in the scientific integrity of POM's research (RFF 502-20), Respondents dispute that they ever intended

to convey or that the Challenged Ads do convey the claim that the Challenged Products treat, prevent or reduce the risk of heart disease, prostate cancer and erectile dysfunction or that they are "clinically proven" to do so. (RFF 496, 535, 538, 540, 545-50, 2209-11, 2280; CX1375 (L. Resnick, Trop., Dep. at 79-81).

Additionally, POM never states, expressly or by implication, conspicuously on the face of any of the Challenged Ads that scientific tests "prove" that the Challenged Products "prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction," or even that they "prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction." (RFF 2209-11, 2467-68, 2506, 2517; Reply Ad Appendix; Appendix of Advertisements). Even where medical research was referenced in advertising, the ads conveyed qualified messages about the health benefits of the Challenged Products, not definitive claims that the products will treat, prevent or reduce the risk of heart disease, prostate cancer or erectile dysfunction. (RFF 2517). Throughout its advertising, POM highlights that POM Juice is a 100% juice product wholly-derived from the pomegranate fruit, and that POMx has the same content as the pomegranate fruit itself and is 100% derived from the exact same fruit. (RFF 493-94, 2518-44; Reply Ad Appendix). Indeed, Respondents have never advertised their products as a pharmaceutical drug, nor intended to advertise their products as drugs. (RFF 495-96, 524-30). Rather, Respondents have always marketed the Challenged Products for what they intrinsically are: whole-food products. (RFF 497-99).

318. Mr. Tupper also claimed that "generally speaking when we talk about the healthful properties of POM, the health properties that we talk about are all backed up by science that is supportive of what we talk about." By "backed up by science," Mr. Tupper testified he meant "published research and peer review journals." (CX1364 (Tupper, TCCC Dep. at 54)).

Response to Finding No. 318:

Respondents do not disagree that they have developed a truly unprecedented amount of scientific research on the Challenged Products that support claims in the Challenged Ads. The results of their sponsored research have appeared in more than 70 peer-reviewed journals. (RFF 393). Mr. Tupper testified that Mr. Resnick's stated policy on the relationship between scientific studies and POM's advertising requires that the advertisements accurately represent the scientific conclusions. (RFF 291).

Moreover, Respondents object to the proposed finding to the extent that Complaint Counsel construe Mr. Tupper's testimony to bolster their argument that Respondents intended to convey to consumers that the Challenged Products treat, prevent or reduce the risk of diseases. Although Respondents genuinely believe in the health benefits of the Challenged Products and in the scientific integrity of POM's research (RFF 502-20), they dispute that they ever intended to convey or that the Challenged Ads do convey the claim that the Challenged Products treat, prevent or reduce the risk of heart disease, prostate cancer and erectile dysfunction or that they are "clinically proven" to do so. (RFF 496, 535, 538, 540, 545-50, 2209-11, 2280; CX1375 (L. Resnick, Trop., Dep. at 79-81).

Additionally, POM never states, expressly or by implication, conspicuously on the face of any of the Challenged Ads that scientific tests "prove" that the Challenged Products "prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction," or even that they "prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction." (RFF 2209-11, 2467-68, 2506, 2517; Reply Ad Appendix; Appendix of Advertisements). Even where medical research was referenced in advertising, the ads conveyed qualified messages about the health benefits of the Challenged Products, not definitive claims that the products will treat, prevent or reduce the risk of heart disease, prostate cancer or erectile dysfunction. (RFF 2517).

Throughout its advertising, POM highlights that POM Juice is a 100% juice product wholly-derived from the pomegranate fruit, and that POMx has the same content as the pomegranate fruit itself and is 100% derived from the exact same fruit. (RFF 493-94, 2518-44; Reply Ad Appendix). Indeed, Respondents have never advertised their products as a pharmaceutical drug, nor intended to advertise their products as drugs. (RFF 495-96, 524-30). Rather, Respondents have always marketed the Challenged Products for what they intrinsically are: whole-food products. (RFF 497-99).

319. The medical research figure cited in POM's advertising, however, was not for completed, published, peer-reviewed studies. The number simply reflected the cumulative amount of research expenses at that point in time, derived from POM's database. (Tupper, Tr. 1017, 1021; CX1353 (Tupper, Dep. at 171, 181-82, 191)).

Response to Finding No. 319:

Respondents object to the proposed finding to the extent that Complaint Counsel construe the cited evidence to bolster their argument that Respondents intended to convey to consumers that the Challenged Products treat, prevent or reduce the risk of diseases. Although Respondents genuinely believe in the health benefits of the Challenged Products and in the scientific integrity of POM's research (RFF 502-20), they dispute that they ever intended to convey or that the Challenged Ads do convey the claim that the Challenged Products treat, prevent or reduce the risk of heart disease, prostate cancer and erectile dysfunction or that they are "clinically proven" to do so. (RFF 496, 535, 538, 540, 545-50, 2209-11, 2280; CX1375 (L. Resnick, Trop., Dep. at 79-81)).

Additionally, the proposed finding is not relevant to Respondents' purported intent to convey the Challenged Claims, but rather, is simply an unsubstantiated attack on the expenditures Respondents include in POM's "backed by" ads. POM's "backed by" ads stated that Respondents spent a particular amount of money on their scientific studies on the Challenged Products to back-up POM's healthy claims. (RFF 2507-09). POM's "backed by" ads truthfully represent Respondents' scientific expenditures.

First, Respondents accurately represented the dollars spent by them on the totality of the science on the Challenged Products, including basic, animal and human clinical studies, at the time the representations were made. (RFF 2510; Tupper, Tr. 3001-02). The amounts in the "backed by" ads included expenditures for planning, executing and interpreting the results from the studies, as well as setting the continued direction for Respondents' research program. (Tupper, Tr. 2998). In fact, Respondents substantially understated the dollars spent on research in POM's advertising because they excluded all overhead items, such as rent and salaries very significant added costs. (RFF 2514).

Second, it was appropriate to use the total dollars spent on Respondents' research program regardless of the area of health referenced in the advertisement because (1) the intention was to communicate the expanse, depth and breadth of Respondents' commitment to science; and (2) "the science interrelates." (Tupper, Tr. 2999, 3037-38). Mr. Tupper testified that "[t]he learnings that we get from one study apply to other studies in different areas because we're dealing with some basic fundamentals of mechanistic action within the human physiology that are really centered around antioxidation, antimicrobial activity and antiinflammation, and those span across all the areas as these nutrients essentially have a systemic effect throughout the body." (Tupper, Tr. 2999). Simply, put Respondents' science is "completely interrelated." (Tupper, Tr. 3038). Therefore, studies done concerning one disease or condition, such as the effect of antioxidants or of nitric oxide on blood flow, are sufficiently interrelated to other diseases and conditions (*e.g.*, the research can be applied to the heart as well as erectile function and prostate health) that it is not misleading to treat all of Respondents' scientific expenditures as "backing" the Challenged Ads. (RFF 2511; Tupper, Tr. 2999, 3037-38).

Third, even the fact that POM's ads listed an amount of money spent on Respondents' studies that had a null or even negative result is not false or misleading. (RFF 2512). The lack of a statistical significant result does not undermine the value of the study and

does not mean that experts cannot rely upon the study to infer a causal link. (RFF 599-609). As testified to by world-renowned doctor and research Dean Ornish, using statistical significance as the primary gauge in the determination of whether or not pomegranate juice offers a beneficial health property is an arbitrary and unnecessary convention. (RFF 605). Indeed, a study may show clinically significant results even where statistical significance is not reached. (RFF 606). Also, a lack of statistical significance for a positive result is not proof of the opposite or that pomegranate juice has no beneficial effect. (RFF 604, 611-13). Complaint Counsel's own expert, Dr. Sacks, concedes this important fact. (RFF 614). Simply put, a lack of statistical significant data does not mean that there is no reliable basis for inferring a causal link between the consumption of pomegranate juice and a beneficial effect. (RFF 608).

Fourth, Mr. Tupper testified that Respondents included dollars in the "backed by" ads attributable to science that was both published and unpublished because Respondents learned a great deal even from the unpublished studies, and all of Respondents' studies were important sources of knowledge that allowed them to make informed decisions. (RFF 2513). In regard to including expenditures for unpublished studies, Mr. Tupper testified "[t]hat knowledge informs the direction of future studies. It adds to our understanding of the basic mechanisms for how pomegranate works in the human body, so again, you have to take all of that into account, and it's appropriate to again demonstrate the depth and breadth of the [research] program." (Tupper, Tr. 3000). Inclusion of information relating to unpublished studies also reflects Respondents' desire "to push the boundaries of the science and help us better understand what's going on. And sometimes the result of that is that the study doesn't end up being published, but nevertheless, they're all important. And again, that's what we think sets our program apart, and that's what we want to communicate to the public." (Tupper, Tr. 3001). For

the same reasons, Mr. Tupper testified that it was appropriate to include expenditures in the "backed by" ads from both positive and inconclusive studies. (Tupper, Tr. 3002).

In sum, based on all of the above-referenced reasons, it was appropriate for Respondents to include expenditures incurred from the totality of the research program.

320. Mr. Resnick knows that some studies POM conducted or is conducting will never be published, despite including the costs of those studies in the millions of dollars of medical research funding "supporting" or "backing" POM's claims in its advertising. (S. Resnick, Tr. 1781). He feels that whether studies are published, not published, good results, bad results, or incomplete, all are still appropriately included in the "backed by $32 million" claims in POM's advertisements. (S. Resnick, Tr. 1711-12, 1764, 1776-77).

Response to Finding No. 320:

See Response to Finding No. 319.

321. All components of research are tallied in coming up with the figure in the advertisements for how much medical research supports POM's products, not just research on a particular area such as prostate health. (Tupper, Tr. 1039-40; CX1353 (Tupper, Dep. at 175)).

Response to Finding No. 321:

See Response to Finding No. 319.

322. The medical research dollar amounts cited in POM's advertisements includes the expenditures for:

- Ongoing studies, which have not been completed and have no results (Tupper, Tr. 1017-18, 3028; CX1353 (Tupper, Dep. at 172, 192);
- Studies that did not show a statistically significant effect, showed "no effect," or were inconclusive (Tupper, Tr. 1018-19; S. Resnick, Tr. 1762-64; CX1376 (S. Resnick, OS Dep. at 316));
- Studies where no publication resulted (Tupper, Tr. 936);
- Studies on areas such as "Joint/Bone Health," "Urinary Tract Infection," "Cattle Health," "Weight loss," "Neuro/Brain," "Alzheimer's" [*sic*], "Authenticity," "Cold/Flu," "Dairy/Cattle Health," "Fertility," "Organic Candy Test Run," "Osteoporosis, Lymphoma, Bone Density," and "Skincare," which were not related to the products or health conditions described in POM's advertisements (CX1276_0003-05);

- Meeting expenses, including "Brochure Printing," "Conference Fee," "Medical Exhibition Fees and Rental Space," "Member Contribution," "Membership fee," "Photo Shoot & Tapes," "Research Summit Expenses," and "Trade Shows." (Tupper, Tr. 1026; CX1276_0004-05); and

- Membership fees and member contributions to organizations such as the American Herbal Products Association and American Society for Nutrition. (Tupper, Tr. 1026-27).

Response to Finding No. 322:

See Response to Finding No. 319.

323. Mr. Tupper was unable to say what percentage of the medical research figure cited in an advertisement was for results for prostate and cardiovascular health. (CX1353 (Tupper, Dep. at 148, 150-51)). Similarly, Mr. Resnick does not know what portion of the $34 million in medical research cited in POM's advertisements has been spent on the 55 total studies that POM relies upon in its website. (S. Resnick, Tr. 1780).

Response to Finding No. 323:

See Response to Finding No. 319.

324. Of the $34 million in medical research cited in POM's advertisements, the five frequently-advertised studies cost less than $2.49 million combined. (*See* CCFF ¶VIII.168).

Response to Finding No. 324:

See Response to Finding No. 319.

D. Health Claims in Print Advertising

1. POM Juice Print Ads Made Efficacy and Establishment Claims Regarding Heart Disease

a. "Drink and Be Healthy" Print Ad (CX0016)

325. As early as October 2003, POM disseminated in the *Chicago Tribune* a POM Juice advertisement with a headline, "**Drink and Be Healthy**." (CX0016_0002).

Response to Finding No. 325:

Complaint Counsel have presented no other definitive dissemination information regarding this particular ad. The "Drink and be healthy" advertisement featured the

image of a POM 100% Pomegranate Juice glass bottle, (CX0016_0001; Tupper, Tr. 2995), which Mr. Tupper testified that POM stopped using in the beginning of 2004. (Tupper, Tr. 2995). Mr. Tupper further testified that this advertisement ran in 2003 as part of the original launch of POM's 100% pomegranate juice and has not been disseminated since 2003. (Tupper, Tr. 2995). Mrs. Resnick also testified that this ad was one of the first ads Respondents ever ran. (L. Resnick, Tr. 157). Complaint Counsel have presented no evidence to contradict Mr. Tupper's testimony that this "Drink and be healthy" ad has not run in over nine years. Moreover, Complaint Counsel have presented no evidence that it is probable that Respondents would run this type of ad again. This ad cannot provide a basis for injunctive relief because (a) it ran more than nine years ago; and (b) no evidence exists to show that Respondents are likely to run this ad in the future.

326. The advertisement contained images of a bottle of POM Juice with the heart symbol in place of the "O" next to a pomegranate fruit. The body copy of this advertisement stated that POM Juice has "**more naturally occurring antioxidant power than any other drink**" with a chart comparing the antioxidant content of various beverages, including POM Juice. The advertisement further stated that "**[a]ntioxidants guard your body against harmful free radicals** that can cause heart disease, premature aging, Alzheimer's disease, even cancer" and that "**Medical studies have shown that drinking 8 oz. of POM Wonderful** pomegranate juice daily minimizes factors that lead to atherosclerosis (plaque buildup in the arteries), a major cause of heart disease." The advertisement also directed consumers in bold red font to the company's website, "**www.pomwonderful.com**." (CX0016).

Response to Finding No. 326:

Objection, misstates the evidence and the document speaks for itself. The headline body copy and imagery are accurately depicted on the exhibit itself, CX0016-0002. The fact that this ad depicts juice that is wholly-derived from the pomegranate fruit is heavily emphasized in the body copy and the visual imagery of the ad as well as on the product itself. There is a dominant image of deep, ruby red pomegranate juice in a bottle shaped like two pomegranates stacked on top of one another, the words "100% Pomegranate Juice" are clearly displayed on the face of the POM Juice bottle depicted and there is textual reference to "POM Wonderful 100% Pomegranate Juice". The ad emphasizes that

POM Juice contains abundant naturally occurring antioxidants that may help guard your body against free radicals. For example, this ad references: a) "antioxidant power" and b) "free radicals." Complaint Counsel ignores, among other elements, the blatant fact that POM Juice is 100% fruit juice.

327. Dr. Butters, Respondents' linguistic expert, testified that a reasonable viewer could take from this entire advertisement a message that POM Juice can reduce or help reduce the risk of heart disease. (Butters, Tr. 2929-30).

Response to Finding No. 327:

Professor Butters also opined that it was unlikely that a reasonable consumer would conclude that drinking eight ounces of POM Juice would treat atherosclerosis. (Butters, Tr. 2930).

328. This advertisement expressly states that POM Juice reduces factors that lead to atherosclerosis and heart disease. In connection with the statements that antioxidants guard the body against agents that can cause heart disease, this advertisement conveys the net impression that consuming eight ounces of POM Juice daily prevents or reduces the risk of heart disease, including by reducing arterial plaque, and that this benefit is clinically proven. (CCFF ¶¶ 325-27).

Response to Finding No. 328:

Complaint Counsel failed to present any evidence that Respondents would run this ad in the future, let alone whether it is probable they would do so. This ad cannot provide a basis for injunctive relief because (a) it ran more than nine years ago; and (b) no evidence exists to show that Respondents are likely to run this ad in the future.

Nowhere in this ad do Respondents expressly (i.e., unequivocally and directly) state that (a) POM Juice "prevents", "treats" or "reduces the risk" of heart disease, prostate cancer and erectile dysfunction; or (b) POM Juice is "clinically proven" to "prevent," "treat," or "reduce the risk" of heart disease, prostate cancer and erectile dysfunction. (CX0016). Complaint Counsel's assertion that the ad implicitly conveys these messages is also not

conspicuous, self-evident, or reasonably clear from the face of the ad. (CX0016). Extrinsic evidence must be examined. (Mazis, Tr. 2752).

Complaint Counsel erroneously rely upon the impact of only a few, select elements for their overall view of the net impression of an ad, and seemingly neglect at least two significant elements that are key to any facial or common sense net impression analysis—that POM Juice is wholly-derived from pomegranates, and POM Juice's effectiveness is based, at least in significant part, on the products' abundant antioxidants.

Viewing the ad as a whole, taking into account all the various elements, including the prevalence and pervasiveness of the "whole-food" graphic, in the form of the POM Juice bottle, and body copy as well as the emphasis on the fact that POM Juice is a concentrated and potent source of antioxidants, it is far more logical that POM consumers would view POM Juice the way they perceive many other whole foods, like broccoli, blueberries, grapes or tomatoes, which may help prevent or improve your odds against disease, but which would not act like a drug with a single target of action against a particular disease or condition.

To the extent a "reduce the risk" claim can be implied from this ad, the overall net impression is not that drinking eight ounces of POM Juice "reduces the risk" of certain diseases, such as heart disease or prostate cancer, like a drug with a single target of action, but that it may help "reduce the risk," like many other whole foods, or like an especially healthy fruit or vegetable, or like a healthy diet of fruits and vegetables and exercise "reduces the risk" of disease.

To the extent a "treat" claim can be implied from this ad (which it cannot), the overall net impression of any ad is not that POM Juice is a substitute for conventional medical treatment. (Butters, Tr. 2821-22; Appendix of Advertisements).

To the extent a "proven" claim can be implied from this ad (which it cannot), the overall net impression of this ad is not that POM Juice is "proven" to be 100% effective in preventing, treating or reducing the risk of heart disease or prostate cancer because (1) all of the qualifying language contradicts an implied "clinically proven" interpretation, and (2) "proven" in science and to consumers means the "average person in the study benefitted," not that "everyone in the study necessarily benefitted" or that everyone will benefit like the persons who benefitted in the study. (Heber, Tr. 2011; Butters, Tr. 2893-2894; PX0361 (Sacks, Dep. at 81)).

Instead, the "Drink and be healthy" advertisement makes multiple efforts to convey the POM Juice is a whole food product that is wholly-derived from pomegranates, including: a) prevalent visual imagery of a ruby red pomegranate; b) dominate imagery of deep, ruby red pomegranate juice in a bottle shaped like two pomegranates stacked on top of one another; c) the words "100% Pomegranate Juice" clearly displayed on the face of the bottle and repeated references to "100% Pomegranate Juice" in the ad; d) the dominant sub-headline reading "100% all-natural pomegranate juice;" and e) advertising that POM Juice can be found in the "produce section" of the grocery store.

Additionally, the ad emphasizes that POM Juice contains abundant naturally occurring antioxidants that may help guard your body against free radicals. For example, the "Drink and be healthy" ad references: a) "naturally occurring antioxidant[s];" b) "refreshing antioxidant superpower;" and c) "free radicals."

Respondents' linguistics expert, Professor Butters, testified, for example, that it was unlikely that a reasonable consumer would conclude that drinking eight ounces of POM Juices would treat atherosclerosis. (Butters, Tr. 2930).

Complaint Counsel have presented no extrinsic evidence or expert opinion on the meaning of this "Drink and be healthy" ad or of consumer perceptions or interpretations

of the ad. (Mazis, Tr. 2752). Even assuming *arguendo* that this "Drink and be healthy" ad conveys the message Complaint Counsel assign to it, Professor Reibstein's survey effectively and powerfully demonstrates that any alleged disease claims made by Respondents were not material to the purchasing decisions of POM consumers. (See infra XVIII(A)).

b. "10 OUT OF 10 PEOPLE" Print Ad (CX0029)

329. In 2004 and 2005, POM disseminated a POM Juice advertisement with the headline, "**STUDIES SHOW THAT 10 OUT OF 10 PEOPLE DON'T WANT TO DIE.**" It appeared in *Prevention* magazine in November 2004 and January 2005, and *Martha Stewart Living* magazine in May 2005. (CX0029_0003).

Response to Finding No. 329:

Complaint Counsel misstates the evidence and the document speaks for itself. Complaint Counsel misconstrue and misrepresent the message of this ad. This ad, like others, describes the results of the studies using very qualified language. Complaint counsel left out the copy on this ad, which stated that antioxidants are "helping to prevent" and that the study shows "heartening results." (CX0029).

330. The advertisement resembled a news article, with a graphic of a human heart on the first page and a chart comparing in various beverages the "ability to prevent LDL oxidation." On the second page of the advertisement, under a bold-font heading, "**Our Research: Heartening**," the advertisement stated, "a clinical pilot study shows that an 8 oz. glass of POM Wonderful 100% Pomegranate Juice, consumed daily, reduces plaque in the arteries up to 30%." A footnote cited a study by Dr. Aviram published in *Clinical Nutrition* in 2004. (CX0029).

Response to Finding No. 330:

Complaint Counsel misstates the evidence and the document speaks for itself. Complaint Counsel misconstrue and misrepresent the message of this ad. This ad, like others, describes the results of the studies using very qualified language. Complaint counsel left out the copy on this ad, which stated that antioxidants are "helping to prevent" and that the study shows "heartening results." (CX0029).

331. Under another bold-font headline, "**The Heart Stopping Truth**," the advertisement emphasized the role of arterial plaque in causing heart attacks, stroke, and death, stating,

> Remember: heart disease is America's number one killer. For women as well as men. 98% of heart attacks are due to atherosclerosis, or too much plaque in the arteries. That same plaque increases your chance of stroke. One final scary statistic: half of patients who have a severe heart attack have normal cholesterol levels. In other words, we're all at risk.
>
> (CX0029_0002).

Response to Finding No. 331:

Complaint Counsel misstate the evidence and the document speaks for itself. Complaint Counsel misconstrue and misrepresent the message of this ad. This ad, like others, describes the results of the studies using very qualified language. Complaint counsel left out the copy on this ad, which stated that antioxidants are "helping to prevent" and that the study shows "heartening results." (CX0029).

332. After these citations and statistics, the advertisement recommended POM Juice to consumers. Under a bold font headline, "**Just a Glass a Day**," adjacent to images of a POM Juice bottle with logo and a pomegranate fruit, the copy advised, "To keep your heart healthy: exercise regularly. Eat a healthy diet. And drink 8 ounces of POM Wonderful Pomegranate Juice. Make every day a good day to be alive." (CX0029_0002).

Response to Finding No. 332:

Complaint Counsel misstate the evidence and the document speaks for itself. Complaint Counsel misconstrue and misrepresent the message of this ad. This ad, like others, describes the results of the studies using very qualified language. Complaint counsel left out the copy on this ad, which stated that antioxidants are "helping to prevent" and that the study shows "heartening results." (CX0029).

333. Mrs. Resnick was involved in the approval of this specific advertisement. (CX0471_0007-08; L. Resnick, Tr. 158).

Response to Finding No. 333:

Respondents have no specific response.

334. John Regal, POM's head of marketing at the time, stated that POM's intent in its *Prevention* advertorial was to convey "how POM is particularly good for clean & healthy arteries. We also wanted to highlight the new Aviram study regarding plaque reduction in humans." (CX0667_0001).

Response to Finding No. 334:

Respondents object to this finding on the basis that the statements in the document are hearsay, from a witness who did not testify at trial. Further, Complaint Counsel mischaracterizes the statement in the document, which does not state POM's intent was to convey "how POM is particularly good for clean & healthy arteries." Even if the document were not hearsay, it speaks for itself and cannot be re-written by Complaint Counsel to convey a meaning that it does not contain. Complaint Counsel fails to cite any trial testimony to corroborate the statements in the document. Additionally, Respondents had competent and reliable scientific evidence to support their representation at the time it was made, including the Aviram Study (2004), that "Medical studies show that drinking 8 oz. of POM Wonderful pomegranate juice daily minimizes factors that lead to atherosclerosis (plaque buildup in the arteries), a major cause of heart disease." (RFF 2311). Moreover, at the time the "Floss your arteries" ad, for example, was run in 2004, the phrase "a glass a day can reduce plaque by up to 30%" was supported by competent and reliable scientific evidence, including the Aviram Study (2004), which found a 35% decrease in CIMT in people that had severe carotid stenosis and significant plaque build-up (i.e., a baseline IMT more than 1.5 mm). (Tupper, Tr. 954). (RFF 2357).

335. The specific reference to 30% reduction in plaque as well as the citation to a published study, the statistics regarding the role of arterial plaque in heart attacks and heart disease, and the recommendation to "drink 8 ounces" of POM Juice a day for heart health, along with the images in the advertisement, convey the net impression that drinking eight ounces of POM Juice daily treats, prevents, or reduces the risk of heart disease, including

by reducing arterial plaque, and that this benefit is clinically proven. (CCFF ¶¶ 329-32, 334).

Response to Finding No. 335:

This ad, like Respondents' other ads, describes the results of the studies using very qualified language, and does not create the "net impression" that Complaint Counsel asserts. (CX0029). (RFF 2506). Further, in 2004, the phrase "a glass a day can reduce plaque by up to 30%" was supported by competent and reliable scientific evidence, including the Aviram Study (2004), which found a 35% decrease in CIMT in people that had severe carotid stenosis and significant plaque build-up (i.e., a baseline IMT more than 1.5 mm). (Tupper, Tr. 954). (RFF 2357). Nowhere in this ad do Respondents expressly (*i.e.*, unequivocally and directly) state that (a) POM Juice "prevents," "treats," or "reduces the risk" of heart disease; or (b) POM Juice is "clinically proven" to "prevent," "treat," or "reduce the risk" of heart disease. (CX0029_0001).

Complaint Counsel failed to present any other definitive information regarding this ad's dissemination. Complaint Counsel also failed to present any evidence that Respondents would run this ad in the future, let alone whether it is probable they would do so. This ad cannot provide a basis for injunctive relief because (a) it ran over seven years ago; and (b) no evidence exists to show that Respondents are likely to run this ad in the future.

Nowhere in this ad do Respondents expressly (*i.e.*, unequivocally and directly) state that (a) POM Juice "prevents," "treats," or "reduces the risk" of heart disease; or (b) POM Juice is "clinically proven" to "prevent," "treat," or "reduce the risk" of heart disease. (CX0029_0001).

Complaint Counsel's assertion that the ad conveys the message that (a) POM Juice "prevents," "treats," or "reduces the risk" of heart disease; or (b) POM Juice is "clinically proven" to "prevent," "treat," or "reduce the risk" of heart disease is not conspicuous,

self-evident, or reasonably clear from the face of the ad. (CX0029_0001-0002). Consequently, because the above-referenced challenged implied claim may not be determined with confidence from the face of the ad, extrinsic evidence must be examined.

The overall net impression of this ad is not that (a) drinking eight ounces of POM Juice prevents or treats heart disease; or (b) drinking eight ounces of POM Juice is "clinically proven" to prevent, treat or reduce the risk of certain diseases, such as heart disease. (CX0029_0001-0002). Even the language of the ad itself uses such qualifiers as "might be," "heartening results," and "pilot study." (CX0029_0001-0002).

To the extent a "reduce the risk" claim can be implied from this ad, the overall net impression is not that drinking eight ounces of POM Juice "reduces the risk" of certain diseases, such as heart disease or prostate cancer, like a drug with a single target of action, but "reduces the risk," like a healthy diet of fruits and vegetables and exercise "reduces the risk" of disease. (CX0029_0001-0002).

To the extent a "treat" claim can be implied from this ad (which it cannot), the overall net impression of any ad is not that POM Juice is a substitute for conventional medical treatment. (Butters, Tr. 2821-22).

To the extent a "proven" claim can be implied from this ad (which it cannot), the overall impression of "this ad is not that POM Juice is "proven" to be 100% effective in preventing, treating or reducing the risk of heart disease because (1) all of the qualifying language contradicts an implied "clinically proven" interpretation, and (2) "proven" in science means the "average person in the study benefitted," not that "everyone in the study necessarily benefitted." (Heber, Tr. 2011; Butters, Tr. 2893-2894; PX0361 (Sacks, Dep. at 81)).

Complaint Counsel presented no extrinsic evidence or expert opinion on this ad's meaning, consumer perceptions of this ad, or consumer interpretations regarding this ad. (PX0357 (Stewart, Dep. at 49, 52)). Furthermore, Complaint Counsel failed to present any evidence that the claims in this ad reasonably convey that POM Juice is "clinically proven" to prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction. Complaint Counsel also failed to present any evidence regarding the number of exposures consumers had to this ad or any particular POM advertisement. (Mazis, Tr. 2752).

Complaint Counsel erroneously rely upon the impact of only a few, select elements for their overall view of the net impression of an ad, and seemingly neglect at least two significant elements that are key to any facial or common sense net impression analysis—that POM Juice is wholly-derived from pomegranates, and POM Juice's effectiveness is based, at least in significant part, on the products' abundant antioxidants.

Despite the Complaint Counsel's disregard of the very significant common sense distinction between a drug and a product derived 100% from fruit, Respondents makes multiple efforts to convey POM Juice as a whole food product that is wholly-derived from pomegranates, including: a) visual imagery of a ruby red pomegranate; b) imagery of deep, ruby red pomegranate juice in a bottle shaped like two pomegranates stacked on top of one another; c) the headline above "Studies Show that 10 out of 10 People Don't Want to Die" reminds consumers, prior to reading the advertisement, that the product being discussed is "Pomegranate Juice"; and d) the challenged ad notes at the bottom of the page that the product can be found "in the refrigerated produce section of your grocer," serving as a further reminder to consumers that the challenged product is indeed one derived from 100% pomegranates.

Additionally, the ad emphasizes that POM Juice contains abundant naturally occurring antioxidants that may guard your body against free radicals. For example, the "Studies Show that 10 out of 10 People Don't Want to Die" ad references: a) "naturally occurring antioxidant[s];" b) "the antioxidant superpower;" and c) "a higher level of antioxidants than any other drink"; and d) "free radicals."

Both the whole food aspect of the advertising and the emphasis on antioxidant content, directly counter any suggestion that POM Juice is going to act like a drug, as distinguished from a very healthy fruit or vegetable and a healthy diet.

Viewing the ad as a whole, taking into account all the various elements, including the prevalence and pervasiveness of these "whole-food" graphics, in the form of a pomegranate as well as the shape of the POM Juice bottle, and body copy as well as the repeated emphasis on the fact that POM Juice is a concentrated and potent source of antioxidants, it is far more logical that POM consumers would view POM Juice the way they perceive many other whole foods, like broccoli, blueberries, grapes or tomatoes, which may help prevent or improve your odds against disease, but which would not act like a drug with a single target of action against a particular disease or condition.

c. "Floss your arteries. Daily." Print Ad (CX0031)

336. In December 2004, POM disseminated in *Details* magazine and *Fitness* magazine a POM Juice advertisement with the bold headline "**Floss your arteries. Daily**." The advertisement contained an image of a POM bottle with logo on a medicine cabinet shelf along with items such as a toothbrush, toothpaste, and soap. The advertisement's body copy stated:

Clogged arteries lead to heart trouble. It's that simple. That's where we come in. Delicious P♥M Wonderful P♥megranate Juice has more naturally occurring antioxidants than any other drink. These antioxidants fight free radicals – molecules that are the cause of sticky, artery clogging plaque. Just eight ounces a day can reduce plaque by up to 30%!* So every day: wash your face, brush your teeth, and drink your P♥M Wonderful. **P♥M Wonderful P♥megranate Juice. The Antioxidant Superpower.**

In very small type after the asterisk, the advertisement cited to one of the studies conducted by Dr. Aviram: "Aviram, M. *Clinical Nutrition,* 2004. Based on a clinical pilot study." (CX0031 (referring to the Aviram CIMT/BP Study (2004))).

Response to Finding No. 336:

Claimant Counsel attempts to misconstrue this ad. The "Floss your arteries" ad included a quantified performance claim. (CX0031_001; CX0055_0011-0012). Additionally, the use of the phrase "up to" and the word "can" instead of "will" qualifies the statement "A glass a day can reduce plaque by up to 30%". (Butters, Tr. 2913). Mr. Tupper testified that POM first ran this advertisement in 2004 and stopped running it that same year. Thus, the "Floss your arteries" headline, image and body copy thus have not run as part of any advertisement for more than seven years. (Tupper, Tr. 2996). Complaint Counsel presented no evidence to show otherwise. Moreover, Complaint Counsel have presented no evidence that it is probable or likely that Respondents would run this type of ad again. Because this ad ran over seven years ago and there is no evidence that Respondents are likely to run this ad in the future, the ad provides no basis for injunctive relief. Finally, at the time the "Floss your arteries" ad was run in 2004, the phrase "a glass a day can reduce plaque by up to 30%" was supported by competent and reliable scientific evidence, including the Aviram Study (2004), which found a 35% decrease in CIMT in people that had severe carotid stenosis and significant plaque build-up (i.e., a baseline IMT more than 1.5 mm). (Tupper, Tr. 954; (see supra XVII(G))). The advertisement's statement that "antioxidants fight free radicals that cause plaque" is also true and substantiated by competent and reliable scientific evidence. (*See* RFF 2350-59].

337. Monique McLaws, former brand manager for POM Juice, testified that the message POM intended to convey with this advertisement and headline was "cleaning out your arteries." (CX1351 (McLaws, Dep. at 123-24)).

Response to Finding No. 337:

Ms. McLaws was a low level manager not qualified to make representations or admissions on POM's behalf, or to speak with authority regarding POM's intent. Further, a reading of the cited deposition testimony shows that all this deponent was

doing was reading the ad and giving her personal interpretation of its meaning, not testifying as to POM's actual intent. Finally, Mr. Resnick testified that POM's advertisements are not intended to convey the message that they can prevent or treat coronary heart disease. (S. Resnick, Tropicana, Dep. at 58-59). Although Mr. Resnick testified that POM believes pomegranate juice is beneficial in preventing and treating coronary heart disease, he does not want consumers to share this belief, but rather to look at their science and make up their own mind. (S. Resnick, Tropicana, Dep. at 42-43). Mr. Resnick never intended POM products to be a substitute for recommended medical treatment or anything else recommended by a doctor. (S. Resnick, Tr. 1870). Mr. Tupper testified that it is absolutely against company policy to say or suggest that POM products are a substitute for proper medical treatment. (Tupper, Tr. 3018). In responding to health-related inquires or a question about a medical condition, POM instructs its employees to tell consumers to consult with his or her physician and strongly encourage this recommendation. (CX0308; Tupper, Tr. 3019).

338. A 2005 creative brief about print and outdoor advertising aimed at women's lifestyles also indicates that POM Marketing believed the phrase "Floss Your Arteries Daily" communicated the benefit that "*If you drink POM Wonderful DAILY, you will have clean and healthy arteries[.]*" (CX0409_0010).

Response to Finding No. 338:

Respondents object to this finding of fact on the basis that it lacks of foundation and lacks authentication for the document cited. Complaint Counsel fails to cite testimony from any witness identifying this document or demonstrating that it was authored by any person at POM with authority to make statements on POM's behalf. There is no indication that this document was approved or ratified by Respondents or that Respondents adopted the statements therein. Further, Mr. Resnick testified that POM's advertisements are not intended to convey the message that they can prevent or treat coronary heart disease. (S. Resnick, Tropicana, Dep. at 58-59). Although Mr. Resnick

testified that POM believes pomegranate juice is beneficial in preventing and treating coronary heart disease, he does not want consumers to share this belief, but rather to look at their science and make up their own mind. (S. Resnick, Tropicana, Dep. at 42-43). Mr. Resnick never intended POM products to be a substitute for recommended medical treatment or anything else recommended by a doctor. (S. Resnick, Tr. 1870). Mr. Tupper testified that it is absolutely against company policy to say or suggest that POM products are a substitute for proper medical treatment. (Tupper, Tr. 3018). In responding to health-related inquires or a question about a medical condition, POM instructs its employees to tell consumers to consult with his or her physician and strongly encourage this recommendation. (CX0308; Tupper, Tr. 3019). *[TAKEN FROM 547, 524, 527, 530, 542].* Finally, at the time the "Floss your arteries" ad was run in 2004, the phrase "a glass a day can reduce plaque by up to 30%" was supported by competent and reliable scientific evidence, including the Aviram Study (2004), which found a 35% decrease in CIMT in people that had severe carotid stenosis and significant plaque build-up (i.e., a baseline IMT more than 1.5 mm). (Tupper, Tr. 954; (see supra XVII(G))). The advertisement's statement that "antioxidants fight free radicals that cause plaque" is also true and substantiated by competent and reliable scientific evidence. (*See* RFF 2350-59).

339. Mrs. Resnick approved this specific advertisement. (CX0471_0010; L. Resnick, Tr. 158-59).

Response to Finding No. 339:

Respondents have no specific response.

340. The imagery and text of this advertisement, for example, placing the POM Juice bottle in a medicine cabinet, referring to "floss[ing]" one's arteries, and referring to a specific percentage reduction in plaque with a study citation, convey the net impression that drinking eight ounces of POM Juice daily treats, prevents, or reduces the risk of heart disease, including by reducing arterial plaque, and that this benefit is clinically proven. (CCFF ¶¶ 336-38).

Response to Finding No. 340:

Complaint Counsel misstate the evidence and the document speaks for itself. Complaint Counsel misconstrue and misrepresent the message of this ad. This ad, like others, describes the results of the studies using very qualified language. Complaint Counsel left out the copy on this ad, which stated that antioxidants are "helping to prevent" and that the study shows "heartening results." (CX0029). Further, Mr. Resnick testified that POM's advertisements are not intended to convey the message that they can prevent or treat coronary heart disease. (S. Resnick, Tropicana, Dep. at 58-59). Although Mr. Resnick testified that POM believes pomegranate juice is beneficial in preventing and treating coronary heart disease, he does not want consumers to share this belief, but rather to look at their science and make up their own mind. (S. Resnick, Tropicana, Dep. at 42-43). Mr. Resnick never intended POM products to be a substitute for recommended medical treatment or anything else recommended by a doctor. (S. Resnick, Tr. 1870). Mr. Tupper testified that it is absolutely against company policy to say or suggest that POM products are a substitute for proper medical treatment. (Tupper, Tr. 3018). In responding to health-related inquires or a question about a medical condition, POM instructs its employees to tell consumers to consult with his or her physician and strongly encourage this recommendation. (CX0308; Tupper, Tr. 3019). Finally, at the time the "Floss your arteries" ad was run in 2004, the phrase "a glass a day can reduce plaque by up to 30%" was supported by competent and reliable scientific evidence, including the Aviram Study (2004), which found a 35% decrease in CIMT in people that had severe carotid stenosis and significant plaque build-up (i.e., a baseline IMT more than 1.5 mm). (Tupper, Tr. 954; (see supra XVII(G))). The advertisement's statement that "antioxidants fight free radicals that cause plaque" is also true and substantiated by competent and reliable scientific evidence. (*See* RFF 2350-59).

d. "Life Support" Print Ad (CX0033)

341. As early as 2004, POM disseminated a POM Juice advertisement with the headline "**Life Support.**" The advertisement ran in *Rolling Stone* magazine in December 2004 and in *Details* magazine in February 2005. (CX0033_0002). The page was dominated by an image of a bottle of POM Juice with logo, hanging upside down on a pole, with the juice running through a tube at the bottom of the bottle, in the manner of a hospital intravenous line. The advertisement's body copy stated:

P♥M Wonderful P♥megranate Juice fills your body with what it needs. On top of being refreshing and delicious, this amazing juice has more naturally occurring antioxidants than any other drink. These antioxidants fight hard against free radicals that can cause heart disease, premature aging, Alzheimer's, even cancer. Just drink eight ounces a day and you'll be on life support – in a good way. **P♥M Wonderful P♥megranate Juice. The Antioxidant Superpower.**

The advertisement also directed consumers to POM's website, pomwonderful.com, directly under the POM logo. (CX0033).

Response to Finding No. 341:

Complaint Counsel misstates the evidence and the document speaks for itself. Complaint Counsel failed to present any evidence that Respondents would run this ad in the future, let alone whether it is probable they would do so. This ad cannot provide a basis for injunctive relief because (a) it ran almost seven years ago; and (b) no evidence exists to show that Respondents are likely to run this ad in the future.

The fact that this ad depicts juice that is wholly-derived from the pomegranate fruit is heavily emphasized in the body copy and the visual imagery of the ad as well as on the product itself. There is a dominant image of deep, ruby red pomegranate juice in a bottle shaped like two pomegranates stacked on top of one another, the words "100% Pomegranate Juice" are clearly displayed on the face of the POM Juice bottle depicted and there is textual reference to "POM Wonderful 100% Pomegranate Juice". The ad emphasizes that POM Juice contains abundant naturally occurring antioxidants that may help guard your body against free radicals. For example, this ad references: a) "antioxidant superpower" and b) "free radicals." Complaint Counsel ignores, among

other elements, the overt puffery, outrageousness and humor in the headline and imagery and the blatant fact that POM Juice is 100% fruit juice.

The ad does not convey the message that (a) POM Juice "prevents," "treats," or "reduces the risk" of heart disease or prostate cancer; or (b) POM Juice is "clinically proven" to "prevent," "treat," or "reduce the risk" of heart disease or prostate cancer since this message is not conspicuous, self-evident, or reasonably clear from the face of the ad. Consequently, because no implied claim relating to prevention, treatment or reduction of risk may be determined with confidence from the face of the ad, extrinsic evidence must be examined. The overall net impression of this ad is not that (a) drinking eight ounces of POM Juice prevents, treats or reduces the risk of certain diseases, such as heart disease or prostate cancer; or (b) drinking eight ounces of POM Juice is "clinically proven" to prevent, treat or reduce the risk of certain diseases, such as heart disease or prostate cancer.

To the extent a "reduce the risk" claim can be implied from this ad, the overall net impression is not that drinking eight ounces of POM Juice "reduces the risk" of certain diseases, such as heart disease or prostate cancer, like a drug with a single target of action, but that it may help "reduce the risk," like many other whole foods, or like an especially healthy fruit or vegetable, or like a a healthy diet of fruits and vegetables and exercise "reduces the risk" of disease.

To the extent a "treat" claim can be implied from this ad (which it cannot), the overall net impression of any ad is not that POM Juice is a substitute for conventional medical treatment. (Butters, Tr. 2821-22; Appendix of Advertisements).

To the extent a "proven" claim can be implied from this ad (which it cannot), the overall net impression of this ad is not that POM Juice is "proven" to be 100% effective in preventing, treating or reducing the risk of heart disease or prostate cancer because (1) all

of the qualifying language contradicts an implied "clinically proven" interpretation, and (2) "proven" in science and to consumers means the "average person in the study benefitted," not that "everyone in the study necessarily benefitted" or that everyone will benefit like the persons who benefitted in the study. (Heber, Tr. 2011; Butters, Tr. 2893-2894; PX0361 (Sacks, Dep. at 81)).

Professor Butters concluded that POM's ads in general depend on parody, exaggeration and humor to bring their message to the potential consumer; including the following messages: 1) POM is the best pomegranate that anyone can buy; 2) POM Juice is healthy; 3) POM Juice is tasty; 4) POM Juice is arguably the best source of antioxidants of any of the comparable beverages available; 5) medical research has suggested that antioxidants combat free radicals, which are unhealthy, and may contribute to diseases of the heart, arteries, and prostate, as well as erectile dysfunction; and 6) POM also offers concentrated forms of pomegranate extract for those who wish to ingest antioxidants in even more concentrated form than pomegranate juice itself. (PX0158-0033).

Complaint Counsel presented no extrinsic evidence or expert opinion on this ad's meaning, consumer perceptions of this ad, or consumer interpretations regarding this ad. (PX0357 (Stewart, Dep. at 49, 52))

Complaint Counsel failed to present any evidence that the claims in this ad reasonably convey that POM Juice is "clinically proven" to prevent, treat or reduce the risk of heart disease or prostate cancer.

Complaint Counsel failed to present any evidence regarding the number of exposures consumers had to this ad or any particular POM advertisement. (Mazis, Tr. 2752). Complaint Counsel failed to present any evidence that the claims in this ad reasonably convey that the Challenged Products are "clinically proven" to prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction.

Therefore, Respondents' interpretation, which examines all the elements of the ad as whole, including, among other elements, the (1) outrageous and puffing headlines, (2) humorous visual images and (3) fact that the product is 100% fruit juice, is thus the most common-sense approach. Viewing the "Life Support" ad a whole, including the interaction of the words and visual imagery, the overall net impression of this ad is that POM Juice is a healthy product. (CX1364 (Tupper, Dep. at 281)).

342. Respondents' expert, Dr. Butters, testified that in the proper context, a visual of an intravenous drip bottle could be a symbol for drugs and medicine. (Butters, Tr. 2947).

Response to Finding No. 342:

Complaint Counsel mischaracterizes Professor Butters' testimony. Professor Butters said it could be in the proper context but he did not testify that this was the message conveyed to consumers via POM's advertising. Professor Butters testified about a theoretical possibility, for example, on a product used on a product box that is labeled "IV Drip Equipment" and sold in a medical supply store, it could be. The sentence, however, whether on POM Juice or a beach ball, would obviously not be a symbol for drugs and medicine.

343. The copy and images in this advertisement, particularly the image of the POM bottle "dressed" as an intravenous line, which is frequently used in medical treatment, along with the references to specific diseases juxtaposed with the recommendation to drink eight ounces a day for "life support," convey the net impression that drinking eight ounces of POM Juice daily prevents or reduces the risk of heart disease, among other diseases. (CCFF ¶¶ 341-42).

Response to Finding No. 343:

Complaint Counsel misstates the evidence and the document speaks for itself. Complaint Counsel misconstrue and misrepresent the message of this ad.

The fact that the POM Juice is wholly-derived from the pomegranate fruit is heavily emphasized in the body copy and the visual imagery of this ad as well as on the product

itself. This ad depicts a dominant image of a POM Juice bottle with the words "100% Pomegranate Juice" on the face of bottle, which is shaped like two pomegranates stacked on top of each other. (CX0033_0001).

Complaint Counsel's assertion that the ad implicitly conveys the message that drinking eight ounces of POM Juice daily prevents or reduces the risk of heart disease, among other diseases is not conspicuous, self-evident, or reasonably clear from the face of the ad. (CX0033_0001). Consequently, because the above-referenced challenged implied claim may not be determined with confidence from the face of the ad, extrinsic evidence must be examined.

Complaint Counsel erroneously rely upon the impact of only a few, select elements for their overall view of the net impression of an ad, and seemingly neglect at least two significant elements that are key to any facial or common sense net impression analysis—that the Challenged Products are products wholly-derived from pomegranates, and the Challenged Products' effectiveness is based, at least in significant part, on the products' abundant antioxidants.

The overall net impression of this ad is not that (a) drinking eight ounces of POM Juice prevents, treats or reduces the risk of certain diseases, such as heart disease or prostate cancer; or (b) drinking eight ounces of POM Juice is "clinically proven" to prevent, treat or reduce the risk of certain diseases, such as heart disease or prostate cancer. (CX0033_0001). Even the language of the ad itself uses such qualifiers as "can cause" and "fight." (CX0033_0001).

Instead, the "Life Support" advertisement makes multiple efforts to convey that POM Juice is a whole food product that is wholly-derived from pomegranates, including: a) dominate imagery of deep, ruby red pomegranate juice in a bottle shaped like two pomegranates stacked on top of one another; b) the words "100% Pomegranate Juice"

clearly displayed on the face of the bottle; and c) repeated textual references to POM Wonderful Pomegranate Juice

Additionally, the ad emphasizes that POM Juice contains abundant naturally occurring antioxidants. For example, the "Heart therapy" ad references: a) POM Juice as "The Antioxidant Superpower;" b) that POM Juice has "naturally occurring antioxidants."

Both the whole food aspect of the advertising and the emphasis on antioxidant content, directly counter any suggestion that POM Juice is going to act like a drug, as distinguished from a very healthy fruit or vegetable and a healthy diet.

Viewing the ad as a whole, taking into account all the various elements, including the prevalence and pervasiveness of the "whole-food" graphic, in the form of the POM Juice bottle, and body copy as well as the emphasis on the fact that POM Juice is a concentrated and potent source of antioxidants, it is far more logical that POM consumers would view POM Juice the way they perceive many other whole foods, like broccoli, blueberries, grapes or tomatoes, which may help prevent or improve your odds against disease, but which would not act like a drug with a single target of action against a particular disease or condition.

To the extent a "reduce the risk" claim can be implied from ad, the overall net impression is not that drinking eight ounces of POM Juice "reduces the risk" of certain diseases, such as heart disease or prostate cancer, like a drug with a single target of action, but that it may help "reduce the risk," like many whole foods, or like an especially healthy fruit or vegetable, or like a healthy diet of fruits and vegetables and exercise "reduces the risk" of disease. (CX0033_0001).

To the extent a "treat" claim can be implied from this ad (which it cannot), the overall net impression of any ad is not that POM Juice is a substitute for conventional medical treatment. (Butters, Tr. 2821-22).

To the extent a "proven" claim can be implied from this ad (which it cannot), the overall impression of this ad is not that POM Juice is "proven" to be 100% effective in preventing, treating or reducing the risk of heart disease or prostate cancer because (1) all of the qualifying language contradicts an implied "clinically proven" interpretation, and (2) "proven" in science and to consumers means the "average person in the study benefitted." "Proven" does not mean that "everyone in the study necessarily benefitted" or that everyone will benefit like the persons who benefitted in the study. (Heber, Tr. 2011; Butters, Tr. 2893-2894; PX0361 (Sacks, Dep. at 81)).

Mr. Tupper testified that the meaning of this "Life Support" ad is that POM Juice is an incredibly healthful product that helps support a healthy life driven by the antioxidant content of the juice. (CX1364 (Tupper, Dep. at 281)). Professor Butters concluded that POM's ads in general depend on parody, exaggeration and humor to bring their message to the potential consumer. (PX0158-0033). This ad, like many of POM's ads, uses humor and puffery. (CX0033_0001). Complaint Counsel's net impression analysis completely disregards the blatant puffery and humor as well as the fact that the ad's body copy and imagery focus on the fact that the product is a 100% juice product wholly-derived from the pomegranate fruit. Additionally, the phrases, "POM Wonderful Pomegranate Juice fills your body with what it needs" and "Just drink eight ounces a day and you'll be on life support – in a good way" are further humorous, non-actionable puffing.

Complaint Counsel presented no extrinsic evidence or expert opinion on this ad's meaning, consumer perceptions of this ad, or consumer interpretations regarding this ad. (PX0357 (Stewart, Dep. at 49, 52)).

Complaint Counsel failed to present any evidence that the claims in this ad reasonably convey that the Challenged Products are "clinically proven" to prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction.

Complaint Counsel failed to present any evidence regarding the number of exposures consumers had to this ad or any particular POM advertisement. (Mazis, Tr. 2752).

e. "Amaze your cardiologist" Print Ad (CX0034)

344. In February 2005, POM disseminated in *Prevention* magazine a POM Juice advertisement with the headline "**Amaze your cardiologist**." The advertisement featured an image of a bottle of POM Juice with electrocardiogram (EKG) leads attached to it. The advertisement's body copy stated:

Ace your EKG: just drink 8 ounces of delicious P♥M Wonderful P♥megranate Juice a day. It has more naturally occurring antioxidants than any other drink. Antioxidants fight free radicals . . . nasty little molecules that can cause sticky, artery clogging plaque. A glass a day can reduce plaque by up to 30%!* Trust us, your cardiologist will be amazed. **P♥M Wonderful P♥megranate Juice. The Antioxidant Superpower.**

(CX0034).

Response to Finding No. 344:

Respondents object to Complaint Counsel's citation to CX0034 as it was conditionally admitted at trial. Mr. Tupper testified that POM first ran this advertisement stopped running in 2005 and that it has not been disseminated in more than six years. Thus, the "Amaze your cardiologist" headline, image and body copy thus have not run as part of any advertisement for more than six years. (Tupper, Tr. 2996-97; CX1353 (Tupper, Dep. at 131)). Mr. Perdigao testified that Fire Station wrote a copy stating "Amaze your urologist," because pomegranate juice is a healthy product and there have been studies that suggested it is good for prostate health. (CX1373 (Perdigao, Dep. at 290-93)).

Complaint Counsel presented no evidence to show otherwise. This ad cannot provide a basis for injunctive relief because (a) it ran more than six years ago; and (b) no evidence exists to show that Respondents are likely to run this ad in the future.

The fact that this ad depicts juice that is wholly-derived from the pomegranate fruit is heavily emphasized in the body copy and the visual imagery of the ad as well as on the product itself. There is a dominant image of deep, ruby red pomegranate juice in a bottle shaped like two pomegranates stacked on top of one another, the words "100% Pomegranate Juice" are clearly displayed on the face of the POM Juice bottle depicted and there is textual reference to "POM Wonderful 100% Pomegranate Juice". The ad emphasizes that POM Juice contains abundant naturally occurring antioxidants that may help guard your body against free radicals. For example, this ad references: a) "antioxidant superpower" and b) "free radicals." Complaint Counsel ignores, among other elements, the overt puffery, outrageousness and humor in the headline and imagery and the blatant fact that POM Juice is 100% fruit juice.

The fact that POM advertised in Prevention magazine is not damning. Prevention magazine caters to health-conscious consumers and has sections on beauty, shopping, health, fitness, diet and nutrition. POM's advertising in Prevention is entirely consistent with advertising of a food product whose messaging is how a whole food product fits into a healthy lifestyle and diet program. Contrary to the marketing themes suggested by Complaint Counsel that POM marketed POM Juice as a pharmaceutical drug with a single or narrow target of action, advertising in Prevention does not show intent to convey that POM Juice "prevents," "treats," or "reduces the risk" of heart disease or prostate cancer.

The ad does not convey the message that (a) POM Juice "prevents," "treats," or "reduces the risk" of heart disease or prostate cancer; or (b) POM Juice is "clinically proven" to

"prevent," "treat," or "reduce the risk" of heart disease or prostate cancer since this message is not conspicuous, self-evident, or reasonably clear from the face of the ad. Consequently, because no implied claim relating to prevention, treatment or reduction of risk may be determined with confidence from the face of the ad, extrinsic evidence must be examined. The overall net impression of this ad is not that (a) drinking eight ounces of POM Juice prevents, treats or reduces the risk of certain diseases, such as heart disease or prostate cancer; or (b) drinking eight ounces of POM Juice is "clinically proven" to prevent, treat or reduce the risk of certain diseases, such as heart disease or prostate cancer.

To the extent a "reduce the risk" claim can be implied from this ad, the overall net impression is not that drinking eight ounces of POM Juice "reduces the risk" of certain diseases, such as heart disease or prostate cancer, like a drug with a single target of action, but that it may help "reduce the risk," like many other whole foods, or like an especially healthy fruit or vegetable, or like a a healthy diet of fruits and vegetables and exercise "reduces the risk" of disease.

To the extent a "treat" claim can be implied from this ad (which it cannot), the overall net impression of any ad is not that POM Juice is a substitute for conventional medical treatment. (Butters, Tr. 2821-22; Appendix of Advertisements).

To the extent a "proven" claim can be implied from this ad (which it cannot), the overall net impression of this ad is not that POM Juice is "proven" to be 100% effective in preventing, treating or reducing the risk of heart disease or prostate cancer because (1) all of the qualifying language contradicts an implied "clinically proven" interpretation, and (2) "proven" in science and to consumers means the "average person in the study benefitted," not that "everyone in the study necessarily benefitted" or that everyone will

benefit like the persons who benefitted in the study. (Heber, Tr. 2011; Butters, Tr. 2893-2894; PX0361 (Sacks, Dep. at 81)).

Professor Butters concluded that POM's ads in general depend on parody, exaggeration and humor to bring their message to the potential consumer; including the following messages: 1) POM is the best pomegranate that anyone can buy; 2) POM Juice is healthy; 3) POM Juice is tasty; 4) POM Juice is arguably the best source of antioxidants of any of the comparable beverages available; 5) medical research has suggested that antioxidants combat free radicals, which are unhealthy, and may contribute to diseases of the heart, arteries, and prostate, as well as erectile dysfunction; and 6) POM also offers concentrated forms of pomegranate extract for those who wish to ingest antioxidants in even more concentrated form than pomegranate juice itself. (PX0158-0033).

Viewing the "Amaze your urologist" ad as a whole, including the interaction of the words and visual imagery, the overall net impression of the ad is that POM Juice is a healthy product. (CX1373 (Perdigao, Dep. at 290-93)). The imagery of the bottle dressed-up in EKG sensors is humorous and does not necessarily portray a "heart-diseased" EKG patient. A doctor could order a baseline EKG for a patient before any problems develop or to check how well certain medicines are working and whether they are causing side effects that affect the heart. The headline "Amaze your cardiologist" and phrases "Ace your EKG" and "Trust us your cardiologist will be amazed" are also humorous puffing – *i.e.*, exaggerated advertising and incapable of being measured. (RFF2392). They make no mention of "heart disease." *Cf. In re Daniel Chapter One*, No. 9329, 2009 WL 2584873, at *69 (Initial Decision Aug. 5, 2009 ("the title of the publication, 'How to fight cancer is your choice,' . . . sets the stage [that the Challenged Products treat or cure cancer] by strongly implying if not expressly stating, that the products described in the newsletter will "fight" cancer.").

Complaint Counsel presented no extrinsic evidence or expert opinion on this ad's meaning, consumer perceptions of this ad, or consumer interpretations regarding this ad. (PX0357 (Stewart, Dep. at 49, 52))

Complaint Counsel failed to present any evidence that the claims in this ad reasonably convey that POM Juice is "clinically proven" to prevent, treat or reduce the risk of heart disease or prostate cancer.

Complaint Counsel failed to present any evidence regarding the number of exposures consumers had to this ad or any particular POM advertisement. (Mazis, Tr. 2752).

Therefore, Respondents' interpretation, which examines all the elements of the ad as whole, including, among other elements, the (1) outrageous and puffing headlines, (2) humorous visual images and (3) fact that the product is 100% fruit juice, is thus the most common-sense approach.

345. In very small type after the asterisk, the advertisement cited to one of the studies conducted by Michael Aviram: "Aviram, M., *Clinical Nutrition,* 2004. Based on a clinical pilot study." The advertisement also directed consumers to POM's website, pomwonderful.com, directly under the POM logo. (CX0034).

Response to Finding No. 345:

The document speaks for itself.

346. Dr. Butters testified that the phrase "amaze your cardiologist" makes explicit the theme of the importance of heart health. (Butters, Tr. 2911).

Response to Finding No. 346:

Dr. Butters also testified that the headline, "Amaze your cardiologist" is hyperbolic. (Butters, Tr. 2914-15). Even Dr. Stewart, Complaint Counsel's own expert, testified that the headline "Amaze your cardiologist" is not to be taken literally. (Stewart, Tr. 3230). The image in the advertisement, the headline "Amaze your cardiologist," and the phrases

"ACE your EKG" and "your cardiologist will be amazed" are puffery. (CX0034). Mr. Tupper testified that POM did intend for the image of the bottle with little EKG sticks on it to be a visual cue drawing attention to the encouraging research about pomegranate juice and cardiovascular health. (Tupper, Tr. 3005).

347. Mr. Resnick testified that he is comfortable with the "Amaze your cardiologist" claim given the company's "very positive results around heart health," citing, for example, the clinical study by Dr. Ornish on blood flow to the heart, and the study of "patients that had serious carotid artery problems [showing] it did reduce the plaque by up to 40 percent." (CX1376 (S. Resnick, OS Dep. at 159-60)).

Response to Finding No. 347:

Complaint Counsel have mischaracterized Mr. Resnick's testimony. Furthermore, Complaint Counsel only uses one of the studies conducted in the example given. Firstly, he ad does not convey the message that (a) POM Juice "prevents," "treats," or "reduces the risk" of heart disease; or (b) POM Juice is "clinically proven" to "prevent," "treat," or "reduce the risk" of heart disease or prostate cancer since this message is not conspicuous, self-evident, or reasonably clear from the face of the ad. Secondly, Mr. Resnick does not believe that POM's advertisements communicate that POM Juice can prevent of delay the onset of heart disease, but rather he does believe that POM's science supports the claims made in the ad reflecting hopeful results for heart health.

The Aviram CIMT/BP Study (2004) and Davidson CIMT Study (2009) constitute competent and reliable scientific evidence that the consumption of POM Juice is beneficial to cardiovascular health by, among other things, reducing arterial plaque. (RFF 1111-1126; 1139-1146; 1288-1302; 1427-1504; PX0014; PX0611; PX0025-0009-0010; 0019-0022; PX0192-0036-0037, 0039; 0048, 005; Heber Tr. 1979-86; PX0014). The Ornish MP Study (2005) constitutes competent and reliable scientific evidence that the consumption of POM Juice is beneficial to cardiovascular health by, among other things, improving blood flow. (RFF 1127-1138; 1303-1414; PX0023; PX0025-0011-0018;

PX0192-0037-0038; 0053, Ornish, Tr. 2354-55). Finally, the Aviram ACE/BP Study (2001) and Aviram CIMT/BP Study (2004) constitute competent and reliable scientific evidence that the consumption of POM Juice is beneficial to cardiovascular health by, among other things, improving blood pressure. (RFF 1107-1126; 1280-1302; CX0542; CX0611; PX0025-0009-0011; PX0192-0035-0037; 0052).

Mr. Resnick testified that POM's advertisements are not intended to convey the message that they can prevent or treat coronary heart disease. (S. Resnick, Tropicana, Dep. at 58-59). Although Mr. Resnick testified that POM believes pomegranate juice is beneficial in preventing and treating coronary heart disease, he does not want consumers to share this belief, but rather to look at their science and make up their own mind. (S. Resnick, Tropicana, Dep. at 42-43). Mr. Resnick never intended POM products to be a substitute for recommended medical treatment or anything else recommended by a doctor. (S. Resnick, Tr. 1870). Therefore, Mr. Resnick's statements reflect his belief that POM never made the claims alleged, and that, in any event, such claims would be supported by the science.

348. The copy and images in this advertisement draw a clear association with cardiovascular disease diagnosis and treatment, particularly the bottle "dressed" as an EKG patient, references to a cardiologist and "ac[ing] your EKG," and specific citations to a study purportedly showing 30% reduction of arterial plaque. This advertisement conveys the net impression that drinking eight ounces of POM Juice daily treats, prevents, or reduces the risk of heart disease, including by reducing arterial plaque, and that this benefit is clinically proven. (CCFF ¶¶ 344-47).

Response to Finding No. 348:

Complaint Counsel's finding misstates the evidence and the document speaks for itself. Complaint Counsel misconstrue and misrepresent the message of this ad. Complaint Counsel ignore the (1) outrageousness of the headline, (2) silliness of a "dressed bottle," and (3) fact the product is 100% fruit juice. (CX0034_0001). Also, the ad makes clear on its face that it is for a wholly-derived fruit product. The POM Juice bottle is filled

with deep, ruby red pomegranate juice, the shape of the bottle resembles two pomegranates stacked on top of one another and the face of the bottle prominently displays "100% P♥MEGRANATE JUICE." (CX0034_0001).

Complaint Counsel erroneously rely upon the impact of only a few, select elements for their overall view of the net impression of an ad, and seemingly neglect at least two significant elements that are key to any facial or common sense net impression analysis—that POM Juice is a product wholly-derived from pomegranates, and POM Juice's effectiveness is based, at least in significant part, on the product's abundant antioxidants. The ad emphasizes that POM Juice contains abundant naturally occurring antioxidants that may help guard your body against free radicals. For example, this ad references: a) "antioxidant superpower" and b) "free radicals." Complaint Counsel ignores, among other elements, the overt puffery, outrageousness and humor in the headline and imagery and the blatant fact that POM Juice is 100% fruit juice.

Nowhere in this ad do Respondents expressly (*i.e.*, unequivocally and directly) state that (a) POM Juice "prevents," "treats," or "reduces the risk" of heart disease; or (b) POM Juice is "clinically proven" to "prevent," "treat," or "reduce the risk" of heart disease. (CX0034).

Complaint Counsel's assertion that the ad conveys the message that (a) POM Juice "prevents," "treats," or "reduces the risk" of heart disease; or (b) POM Juice is "clinically proven" to "prevent," "treat," or "reduce the risk" of heart disease is not conspicuous, self-evident, or reasonably clear from the face of the ad. (CX0034). Consequently, extrinsic evidence must be examined. (Mazis, Tr. 2752).

In 2005, the NAD found that the statement "A glass a day can reduce plaque by up to 30%" was not an establishment claim (*i.e.*, a "clinically proven" claim). (CX0037_0006-0007). The "Amaze your cardiologist" advertisement featured the image of a POM

Wonderful 100% Pomegranate Juice bottle attached with EKG sensors. (CX0034_0001;CX0471_0012).

The overall net impression of this "Amaze your cardiologist" ad is not that (a) drinking eight ounces of POM Juice prevents, treats or reduces the risk of certain diseases, such as heart disease; or (b) drinking eight ounces of POM Juice is "clinically proven" to prevent, treat or reduce the risk of certain diseases, such as heart disease. (CX0034_0001).

Instead, the "Amaze your cardiologist" advertisement makes multiple efforts to convey that POM Juice is a whole food product that is wholly-derived from pomegranates, including: a) dominate imagery of deep, ruby red pomegranate juice in a bottle shaped like two pomegranates stacked on top of one another; b) the words "100% Pomegranate Juice" clearly displayed on the face of the bottle; and c) repeated textual references to POM Wonderful Pomegranate Juice.

Both the whole food aspect of the advertising and the emphasis on antioxidant content, directly counter any suggestion that POM Juice is going to act like a drug, as distinguished from an especially healthy fruit or vegetable and a healthy diet.

Viewing the ad as a whole, taking into account all the various elements, including the prevalence and pervasiveness of the "whole-food" graphic, in the form of the POM Juice bottle, and body copy as well as the repeated emphasis on the fact that POM Juice is a concentrated and potent source of antioxidants, it is far more logical that POM consumers would view POM Juice the way they perceive many other whole foods, like broccoli, blueberries, grapes or tomatoes, which may help prevent or improve your odds against disease, but which would not act like a drug with a single target of action against a particular disease or condition.

To the extent a "may reduce the risk" claim can be implied from this ad, the overall net impression is not that drinking eight ounces of POM Juice "reduces the risk" of heart disease, like a drug with a single target of action, but that it may help "reduce the risk," like many whole foods, or like an especially healthy fruit or vegetable, or like a healthy diet of fruits and vegetables and exercise "reduces the risk" of disease. (CX0034_0001).

To the extent a "treat" claim can be implied from this ad (which it cannot), the overall net impression of any ad is not that POM Juice is a substitute for conventional medical treatment. (Butters, Tr. 2821-22).

To the extent a "proven" claim can be implied from this ad (which it cannot), the overall impression of "Amaze your cardiologist" is not that POM Juice is "proven" to be 100% effective in preventing, treating or reducing the risk of heart disease. "Proven" in science and to consumers means the "average person in the study benefitted." "Proven" does not mean that "everyone in the study necessarily benefitted" or that everyone will benefit like the persons who benefitted in the study. (Heber, Tr. 2011; Butters, Tr. 2893-2894; PX0361 (Sacks, Dep. at 81)).

The fact that POM advertised in *Prevention* is not damning. *Prevention* magazine caters to health-conscious consumers and has sections on beauty, shopping, health, fitness, diet and nutrition. POM's advertising in *Prevention* is entirely consistent with advertising of a food product whose messaging is how a whole food product fits into a healthy lifestyle and diet program. Contrary to the marketing themes suggested by Complaint Counsel that POM marketed POM Juice as a pharmaceutical drug with a single or narrow target of action, advertising in *Prevention* does not show intent to convey that POM Juice "prevents," "treats," or "reduces the risk" of heart disease.

Mr. Resnick testified that POM's advertisements are not intended to convey the message that they can prevent or treat coronary heart disease. (S. Resnick, Tropicana, Dep. at 58-

59). Although Mr. Resnick testified that POM believes pomegranate juice is beneficial in preventing and treating coronary heart disease, he does not want consumers to share this belief, but rather to look at their science and make up their own mind. (S. Resnick, Tropicana, Dep. at 42-43). Mr. Resnick never intended POM products to be a substitute for recommended medical treatment or anything else recommended by a doctor. (S. Resnick, Tr. 1870). Mr. Tupper testified that it is absolutely against company policy to say or suggest that POM products are a substitute for proper medical treatment. (Tupper, Tr. 3018). In responding to health-related inquires or a question about a medical condition, POM instructs its employees to tell consumers to consult with his or her physician and strongly encourage this recommendation. (CX0308; Tupper, Tr. 3019).

Further, at the time the "Amaze your cardiologist" ad was run in 2005, the phrase "a glass a day can reduce plaque by up to 30%" was supported by competent and reliable scientific evidence, including the Aviram Study (2004), which found a 35% decrease in CIMT in people that had severe carotid stenosis and significant plaque build-up (i.e., a baseline IMT more than 1.5 mm). (Tupper, Tr. 954; (see supra XVII(G))). The advertisement's statement that "antioxidants fight free radicals" is also true and substantiated by competent and reliable scientific evidence. (see supra XVII(G)). Complaint Counsel have presented no extrinsic evidence or expert opinion on the meaning of this "Amaze your cardiologist" ad or of consumer perceptions or interpretations of this ad. (PX0357 (Stewart Dep. at 49, 52); (Mazis, Tr. 2752)).

Complaint Counsel also have presented no evidence that this "Amaze your cardiologist" ad conveyed that POM Juice is "clinically proven" to prevent, treat or reduce the risk of heart disease. Even assuming *arguendo* that this "Amaze your cardiologist" ad conveys the message Complaint Counsel assigns to it, Professor Reibstein's survey effectively demonstrates that any alleged disease claims made by Respondents were not material to the purchasing decisions of POM consumers. (RFF 2623, 2630).

Complaint Counsel failed to present any evidence regarding the number of exposures consumers had to this ad or any particular POM advertisement. Complaint Counsel have presented no reliable evidence to rebut Professor's Reibstein's survey findings or to show that any alleged disease claims made in POM's ads were material to the purchasing decisions of POM consumers.

f. "Cheat Death" Print Ad (CX0036)

349. In 2005 and 2006, POM disseminated a POM Juice advertisement with the headline, "**Cheat Death**." The advertisement ran in *Rolling Stone* magazine in March, June, and July 2005; in *Prevention* magazine in May 2005; and in *Fitness* magazine in January 2006. (CX0036_0002). The advertisement featured an image of the POM Juice bottle with logo with a rope noose around the neck of the bottle. The advertisement's body copy stated:

Dying is so dead. Drink to life with P♥M Wonderful P♥megranate Juice, the world's most powerful antioxidant. It has more antioxidants than any other drink and can help prevent premature aging, heart disease, stroke, Alzheimer's, even cancer. Eight ounces a day is all you need. The sooner you drink it, the longer you will enjoy it. **P♥M Wonderful P♥megranate Juice. The Antioxidant Superpower.**

The advertisement also directed consumers to POM's website, pomwonderful.com, directly under the POM logo. (CX0036; *see also* CX0188 (similar advertisement disseminated in June 2008)).

Response to Finding No. 349:

Complaint Counsel misstates the evidence and the document speaks for itself. Complaint Counsel failed to present any other definitive information regarding this ad's dissemination. Mr. Tupper testified that although this early "Cheat death" ad indicated a benefit regarding Alzheimer's, the Alzheimer's references were stopped early on because, although POM had some early preliminary research on Alzheimer's and the formation of plaques in the brain that are ultimately the cause of Alzheimer's, POM decided to focus its advertising on the areas of science that were farther along. (Tupper, Tr. 2994). Mr. Tupper further testified that this "Cheat death" ad, with the above-quoted body copy that POM "can help prevent" certain diseases stopped running five or six years ago and believes that POM stopped this body copy from running in connection with an

NAD ruling. (Tupper, Tr. 2987-90). While Mr. Tupper stated that POM has since used the "Cheat death" headline and imagery, those ads contained no body copy or different body copy which contained no reference to POM helping to prevent any diseases. (Tupper, Tr. 2989). Complaint Counsel have presented no evidence to contradict Mr. Tupper's testimony that this "Cheat death" ad has not run in over five or six years. This ad cannot provide a basis for injunctive relief because (a) it ran more than five years ago; and (b) no evidence exists to show that Respondents are likely to run this ad in the future.

The fact that this ad depicts juice that is wholly-derived from the pomegranate fruit is heavily emphasized in the body copy and the visual imagery of the ad as well as on the product itself. There is a dominant image of deep, ruby red pomegranate juice in bottle shaped like two pomegranates side by side, the words "100% Pomegranate Juice" are clearly displayed on the face of the POM Juice bottle depicted and there is repeated textual reference to "POM Wonderful 100% Pomegranate Juice". The ad emphasizes that POM Juice contains abundant naturally occurring antioxidants that may help guard your body against free radicals. For example, this ad references: a) "antioxidant superpower" and b) "free radicals." Complaint Counsel ignores, among other elements, the overt puffery, outrageousness and humor in the headline and imagery and the blatant fact that POM Juice is 100% fruit juice.

The ad does not convey the message that (a) POM Juice "prevents," "treats," or "reduces the risk" of heart disease or prostate cancer; or (b) POM Juice is "clinically proven" to "prevent," "treat," or "reduce the risk" of heart disease since this message is not conspicuous, self-evident, or reasonably clear from the face of the ad. Consequently, because there is no implied claim relating to prevention, treatment or reduction of risk that may be determined with confidence from the face of the ad, extrinsic evidence must be examined. The overall net impression of this ad is not that (a) drinking eight ounces of POM Juice prevents, treats or reduces the risk of certain diseases, such as heart disease;

or (b) drinking eight ounces of POM Juice is "clinically proven" to prevent, treat or reduce the risk of certain diseases, such as heart.

To the extent a "reduce the risk" claim can be implied from this ad, the overall net impression is not that drinking eight ounces of POM Juice "reduces the risk" of certain diseases, such as heart disease or prostate cancer, like a drug with a single target of action, but that it may help "reduce the risk," like many other whole foods, or like an especially healthy fruit or vegetable, or like a a healthy diet of fruits and vegetables and exercise "reduces the risk" of disease. To the extent a "treat" claim can be implied from this ad (which it cannot), the overall net impression of any ad is not that POM Juice is a substitute for conventional medical treatment. (Butters, Tr. 2821-22; Appendix of Advertisements).

To the extent a "treat" claim can be implied from this ad (which it cannot), the overall net impression of any ad is not that POM Juice is a substitute for conventional medical treatment. (Butters, Tr. 2821-22; Appendix of Advertisements).

To the extent a "proven" claim can be implied from this ad (which it cannot), the overall net impression of this ad is not that POM Juice is "proven" to be 100% effective in preventing, treating or reducing the risk of heart disease or prostate cancer because (1) all of the qualifying language contradicts an implied "clinically proven" interpretation, and (2) "proven" in science and to consumers means the "average person in the study benefitted," not that "everyone in the study necessarily benefitted" or that everyone will benefit like the persons who benefitted in the study. (Heber, Tr. 2011; Butters, Tr. 2893-2894; PX0361 (Sacks, Dep. at 81)).

Professor Butters concluded that POM's ads in general depend on parody, exaggeration and humor to bring their message to the potential consumer; including the following messages: 1) POM is the best pomegranate that anyone can buy; 2) POM Juice is healthy;

3) POM Juice is tasty; 4) POM Juice is arguably the best source of antioxidants of any of the comparable beverages available; 5) medical research has suggested that antioxidants combat free radicals, which are unhealthy, and may contribute to diseases of the heart, arteries, and prostate, as well as erectile dysfunction; and 6) POM also offers concentrated forms of pomegranate extract for those who wish to ingest antioxidants in even more concentrated form than pomegranate juice itself. (PX0158-0033). Mr. Tupper also testified that this ad portrays a take on the female anatomy and conveys that the juice is a healthy product. (CX1364 (Tupper, Dep. at 293-94)).

Mrs. Resnick testified that the idea of the ad is to "make you laugh. And what we're saying here essentially with puffery is that you'll live longer if you -- you can cheat death, which we all know you can't." (L. Resnick, Tr. 194-95). Mrs. Resnick further testified that the intent of the ad is to get the attention of the reader, make the reader read the ad, remember the shape of the bottle and the fact that POM has a healthy message. (L. Resnick, Tr. 195-97). Viewing the "Cheat death" ad as a whole, including the interaction of the words and visual imagery, the overall net impression of the ad is that it is a humorous ad that uses puffery and that POM Juice is a healthy product. (L. Resnick, Tr. 195-97).

Complaint Counsel presented no extrinsic evidence or expert opinion on this ad's meaning, consumer perceptions of this ad, or consumer interpretations regarding this ad. (PX0357 (Stewart, Dep. at 49, 52)). Complaint Counsel also failed to present any evidence that the claims in this ad reasonably convey that POM Juice is "clinically proven" to prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction. Furthermore, Complaint Counsel failed to present any evidence regarding the number of exposures consumers had to this ad or any particular POM advertisement. (Mazis, Tr. 2752).

The fact that POM advertised in Fitness and Men's Health magazines is not damning. Men's Health and Fitness magazines cater to health-conscious consumers and each has sections on beauty, shopping, health, fitness, diet and nutrition. POM's advertising in Men's Health and Fitness is entirely consistent with advertising of a food product whose messaging is how a whole food product fits into a healthy lifestyle and diet program. Contrary to the marketing themes suggested by Complaint Counsel that POM marketed POM Juice as a pharmaceutical drug with a single or narrow target of action, advertising in Men's Health or Fitness does not show intent to convey that POM Juice "prevents," "treats," or "reduces the risk" of heart disease or prostate cancer.

Therefore, Respondents' interpretation, which examines all the elements of the ad as whole, including, among other elements, the (1) outrageous and puffing headlines, (2) humorous visual images and (3) fact that the product is 100% fruit juice, is thus the most common-sense approach.

350. Ms. McLaws testified that the "Cheat Death" advertisement's message was that one could avoid or prevent the diseases mentioned (heart disease, stroke, Alzheimer's) and therefore live longer. (CX1351 (McLaws, Dep. at 134-35).

Response to Finding No. 350:

Complaint Counsel's statement is vague and ambiguous. Of the total Zoomerang study population, in response to an open-ended question, 31% said they knew of specific health benefits of pomegranate juice. (CX0292_0026; CX0453_0004). Of these 31%, in response to a question asking them to rank a list of six health benefits in order of importance, the male respondents responded as follows: approximately 60% said cardiovascular, 40% said prostate health; approximately 30% said anti-aging, approximately 30% said anti-inflammatory, 18% said erectile dysfunction and approximately 17% said oral health. (CX0136_0007). Of these 31%, the women ranked the same list as follows: approximately 65% said cardiovascular, almost 45% said anti-

aging, approximately 40% said anti-inflammatory, 20% said oral health, approximately 15% said prostate health and 12% said erectile dysfunction. (CX0136_0008).

The results of the Zoomerang Survey are unreliable and inflated because the closed-ended question was leading in that respondents were given a limited number of choices and forced to rank health benefits they may not otherwise have thought of. (RFF 2724; *see also* Reibstein, Tr. 2551-52). The use of the closed-ended question also resulted in the exclusion of potential health benefits that were not included on the list of choices because respondents were compelled to rank the health benefits listed. (RFF 2725; Reibstein, Tr. 2519). Complaint Counsel also presented no evidence that the results of the Zoomerang Survey are statistically significant. Nor did Complaint Counsel present evidence that the health benefits listed in the Zoomerang Survey were material to the respondents' decision to drink pomegranate juice, let alone their decision to buy the juice. Of course, even if the health benefits listed in the Zoomerang Survey are "important" to the respondents it does not mean they are material. As Professor Mazis conceded, "an advertising claim may involve information important to consumers, but to be material it has to be important to their decision to buy." (RFF 2692; *see also* RFF 2693).

351. In her book, Mrs. Resnick says the "Cheat Death" advertisement's imagery was intended to symbolically endow the juice with heroic powers: "When you see that brave little bottle with a noose around its neck – a noose broken by the antioxidant power of POM – you identify with it just as you identify with a hero's triumph or last-minute escape from danger on the movie screen." (CX0001_0019-0020).

Response to Finding No. 351:

Several of Respondents' witnesses testified that some of the "Cheat death" ad, including the headline and some words, was meant to be hyperbolic, puffery and humorous. (*See* RFF ¶¶ 2278-2280.) Mrs. Resnick agreed that much of the "Cheat death" ad is puffery and stated that the headline is meant to convey the fact that the product is good for you. (CX1362 (L. Resnick, Dep. at 283-84)). She further testified that the idea of the ad is to

make you laugh. "And what we're saying here essentially with puffery is that you'll live longer if you -- you can cheat death, which we all know you can't." (L. Resnick, Tr. 194).

352. Ms. Leow testified that the intent of the "Dressed Bottle" campaign, which included the "Cheat Death" and other similar juice advertisements (described in CCFF ¶¶ 336, 341, 344, and 357), was to "personify" the product. (Leow, Tr. 475, 487).

Response to Finding No. 352:

Complaint Counsel misconstrues and misrepresents Ms. Leow's testimony. The use of the term "personify" is vague and ambiguous. Ms. Leow's statement regarding "personify" related to the outrageousness of the props given to the bottle, puffing headlines and humorous visual images which made the ad humorous and made people laugh. It did not "personify" the bottle to imitate a person. Complaint Counsel failed to clarify the term "personify" when Ms. Leow used the term.

353. POM considered the "Cheat Death" advertisements to be a "hard-hitting execution," and after a period of little or no advertising, the company, with Mrs. Resnick's approval, decided to revive these and similar prior advertisements in 2008 in order to create some attention among consumers. (Perdigao, Tr. 627; CX0185_0003; CX1368 (L. Resnick, Welch Dep. at 100-01)).

Response to Finding No. 353:

Complaint Counsel misconstrues the document and the document speaks for itself (CX0185_0003). Mrs. Resnick testified that she does not recall bringing back the "Cheat death" headline for use in 2008. (L. Resnick, Tr. 191-92).

354. POM kept a log of consumer complaints. (CX1357 (Kuyoomjian, Dep. at 203)). In response to November 2009 and March 2010 consumer complaints about a billboard version of the "Cheat Death" advertisement, which contained the same headline and image, POM's consumer affairs representative told those consumers:

> The intention of "Cheat Death" is the recognition that disease of the heart and circularity [*sic*] system (cardiovascular disease or CVD) are some of the main causes of death in the US. There are preventative actions that can be taken to decrease this risk and finding healthy options that could potentially increase one's heart health, such as drinking POM, increases one's chances to live longer and healthier, to "cheat death."

(CX0454_0006-07; CX0456_0005).

Response to Finding No. 354:

Several of Respondents' witnesses, including Mrs. Resnick as detailed above, testified that parts of the "Cheat death" ad, including the headline and some words, were meant to be hyperbolic, puffery and humorous. (*See* RFF 2278-2280). Mr. Perdigao testified that the "Cheat death" execution was meant to be edgy and provocative with the unusual visual of a broken noose around the neck of a POM juice bottle. (CX1348 (Perdigao, Dep. 125-28)). Mr. Perdigao further testified that headline, graphics and line "Dying is so dead" were meant to be humorous, hyperbole and puffery. He said "it's going to extreme puffery in terms of the fact that our product is so healthy that this bottle was able to cheat death." (CX1348 (Perdigao, Dep. at 125-28)). Mr. Tupper also testified that much of the "Cheat death" advertisement was not meant to be interpreted literally, but was an example of puffery. (Tupper, Tr. 2987-90). Indeed, the NAD has found that the tagline "Cheat Death" to be in the realm of puffery and hyperbole. (CX0037; CX0055).

355. In response to additional complaints about the "Cheat Death" billboard advertisement, POM's consumer affairs representative also repeatedly told consumers (*e.g.*, in November 2008, January 2009, and again in April 2010) that POM's advertising was created with the intent of using imagery that irreverently and boldly conveys to consumers that drinking POM Juice "may help prevent disease" or is "incredibly healthy." (CX0456_0002-03; CX0454_0009-10).

Response to Finding No. 355:

With respect to whether the intent of this ad is to convey to consumers that drinking POM juice may help prevent disease, Mrs. Resnick specifically testified that this was not the intent of the ad, rather, the intent of the ad "is to stop you, make you chuckle and then go on and read and remember the shape of the bottle and the fact that we have a healthy message." (L. Resnick, Tr. 197).

356. The copy and images in these "Cheat Death" advertisements, particularly the references to prevention of heart disease, stroke, and cancer, convey the net impression that drinking eight ounces of POM Juice daily prevents or reduces the risk of heart disease. (CCFF ¶¶ 349-52, 354-55).

Response to Finding No. 356:

Complaint Counsel's finding misstates the evidence and the "Cheat Death" ads speak for themselves. Complaint Counsel misconstrue and misrepresent the message of these ads. Both "Cheat Death" ads prominently display a POM Juice bottle that resembles two-stacked pomegranates filled with ruby red pomegranate juice. (CX0036/CX0188). The words "100% Pomegranate Juice" appear on the face of the bottle with the P♥M logo in prominent letters. (CX0036/CX0188). Complaint Counsel's assertion that the ad implicitly conveys the message that drinking eight ounces of POM Juice daily prevents or reduces the risk of heart disease is not conspicuous, self-evident, or reasonably clear from the face of the ad. (CX0036/CX0188). Consequently, because the above-referenced challenged implied claim may not be determined with confidence from the face of the ad, extrinsic evidence must be examined.

Complaint Counsel erroneously rely upon the impact of only a few, select elements for their overall view of the net impression of an ad, and seemingly neglect at least two significant elements that are key to any facial or common sense net impression analysis—that POM Juice is wholly-derived from pomegranates, and POM Juice's effectiveness is based, at least in significant part, on the products' abundant antioxidants.

The overall net impression of this ad is not that drinking eight ounces of POM Juice daily prevents or reduces the risk of heart disease. (CX0036/CX0188). Even the language of the ad itself uses such qualifiers as "helps guard," "emerging science suggests," "contribute," and "encouraging results." (CX0036/CX0188). Instead, the "Cheat death" advertisement makes multiple efforts to convey that POM Juice is a whole food product that is wholly-derived from pomegranates, including: a) dominate imagery of deep, ruby red pomegranate juice in a bottle shaped like two pomegranates stacked on top of one

another; b) the words "100% Pomegranate Juice" clearly displayed on the face of the bottle; and c) repeated textual references to POM Wonderful 100% Pomegranate Juice.

Additionally, the ad emphasizes that POM Juice contains abundant naturally occurring antioxidants. For example, the "Heart therapy" ad states "You need antioxidants. And POM Wonderful 100% Pomegranate Juice is loaded with them."

Both the whole food aspect of the advertising and the emphasis on antioxidant content, directly counter any suggestion that POM Juice is going to act like a drug, as distinguished from a very healthy fruit or vegetable and a healthy diet.

Viewing the ad as a whole, taking into account all the various elements, including the prevalence and pervasiveness of the "whole-food" graphic, in the form of the POM Juice bottle, and body copy as well as the emphasis on the fact that POM Juice is a concentrated and potent source of antioxidants, it is far more logical that POM consumers would view POM Juice the way they perceive many other whole foods, like broccoli, blueberries, grapes or tomatoes, which may help prevent or improve your odds against disease, but which would not act like a drug with a single target of action against a particular disease or condition

To the extent a "reduce the risk" claim can be implied from ad, the overall net impression is not that drinking eight ounces of POM Juice "reduces the risk" of certain diseases, such as heart disease or prostate cancer, like a drug with a single target of action, but that it may help "reduce the risk," like many whole foods, or like an especially healthy fruit or vegetable, or like a healthy diet of fruits and vegetables and exercise "reduces the risk" of disease. (CX0036/CX0188).

To the extent a "treat" claim can be implied from this ad (which it cannot), the overall net impression of any ad is not that POM Juice is a substitute for conventional medical treatment. (Butters, Tr. 2821-22).

To the extent a "proven" claim can be implied from this ad (which it cannot), the overall impression of this ad is not that POM Juice is "proven" to be 100% effective in preventing, treating or reducing the risk of heart disease or prostate cancer because (1) all of the qualifying language contradicts an implied "clinically proven" interpretation, and (2) "proven" in science and to consumers means the "average person in the study benefitted." "Proven" does not mean that "everyone in the study necessarily benefitted" or that everyone will benefit like the persons who benefitted in the study. (Heber, Tr. 2011; Butters, Tr. 2893-2894; PX0361 (Sacks, Dep. at 81)).

The fact that POM advertised in *Prevention* and *Fitness* magazines is not damning. *Prevention* and *Fitness* magazines cater to health-conscious consumers and has sections on beauty, shopping, health, fitness, diet and nutrition. POM's advertising in *Prevention* and *Fitness* is entirely consistent with advertising of a food product whose messaging is how a whole food product fits into a healthy lifestyle and diet program. Contrary to the marketing themes suggested by Complaint Counsel that POM marketed POM Juice as a pharmaceutical drug with a single or narrow target of action, advertising in *Prevention* and *Fitness* does not show intent to convey that POM Juice "prevents," "treats," or "reduces the risk" the risk of certain diseases, such as heart disease or prostate cancer.

Mr. Resnick testified that POM's advertisements are not intended to convey the message that they can prevent or treat coronary heart disease. (S. Resnick, Tropicana, Dep. at 58-59). Although Mr. Resnick testified that POM believes pomegranate juice is beneficial in preventing and treating coronary heart disease, he does not want consumers to share this

belief, but rather to look at their science and make up their own mind. (S. Resnick, Tropicana, Dep. at 42-43). Mr. Resnick never intended POM products to be a substitute for recommended medical treatment or anything else recommended by a doctor. (S. Resnick, Tr. 1870). Mr. Tupper testified that it is absolutely against company policy to say or suggest that POM products are a substitute for proper medical treatment. (Tupper, Tr. 3018). In responding to health-related inquires or a question about a medical condition, POM instructs its employees to tell consumers to consult with his or her physician and strongly encourage this recommendation. (CX0308; Tupper, Tr. 3019).

Viewing the "Cheat death" ad as a whole, including the interaction of the words and visual imagery, the overall net impression of the ad is that it is a humorous ad that uses puffery and that POM Juice is a healthy product. (L. Resnick, Tr. 195-97).

Complaint Counsel presented no extrinsic evidence or expert opinion on this ad's meaning, consumer perceptions of this ad, or consumer interpretations regarding this ad. (PX0357 (Stewart, Dep. at 49, 52)). Complaint Counsel failed to present any evidence that the claims in this ad reasonably convey that the Challenged Products are "clinically proven" to prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction. Even assuming *arguendo* that this "Cheat death" ad conveys the message Complaint Counsel assigns to it, Professor Reibstein's survey effectively demonstrates that any alleged disease claims made by Respondents were not material to the purchasing decisions of POM consumers. (RFF 2623, 2630). Complaint Counsel have presented no reliable evidence to rebut Professor's Reibstein's survey findings or to show that any alleged disease claims made in POM's ads were material to the purchasing decisions of POM consumers. Complaint Counsel failed to present any evidence regarding the number of exposures consumers had to this ad or any particular POM advertisement.

g. "Decompress" Print Ad (CX0103)

357. In 2007, POM disseminated a juice advertisement with the headline "**Decompress**," which depicted the POM Juice bottle with logo wrapped in a blood pressure cuff. One version of the advertisement, disseminated in 2007 in *Health* magazine, *Prevention* magazine, and *New York* magazine, stated in the body copy:

Amaze your cardiologist. Drink P♥M Wonderful Pomegranate Juice. It helps guard your body against free radicals, unstable molecules that emerging science suggests aggressively destroy and weaken healthy cells in your body and contribute to disease. P♥M Wonderful Pomegranate Juice is supported by $20 million of initial scientific research from leading universities, which has uncovered encouraging results in prostate and cardiovascular health. Keep your ticker ticking and drink 8 ounces a day. **P♥M Wonderful Pomegranate Juice. The Antioxidant Superpower.**

The advertisement also directed consumers to POM's website, pomwonderful.com, directly under the POM logo. (CX0103).

Response to Finding No. 357:

Complaint Counsel misstates the evidence and the document speaks for itself. Complaint Counsel failed to present any evidence that Respondents would run this ad in the future, let alone whether it is probable they would do so. This ad cannot provide a basis for injunctive relief because (a) it ran almost four years ago; and (b) no evidence exists to show that Respondents are likely to run this ad in the future.

The fact that this ad depicts juice that is wholly-derived from the pomegranate fruit is heavily emphasized in the body copy and the visual imagery of the ad as well as on the product itself. There is a dominant image of deep, ruby red pomegranate juice in a bottle shaped like two pomegranates stacked on top of one another, the words "100% Pomegranate Juice" are clearly displayed on the face of the POM Juice bottle depicted and there is textual reference to "POM Wonderful 100% Pomegranate Juice". The ad emphasizes that POM Juice contains abundant naturally occurring antioxidants that may help guard your body against free radicals. For example, this ad references: a) "antioxidant superpower" and b) "free radicals." Complaint Counsel ignores, among

other elements, the overt puffery, outrageousness and humor in the headline and imagery and the blatant fact that POM Juice is 100% fruit juice.

The ad does not convey the message that (a) POM Juice "prevents," "treats," or "reduces the risk" of heart disease or prostate cancer; or (b) POM Juice is "clinically proven" to "prevent," "treat," or "reduce the risk" of heart disease or prostate cancer since this message is not conspicuous, self-evident, or reasonably clear from the face of the ad. Consequently, because no implied claim relating to prevention, treatment or reduction of risk may be determined with confidence from the face of the ad, extrinsic evidence must be examined. The overall net impression of this ad is not that (a) drinking eight ounces of POM Juice prevents, treats or reduces the risk of certain diseases, such as heart disease or prostate cancer; or (b) drinking eight ounces of POM Juice is "clinically proven" to prevent, treat or reduce the risk of certain diseases, such as heart disease or prostate cancer. Even the language of the ad itself uses such qualifiers as "helps guard," "emerging science suggests," "initial scientific research" and "encouraging results." (CX0103).

To the extent a "reduce the risk" claim can be implied from this ad, the overall net impression is not that drinking eight ounces of POM Juice "reduces the risk" of certain diseases, such as heart disease or prostate cancer, like a drug with a single target of action, but that it may help "reduce the risk," like many other whole foods, or like an especially healthy fruit or vegetable, or like a a healthy diet of fruits and vegetables and exercise "reduces the risk" of disease.

To the extent a "treat" claim can be implied from this ad (which it cannot), the overall net impression of any ad is not that POM Juice is a substitute for conventional medical treatment. (Butters, Tr. 2821-22; Appendix of Advertisements).

To the extent a "proven" claim can be implied from this ad (which it cannot), the overall net impression of this ad is not that POM Juice is "proven" to be 100% effective in preventing, treating or reducing the risk of heart disease or prostate cancer because (1) all of the qualifying language contradicts an implied "clinically proven" interpretation, and (2) "proven" in science and to consumers means the "average person in the study benefitted," not that "everyone in the study necessarily benefitted" or that everyone will benefit like the persons who benefitted in the study. (Heber, Tr. 2011; Butters, Tr. 2893-2894; PX0361 (Sacks, Dep. at 81)).

Professor Butters concluded that POM's ads in general depend on parody, exaggeration and humor to bring their message to the potential consumer; including the following messages: 1) POM is the best pomegranate that anyone can buy; 2) POM Juice is healthy; 3) POM Juice is tasty; 4) POM Juice is arguably the best source of antioxidants of any of the comparable beverages available; 5) medical research has suggested that antioxidants combat free radicals, which are unhealthy, and may contribute to diseases of the heart, arteries, and prostate, as well as erectile dysfunction; and 6) POM also offers concentrated forms of pomegranate extract for those who wish to ingest antioxidants in even more concentrated form than pomegranate juice itself. (PX0158-0033).

Complaint Counsel presented no extrinsic evidence or expert opinion on this ad's meaning, consumer perceptions of this ad, or consumer interpretations regarding this ad. (PX0357 (Stewart, Dep. at 49, 52)).

Complaint Counsel failed to present any evidence that the claims in this ad reasonably convey that POM Juice is "clinically proven" to prevent, treat or reduce the risk of heart disease or prostate cancer.

Complaint Counsel failed to present any evidence regarding the number of exposures consumers had to this ad or any particular POM advertisement. (Mazis, Tr. 2752).

The message that the ad actually conveys is that Respondents are committed to the science, and learning the truth about pomegranates. POM Wonderful 100% Pomegranate Juice is supported by $20 million of initial scientific research from leading universities, which has uncovered encouraging results in prostate and cardiovascular health. As Mrs. Resnick testified, the purpose of including the amount of money related to medical research in the advertising was to convey a message about the company, and its level of dedication to learning the truth about pomegranates. Mrs. Resnick testified, "[Respondents wanted] a very direct of communicating to the consumer that here was a natural food that had gone through rigorous scientific testing and that we cared enough to do this and we wanted to tell people that we had and continue to do scientific research." (L. Resnick, Tr. 251; see also CCFF 309, 311).

Therefore, Respondents' interpretation, which examines all the elements of the ad as whole, including, among other elements, the (1) outrageous and puffing headlines, (2) humorous visual images and (3) fact that the product is 100% fruit juice, is thus the most common-sense approach.

358. POM repeatedly disseminated advertisements with the headline "Decompress" and the blood pressure cuff imagery, including in 2007, 2008, and 2009. (Tupper, Tr. 976).

Response to Finding No. 358:

Complaint Counsel have presented no other definitive dissemination information regarding this particular ad. Mr. Tupper testified initially that the ad ran in 2008 and possibly in 2009. (Tupper, Tr. 976). However, on further reflection, Mr. Tupper testified that he did not think that the ad could have run in 2009. (Tupper, Tr. 3004). Thus, Respondents have not disseminated this advertisement since at least 2008. (Tupper, Tr. 3004). Complaint Counsel have presented no evidence to contradict Mr. Tupper's testimony that this "Decompress" ad has not run in over four years. Moreover, Complaint Counsel have presented no evidence that it is probable that Respondents

would run this type of ad again. Because this ad ceased running more than four years ago and there is no evidence that Respondents are likely to run this ad in the future, the ad provides no basis for injunctive relief.

359. Ms. Leow testified that the purpose of dressing the POM Juice bottle in a blood pressure cuff for the "Decompress" advertisement was to show or suggest that POM may be healthy for the heart and the arteries. (Leow, Tr. 489).

Response to Finding No. 359:

Complaint Counsel misconstrue Ms. Leow's testimony. The Aviram CIMT/BP Study (2004) and Davidson CIMT Study (2009) constitute competent and reliable scientific evidence that the consumption of POM Juice is beneficial to cardiovascular health by, among other things, reducing arterial plaque. (RFF 1111-1126; 1139-1146; 1288-1302; 1427-1504; PX0014; PX0611; PX0025-0009-0010; 0019-0022; PX0192-0036-0037, 0039; 0048, 005; Heber Tr. 1979-86; PX0014). The Ornish MP Study (2005) constitutes competent and reliable scientific evidence that the consumption of POM Juice is beneficial to cardiovascular health by, among other things, improving blood flow. (RFF 1127-1138; 1303-1414; PX0023; PX0025-0011-0018; PX0192-0037-0038; 0053, Ornish, Tr. 2354-55). Finally, the Aviram ACE/BP Study (2001) and Aviram CIMT/BP Study (2004) constitute competent and reliable scientific evidence that the consumption of POM Juice is beneficial to cardiovascular health by, among other things, improving blood pressure. (RFF 1107-1126; 1280-1302; CX0542; CX0611; PX0025-0009-0011; PX0192-0035-0037; 0052).

Mr. Resnick testified that POM's advertisements are not intended to convey the message that they can prevent or treat coronary heart disease. (S. Resnick, Tropicana, Dep. at 58-59). Similarly, Ms. Leow is not testifying that POM's advertisements convey the message that they can prevent or treat heart disease but rather that pomegranate juice may be healthy for the heart. (Leow, Tr. 489).

360. Mr. Tupper, in testifying about a POM advertisement depicting a blood pressure cuff at the trial in *POM Wonderful, LLC vs. Tropicana Products, Inc.*, stated that the advertisement is "*talking about . . . the fairly vast body of published medical research. Many of those studies are, in fact, on various elements of the cardiovascular system, including blood pressure, but many others as well.*" He further acknowledged there was a strong association between the image of the blood pressure cuff and receiving medical care: "[I]t's very obviously a blood pressure cuff, and that's typically the first thing that your doctor will do when you go in for a physical is check your blood pressure as a means of getting an overall picture on your health." (CX1406 (Tupper, Trop. Tr. at 0179) (emphasis added)).

Response to Finding No. 360:

Several of Respondents' witnesses testified that the intended message of the "Decompress" ad was not related to blood pressure. Mr. Tupper expressly stated that Respondents did not intend to convey a message about blood pressure with the "Decompress" headline and image. (Tupper, Tr. 3004). Mr. Tupper testified that the ad was intended to let people know that POM juice is a healthy and natural product, and it is backed by serious science indicating encouraging results for prostate and cardiovascular health. (Tupper, Tr. 3004-05). Mr. Tupper further testified that the blood pressure cuff coupled with the word "Decompress" was intended to convey a meaning of relaxation, de-stressing and general health. (Tupper, Tr. 3005). Indeed, the image of the blood pressure cuff image was intended to be a visual cue or a symbol that you would associate with cardiovascular health. (Tupper, Tr. 3005). Ms. Leow also testified that POM used the blood pressure cuff imagery to show or suggest that pomegranate juice may be healthy for the heart. (Leow, Tr. 489). Similarly, Mr. Resnick testified that the "Decompress" advertisement is a tongue- in-cheek way to show that POM is healthy and it will help your heart. (CX1376 (S. Resnick, Ocean Spray Dep. at 163-64)). Dr. Butters testified that it would be a gross exaggeration for anybody to think that the image of a blood pressure cuff around the POM Juice bottle and the headline "Decompress" could literally mean drink a glass of pomegranate juice and your blood pressure will go down. (Butters, Tr. 2933).

361. The copy and images in the "Decompress" advertisement, including the easily-recognizable blood pressure cuff and reference to cardiologists, as well as the statement that POM Juice would "[k]eep your ticker ticking," convey the net impression that drinking 8 ounces of POM Juice daily treats, prevents, or reduces the risk of heart disease, including by lowering blood pressure. In addition, by expressly stating that "[POM Juice] is supported by $20 million of initial scientific research," the advertisement further conveys the net impression that these benefits regarding heart disease are clinically proven. (CCFF ¶¶ 357, 359-60).

Response to Finding No. 361:

Nowhere in this ad do Respondents expressly (i.e., unequivocally and directly) state that (a) POM Juice "prevents," "treats," or "reduces the risk" of heart disease, prostate cancer and erectile dysfunction; or (b) POM Juice is "clinically proven" to "prevent," "treat," or "reduce the risk" of heart disease, prostate cancer and erectile dysfunction. (CX0103_0001; CX0459_0001).

Complaint Counsel's assertion that the ad implicitly conveys the net impression that drinking eight ounces of POM Juice daily treats, prevents, or reduces the risk of heart disease, including by lowering blood pressure is not conspicuous, self-evident, or reasonably clear from the face of the ad. (CX0103_0001; CX0459_0001). Consequently, extrinsic evidence must be examined.

Complaint Counsel erroneously rely upon the impact of only a few, select elements for their overall view of the net impression of an ad, and seemingly neglect at least two significant elements that are key to any facial or common sense net impression analysis—that POM Juice is wholly-derived from pomegranates, and the Challenged Products' effectiveness is based, at least in significant part, on the products' abundant antioxidants.

The overall net impression of this "Decompress" ad is not that (a) drinking eight ounces of POM Juice prevents, treats or reduces the risk of certain diseases, such as heart disease or prostate cancer; or (b) drinking eight ounces of POM Juice is "clinically proven" to prevent, treat or reduce the risk of certain diseases, such as heart disease or prostate

cancer. (CX0103_0001; CX0459_0001). Even the language of the ad itself uses the qualifiers "helps guard", "emerging science suggests," "initial scientific research," and "encouraging results." (CX0103_0001; CX0459_0001).

The "Decompress" advertisement makes multiple efforts to convey that POM Juice is a whole food product that is wholly-derived from pomegranates, including: a) dominate imagery of deep, ruby red pomegranate juice in a bottle shaped like two pomegranates stacked on top of one another; b) the words "100% Pomegranate Juice" clearly displayed on the face of the bottle; and c) repeated textual references to POM Wonderful Pomegranate Juice.

The ad emphasizes that POM Juice contains abundant naturally occurring antioxidants that may help guard your body against free radicals. For example, this ad references: a) "antioxidant superpower" and b) "free radicals." Complaint Counsel ignores, among other elements, the overt puffery, outrageousness and humor in the headline and imagery and the blatant fact that POM Juice is 100% fruit juice.

Both the whole food aspect of the advertising and the emphasis on antioxidant content, directly counter any suggestion that POM Juice is going to act like a drug, as distinguished from an especially healthy fruit or vegetable and a healthy diet.

Viewing the ad as a whole, taking into account all the various elements, including the prevalence and pervasiveness of the "whole-food" graphic, in the form of the POM Juice bottle, and body copy as well as the emphasis on the fact that POM Juice is a concentrated and potent source of antioxidants, it is far more logical that POM consumers would view POM Juice the way they perceive many other whole foods, like broccoli, blueberries, grapes or tomatoes, which may help prevent or improve your odds against disease, but which would not act like a drug with a single target of action against a particular disease or condition.

The body copy of the ad itself does not use the words "blood pressure" or say anything about "blood pressure." (CX0103_0001; CX0459_0001). The words "100% Pomegranate Juice" are displayed on face of the POM Juice bottle depicted in the "Decompress" ad. (CX0103_0001; CX0459_0001). To the extent, the "Decompress" print ad, which does not use the words "blood pressure" or say anything at all about "blood pressure", makes any claim (which Respondents dispute that it does), it is that POM Juice may help "reduces the risk," like many whole foods, or like an especially healthy fruit or vegetable, or like a healthy diet of fruits and vegetables and exercise "reduces the risk" of disease.

To the extent a "treat" claim can be implied from this ad (which it cannot), the overall net impression of any ad is not that POM Juice is a substitute for conventional medical treatment. (Butters, Tr. 2821-22).

To the extent a "proven" claim can be implied from this ad (which it cannot), the overall impression of "Decompress" is not that POM Juice is "proven" to be 100% effective in preventing, treating or reducing the risk of heart disease, prostate cancer or erectile dysfunction. "Proven" in science and to consumers means the "average person in the study benefitted." "Proven" does not mean that "everyone in the study necessarily benefitted" or that everyone will benefit like the persons who benefitted in the study. (Heber, Tr. 2011; Butters, Tr. 2893-2894; PX0361 (Sacks, Dep. at 81)).

Mr. Resnick testified that POM's advertisements are not intended to convey the message that they can prevent or treat coronary heart disease. (S. Resnick, Tropicana, Dep. at 58-59). Although Mr. Resnick testified that POM believes pomegranate juice is beneficial in preventing and treating coronary heart disease, he does not want consumers to share this belief, but rather to look at their science and make up their own mind. (S. Resnick, Tropicana, Dep. at 42-43). Mr. Resnick never intended POM products to be a substitute

for recommended medical treatment or anything else recommended by a doctor. (S. Resnick, Tr. 1870). Mr. Tupper testified that it is absolutely against company policy to say or suggest that POM products are a substitute for proper medical treatment. (Tupper, Tr. 3018). In responding to health-related inquires or a question about a medical condition, POM instructs its employees to tell consumers to consult with his or her physician and strongly encourage this recommendation. (CX0308; Tupper, Tr. 3019).

The fact that POM advertised in *Prevention* and *Health* magazines is not damning. *Prevention* and *Health* magazines cater to health-conscious consumers and has sections on beauty, shopping, health, fitness, diet and nutrition. POM's advertising in *Prevention* and *Health* is entirely consistent with advertising of a food product whose messaging is how a whole food product fits into a healthy lifestyle and diet program. Contrary to the marketing themes suggested by Complaint Counsel that POM marketed POM Juice as a pharmaceutical drug with a single or narrow target of action, advertising in *Prevention* and *Health* does not show intent to convey that POM Juice "prevents," "treats," or "reduces the risk" the risk of certain diseases, such as heart disease, including by lowering blood pressure.

Contrary to Complaint Counsel's implication, it is completely illogical to infer from the fact that a certain amount of money was invested in research to the conclusion that POM Juice is proven to prevent, treat or reduce the risk of disease. Complaint Counsel's attempts to make a "logical leaps" from "supported by $20 million of initial scientific research from leading universities, which has uncovered encouraging results in prostate and cardiovascular health" to supported by $20 million in research that proved POM Juice prevents, treats or reduces the risk of heart disease, prostate cancer or erectile dysfunction. What the "backed by" ads actually convey is that Respondents are committed to the science and learning the truth about pomegranates. (L. Resnick, Tr. 251). Complaint Counsel presented no evidence that consumers took away the message

presumed by Complaint Counsel because Respondents spent a certain amount of money on science and research. (RFF 28-29, 2515). Moreover, the ad accurately and truthfully represented the dollars spent by Respondents on the totality of the science on POM Juice. (RFF 2510).

Viewing the "Decompress" ad as a whole, including the interaction of the words and visual imagery, the overall net impression of the ad is that POM Juice is healthy, healthy for your heart and good for cardiovascular health. (See RFF 2331-2336; CX0103_0001; CX0459_0001). In contrast, Complaint Counsel failed to provide any expert opinion on the meaning of this "Decompress" ad or of consumer perceptions or interpretations the "Decompress" ad with body copy referenced above. Neither have Complaint Counsel presented any reliable evidence that this "Decompress" ad conveyed that POM Juice is "clinically proven" to prevent, treat or reduce the risk of heart disease.

362. Consumer research confirms that the headline and imagery alone of this advertisement created a net impression to consumers that POM Juice treats, prevents, or reduces the risk of heart disease, including by reducing blood pressure. (CCFF ¶¶ E.1.585-E.1.591).

Response to Finding No. 362:

Instead of providing any expert opinion regarding the meaning of this ad, Complaint Counsel have presented a conclusion from a 2009 survey of health-focused individuals conducted by the Bovitz Research Group (hereinafter "Bovitz Survey"), that found that approximately 14% of respondents who were shown only the "Decompress" billboard ad – i.e., an ad with the "Decompress" headline and image but no body copy - thought that the billboard indicated that POM Juice could help/lower blood pressure. (PX0225; Reibstein, Tr. 2515). Complaint Counsel, however, fail to mention that (1) 64% of the general population and 73% of the POM population stated the "main idea" of the billboard was "healthy/health benefits/juice"; (2) 16% of the general population and 20% of the POM population responded "antioxidants"; and (3) 6% of the general population

and 13% of the POM population said "calming, relieves stress/relaxing." (PX0295a15-0018, 46).

As testified to by Professor Reibstein, the Bovitz Survey is methodologically flawed, and substantively only relates to the "Decompress" ad without body copy. (*See* PX0223-0412). Complaint Counsel accordingly have presented no survey evidence or other evidence that anyone who viewed the "Decompress" headline and imagery with the body copy quoted above would construe that POM Juice is "clinically proven" to prevent, treat or reduce the risk of heart disease by lowering blood pressure.

Moreover, as set forth above, because Respondents stopped running this ad in 2008, which was a year before the Bovitz Survey was even conducted, (*see* RFF 2340, 2343) Complaint Counsel has not presented any evidence that it is probable that Respondents would run this type of ad again. Moreover, even assuming *arguendo* that Complaint Counsel contend that other portions of the ad are false and misleading, the advertisement's reference that POM can help guard your body against free radicals is true, (*see* RFF 780-87), and was substantiated by competent and reliable scientific evidence at the time it was made. (*Id.*). POM Wonderful 100% Pomegranate Juice is supported by $20 million of initial scientific research from leading universities, which has uncovered encouraging results in prostate and cardiovascular health. The advertisement's statement that "initial scientific research . . . has uncovered encouraging results in prostate and cardiovascular health" is also true, and was substantiated by competent and reliable scientific evidence, including the studies by Drs. Aviram, Ornish, Heber, Pantuck, Carducci and DeKernion. The Aviram CIMT/BP Study (2004) and Davidson CIMT Study (2009) constitute competent and reliable scientific evidence that the consumption of POM Juice is beneficial to cardiovascular health by, among other things, reducing arterial plaque. (RFF 1111-1126; 1139-1146; 1288-1302; 1427-1504; PX0014; PX0611; PX0025-0009-0010; 0019-0022; PX0192-0036-0037, 0039; 0048,

005; Heber Tr. 1979-86; PX0014). The Ornish MP Study (2005) constitutes competent and reliable scientific evidence that the consumption of POM Juice is beneficial to cardiovascular health by, among other things, improving blood flow. (RFF 1127-1138; 1303-1414; PX0023; PX0025-0011-0018; PX0192-0037-0038; 0053, Ornish, Tr. 2354-55). And the Aviram ACE/BP Study (2001) and Aviram CIMT/BP Study (2004) constitute competent and reliable scientific evidence that the consumption of POM Juice is beneficial to cardiovascular health by, among other things, improving blood pressure. (RFF 1107-1126; 1280-1302; CX0542; CX0611; PX0025-0009-0011; PX0192-0035-0037; 0052).

Finally, the words "can help," "initial" and "encouraging" also qualified the health-related message contained in the ad. (CX0103_0001; CX0459_0001). Complaint Counsel have failed to present any evidence regarding the number of exposures consumers had to this ad or any particular POM advertisement. (Mazis, Tr. 2752).

h. "Heart therapy" and "What gets your heart pumping?" Print Ads (CX0109) and (CX0192)

363. In April 2007, POM disseminated in *InStyle* and *Town and Country* magazines an advertisement with the headline "Heart therapy." The advertisement depicted a bottle of POM Juice with logo reclining on a couch, as in a therapist's office. The body copy of the advertisement stated:

> Seek professional help for your heart. Drink P♥M Wonderful Pomegranate Juice. It helps guard your body against free radicals, unstable molecules that emerging science suggests aggressively destroy and weaken healthy cells in your body and contribute to disease. P♥M Wonderful Pomegranate Juice is supported by $20 million of initial scientific research from leading universities, which has uncovered encouraging results in prostate and cardiovascular health. Keep your heart healthy and drink 8 ounces a day. **P♥M Wonderful Pomegranate Juice. The Antioxidant Superpower.**

The advertisement also directed consumers to POM's website, pomwonderful.com, directly under the POM logo. (CX0109).

Response to Finding No. 363:

Complaint Counsel misstates the evidence and the document speaks for itself. Complaint Counsel failed to present any evidence that Respondents would run this ad in the future, let alone whether it is probable they would do so. This ad cannot provide a basis for injunctive relief because (a) it ran almost five years ago; and (b) no evidence exists to show that Respondents are likely to run this ad in the future.

The ad featured a POM Juice bottle resembling two stacked pomegranates reclining on a chaise lounge. The fact that this ad depicts juice that is wholly-derived from the pomegranate fruit is heavily emphasized in the body copy and the visual imagery of the ad as well as on the product itself. There is a dominant image of deep, ruby red pomegranate juice in a bottle shaped like two pomegranates stacked on top of one another, the words "100% Pomegranate Juice" are clearly displayed on the face of the POM Juice bottle depicted and there is textual reference to "POM Wonderful 100% Pomegranate Juice". The ad emphasizes that POM Juice contains abundant naturally occurring antioxidants that may help guard your body against free radicals. For example, this ad references: a) "antioxidant superpower" and b) "free radicals." Complaint Counsel ignores, among other elements, the overt puffery, outrageousness and humor in the headline and imagery and the blatant fact that POM Juice is 100% fruit juice.

The ad does not convey the message that (a) POM Juice "prevents," "treats," or "reduces the risk" of heart disease or prostate cancer; or (b) POM Juice is "clinically proven" to "prevent," "treat," or "reduce the risk" of heart disease or prostate cancer since this message is not conspicuous, self-evident, or reasonably clear from the face of the ad. Consequently, because no implied claim relating to prevention, treatment or reduction of risk may be determined with confidence from the face of the ad, extrinsic evidence must be examined. The overall net impression of this ad is not that (a) drinking

eight ounces of POM Juice prevents, treats or reduces the risk of certain diseases, such as heart disease or prostate cancer; or (b) drinking eight ounces of POM Juice is "clinically proven" to prevent, treat or reduce the risk of certain diseases, such as heart disease or prostate cancer. Even the language of the ad itself uses such qualifiers as "helps guard," "emerging science suggests," "initial scientific research" and "encouraging results." (CX0109).

To the extent a "reduce the risk" claim can be implied from this ad, the overall net impression is not that drinking eight ounces of POM Juice "reduces the risk" of certain diseases, such as heart disease or prostate cancer, like a drug with a single target of action, but that it may help "reduce the risk," like many other whole foods, or like an especially healthy fruit or vegetable, or like a a healthy diet of fruits and vegetables and exercise "reduces the risk" of disease.

To the extent a "treat" claim can be implied from this ad (which it cannot), the overall net impression of any ad is not that POM Juice is a substitute for conventional medical treatment. (Butters, Tr. 2821-22; Appendix of Advertisements).

To the extent a "proven" claim can be implied from this ad (which it cannot), the overall net impression of this ad is not that POM Juice is "proven" to be 100% effective in preventing, treating or reducing the risk of heart disease or prostate cancer because (1) all of the qualifying language contradicts an implied "clinically proven" interpretation, and (2) "proven" in science and to consumers means the "average person in the study benefitted," not that "everyone in the study necessarily benefitted" or that everyone will benefit like the persons who benefitted in the study. (Heber, Tr. 2011; Butters, Tr. 2893-2894; PX0361 (Sacks, Dep. at 81)).

Professor Butters concluded that POM's ads in general depend on parody, exaggeration and humor to bring their message to the potential consumer; including the following

messages: 1) POM is the best pomegranate that anyone can buy; 2) POM Juice is healthy; 3) POM Juice is tasty; 4) POM Juice is arguably the best source of antioxidants of any of the comparable beverages available; 5) medical research has suggested that antioxidants combat free radicals, which are unhealthy, and may contribute to diseases of the heart, arteries, and prostate, as well as erectile dysfunction; and 6) POM also offers concentrated forms of pomegranate extract for those who wish to ingest antioxidants in even more concentrated form than pomegranate juice itself. (PX0158-0033).

Complaint Counsel presented no extrinsic evidence or expert opinion on this ad's meaning, consumer perceptions of this ad, or consumer interpretations regarding this ad. (PX0357 (Stewart, Dep. at 49, 52))

Complaint Counsel failed to present any evidence that the claims in this ad reasonably convey that POM Juice is "clinically proven" to prevent, treat or reduce the risk of heart disease or prostate cancer.

Complaint Counsel failed to present any evidence regarding the number of exposures consumers had to this ad or any particular POM advertisement. (Mazis, Tr. 2752).

The message that the ad actually conveys is that Respondents are committed to the science, and learning the truth about pomegranates. POM Wonderful 100% Pomegranate Juice is supported by $20 million of initial scientific research from leading universities, which has uncovered encouraging results in prostate and cardiovascular health. As Mrs. Resnick testified, the purpose of including the amount of money related to medical research in the advertising was to convey a message about the company, and its level of dedication to learning the truth about pomegranates. Mrs. Resnick testified, "[Respondents wanted] a very direct of communicating to the consumer that here was a natural food that had gone through rigorous scientific testing and that we cared enough to

do this and we wanted to tell people that we had and continue to do scientific research." (L. Resnick, Tr. 251; see also CCFF 309, 311).

Therefore, Respondents' interpretation, which examines all the elements of the ad as whole, including, among other elements, the (1) outrageous and puffing headlines, (2) humorous visual images and (3) fact that the product is 100% fruit juice, is thus the most common-sense approach.

Viewing the "Heart Therapy" ad a whole, including the interaction of the words and visual imagery, the overall net impression of this ad is that it is a humorous ad and that POM Juice is a healthy product. ((PX0158-0033); (CX1364 (Tupper, Dep. at 293-94))).

364. In May 2008, POM disseminated an advertisement headlined "What gets your heart pumping?" and featuring an image of a POM bottle sideways, in a bikini top on a clothesline. The body copy read, "Supermodels or beaches? 36-24-36? Or perhaps healthy arteries . . . . P♥M Wonderful 100% Pomegranate Juice is supported by $23 million of initial scientific research from leading universities, which has uncovered encouraging results in prostate and cardiovascular health. Eight ounces a day is enough to keep your heart pumping, even if you're not dating a supermodel." (CX0192 (disseminated in *Men's Health* magazine)).

Response to Finding No. 364:

Complaint Counsel misstates the evidence and the document speaks for itself. Complaint Counsel failed to present any evidence that Respondents would run this ad in the future, let alone whether it is probable they would do so. This ad cannot provide a basis for injunctive relief because (a) it ran almost four years ago; and (b) no evidence exists to show that Respondents are likely to run this ad in the future.

Complaint counsel also omitted textual copy on this ad, which stated that POM Juice "helps" guard your body against free radicals that "emerging" science "suggests" destroy healthy cells in your body and contribute to disease. (CX0192).

The fact that this ad depicts juice that is wholly-derived from the pomegranate fruit is heavily emphasized in the body copy and the visual imagery of the ad as well as on the product itself. There is a dominant image of deep, ruby red pomegranate juice in bottle shaped like two pomegranates side by side, the words "100% Pomegranate Juice" are clearly displayed on the face of the POM Juice bottle depicted and there is repeated textual reference to "POM Wonderful 100% Pomegranate Juice". The ad emphasizes that POM Juice contains abundant naturally occurring antioxidants that may help guard your body against free radicals. For example, this ad references: a) "antioxidant superpower" and b) "free radicals." Complaint Counsel ignores, among other elements, the overt puffery, outrageousness and humor in the headline and imagery and the blatant fact that POM Juice is 100% fruit juice.

The ad does not convey the message that (a) POM Juice "prevents," "treats," or "reduces the risk" of heart disease or prostate cancer; or (b) POM Juice is "clinically proven" to "prevent," "treat," or "reduce the risk" of heart disease since this message is not conspicuous, self-evident, or reasonably clear from the face of the ad. Consequently, because there is no implied claim relating to prevention, treatment or reduction of risk that may be determined with confidence from the face of the ad, extrinsic evidence must be examined. The overall net impression of this ad is not that (a) drinking eight ounces of POM Juice prevents, treats or reduces the risk of certain diseases, such as heart disease; or (b) drinking eight ounces of POM Juice is "clinically proven" to prevent, treat or reduce the risk of certain diseases, such as heart. Even the language of the ad itself uses such qualifiers as "helps guard," "emerging science suggests," "initial scientific research" and "encouraging results." (CX0192).

To the extent a "reduce the risk" claim can be implied from this ad, the overall net impression is not that drinking eight ounces of POM Juice "reduces the risk" of certain diseases, such as heart disease or prostate cancer, like a drug with a single target of

action, but that it may help "reduce the risk," like many other whole foods, or like an especially healthy fruit or vegetable, or like a a healthy diet of fruits and vegetables and exercise "reduces the risk" of disease.

To the extent a "treat" claim can be implied from this ad (which it cannot), the overall net impression of any ad is not that POM Juice is a substitute for conventional medical treatment. (Butters, Tr. 2821-22; Appendix of Advertisements).

To the extent a "proven" claim can be implied from this ad (which it cannot), the overall net impression of this ad is not that POM Juice is "proven" to be 100% effective in preventing, treating or reducing the risk of heart disease or prostate cancer because (1) all of the qualifying language contradicts an implied "clinically proven" interpretation, and (2) "proven" in science and to consumers means the "average person in the study benefitted," not that "everyone in the study necessarily benefitted" or that everyone will benefit like the persons who benefitted in the study. (Heber, Tr. 2011; Butters, Tr. 2893-2894; PX0361 (Sacks, Dep. at 81)).

Professor Butters concluded that POM's ads in general depend on parody, exaggeration and humor to bring their message to the potential consumer; including the following messages: 1) POM is the best pomegranate that anyone can buy; 2) POM Juice is healthy; 3) POM Juice is tasty; 4) POM Juice is arguably the best source of antioxidants of any of the comparable beverages available; 5) medical research has suggested that antioxidants combat free radicals, which are unhealthy, and may contribute to diseases of the heart, arteries, and prostate, as well as erectile dysfunction; and 6) POM also offers concentrated forms of pomegranate extract for those who wish to ingest antioxidants in even more concentrated form than pomegranate juice itself. (PX0158-0033). Mr. Tupper also testified that this ad portrays a take on the female anatomy and conveys that the juice is a healthy product. (CX1364 (Tupper, Dep. at 293-94)).

Complaint Counsel presented no extrinsic evidence or expert opinion on this ad's meaning, consumer perceptions of this ad, or consumer interpretations regarding this ad. (PX0357 (Stewart, Dep. at 49, 52))

Complaint Counsel failed to present any evidence that the claims in this ad reasonably conveys that POM Juice is "clinically proven" to prevent, treat or reduce the risk of heart disease or prostate cancer.

Complaint Counsel failed to present any evidence regarding the number of exposures consumers had to this ad or any particular POM advertisement. (Mazis, Tr. 2752).

The fact that POM advertised in Men's Health is not damning. Men's Health magazine caters to health-conscious consumers and has sections on beauty, shopping, health, fitness, diet and nutrition. POM's advertising in Men's Health is entirely consistent with advertising of a food product whose messaging is how a whole food product fits into a healthy lifestyle and diet program. Contrary to the marketing themes suggested by Complaint Counsel that POM marketed POM Juice as a pharmaceutical drug with a single or narrow target of action, advertising in Men's Health does not show intent to convey that POM Juice "prevents," "treats," or "reduces the risk" of heart disease or prostate cancer.

The message that the ad actually conveys is that Respondents are committed to the science, and learning the truth about pomegranates. POM Wonderful 100% Pomegranate Juice is supported by $23 million of initial scientific research from leading universities, which has uncovered encouraging results in prostate and cardiovascular health. As Mrs. Resnick testified, the purpose of including the amount of money related to medical research in the advertising was to convey a message about the company, and its level of dedication to learning the truth about pomegranates. Mrs. Resnick testified, "[Respondents wanted] a very direct of communicating to the consumer that here was a

natural food that had gone through rigorous scientific testing and that we cared enough to do this and we wanted to tell people that we had and continue to do scientific research." (L. Resnick, Tr. 251; see also CCFF 309, 311).

Therefore, Respondents' interpretation, which examines all the elements of the ad as whole, including, among other elements, the (1) outrageous and puffing headlines, (2) humorous visual images and (3) fact that the product is 100% fruit juice, is thus the most common-sense approach.

Viewing the "What gets your heart pumping?" ad a whole, including the interaction of the words and visual imagery, the overall net impression of this ad is that it is a humorous ad and that POM Juice is a healthy product. ((PX0158-0033); (CX1364 (Tupper, Dep. at 293-94))).

365. When shown the bikini top advertisement in a prior litigation, Mr. Tupper testified that "[t]here's been quite a lot of published medical science around the cardiovascular benefits associated with pomegranate juice, so heart pumping obviously refers to that research." (CX1364 (Tupper, TCCC Dep. at 293-94)).

Response to Finding No. 365:

Complaint Counsel failed to cite the immediately preceding two statements made by Mr. Tupper regarding the POM bottle in the ad, which are as follows (1) "it's encased in what appear to be a bikini top… taken on a form of the female anatomy, if you will" and (2) "That's at least the visual, and so again the notion is incredibly healthy product." What Mr. Tupper is actually referring to in the testimony quoted in Finding No. 365 is the double entendre regarding "heart pumping" and the visual present in the ad. The visual of the ad is a POM bottle lying on its side, placed in a bikini top with each of the two bubbles of the bottle placed strategically in each cup of the bikini to resemble a woman's breasts with the opening copy that reads, "Supermodels or beaches? 36-24-36?" (CX0192). Mr. Tupper was clearly referring to the visual in his testimony. Contrary to

Complaint Counsel's implication, it is completely illogical to infer from the fact that a medical research was published to the conclusion that POM Juice is proven to prevent, treat or reduce the risk of disease.

366. The "Heart Therapy" and "Heart Pumping" advertisements have almost identical body copy to the "Decompress" advertisement. As Mr. Tupper described with respect to the "Decompress" advertisement, POM considers the "scientific research" referred to in these advertisements to be the "fairly vast body of published medical research . . . on various elements of the cardiovascular system[.]" (CX1406 (Tupper, Trop. Tr. at 0179)).

Response to Finding No. 366:

Complaint Counsel misstate and misconstrue the message of the "Heart Therapy" and "Heart Pumping" ads and brazenly state that since they have similar body copy to the "Decompress" advertisement, testimony referring to the "Decompress" ad applies to the "Heart Therapy" and "Heart Pumping" ads. Insinuating that testimony given for one advertisement applies to another is outrageous. Each document speaks for itself and Complaint Counsel cannot re-write the advertisement or apply testimony made regarding a completely separate and distinct advertisement to convey a meaning that it does not contain.

Furthermore, several of Respondents' witnesses testified that the intended message of the "Decompress" ad was not related to blood pressure. Mr. Tupper expressly stated that Respondents did not intend to convey a message about blood pressure with the "Decompress" headline and image. (Tupper, Tr. 3004). Mr. Tupper testified that the ad was intended to let people know that POM juice is a healthy and natural product, as well as that it is backed by serious science indicating encouraging results for prostate and cardiovascular health. (Tupper, Tr. 3004-05). Mr. Tupper further testified that the blood pressure cuff coupled with the word "Decompress" was intended to convey a meaning of relaxation, de-stressing and general health. (Tupper, Tr. 3005). Indeed, the image of the blood pressure cuff image was intended to be a visual cue or a symbol that you would

associate with cardiovascular health. (Tupper, Tr. 3005). Ms. Leow also testified that POM used the blood pressure cuff imagery to show or suggest that pomegranate juice may be healthy for the heart. (Leow, Tr. 489). Similarly, Mr. Resnick testified that the "Decompress" advertisement is a tongue- in-cheek way to show that POM is healthy and it will help your heart. (CX1376 (S. Resnick, Ocean Spray Dep. at 163-64)). Dr. Butters testified that it would be a gross exaggeration for anybody to think that the image of a blood pressure cuff around the POM Juice bottle and the headline "Decompress" could literally mean drink a glass of pomegranate juice and your blood pressure will go down. (Butters, Tr. 2933).

367. The copy and images in the advertisements, including the bold headlines "Heart therapy," and "What gets your heart pumping" and text advising consumers to "[k]eep your heart healthy and drink 8 ounces a day," or "[e]ight ounces a day is enough to keep your heart pumping," convey the net impression that drinking eight ounces of [POM Juice] daily prevents or reduces the risk of heart disease. In addition, by expressly stating that POM Juice is supported by $20 [or $23] million of scientific research, the advertisements further convey the net impression that this benefit regarding heart disease is clinically proven. (CCFF ¶¶ 363-66).

Response to Finding No. 367:

Complaint Counsel misstates the evidence and the documents speak for themselves. Complaint Counsel failed to present any evidence that Respondents would run these ads in the future, let alone whether it is probable they would do so.

The fact that these ads depict juice that is wholly-derived from the pomegranate fruit is heavily emphasized in the body copy and the visual imagery of the ads as well as on the product itself. There is a dominant image of deep, ruby red pomegranate juice in a bottle shaped like two pomegranates stacked on top of one another in each of the ads, the words "100% Pomegranate Juice" are clearly displayed on the face of the POM Juice bottles depicted and there are textual references to "POM Wonderful 100% Pomegranate Juice". The ads emphasize that POM Juice contains abundant naturally occurring antioxidants that may help guard your body against free radicals. For example, these ads reference: a)

"antioxidant superpower" and b) "free radicals." Complaint Counsel ignores, among other elements, the overt puffery, outrageousness and humor in the headlines and imagery and the blatant fact that POM Juice is 100% fruit juice.

The ads do not convey the message that (a) POM Juice "prevents," "treats," or "reduces the risk" of heart disease or prostate cancer; or (b) POM Juice is "clinically proven" to "prevent," "treat," or "reduce the risk" of heart disease or prostate cancer since these messages are not conspicuous, self-evident, or reasonably clear from the face of the ads. Consequently, because no implied claim relating to prevention, treatment or reduction of risk may be determined with confidence from the face of the ads, extrinsic evidence must be examined.

The overall net impressions of these ads are not that (a) drinking eight ounces of POM Juice prevents, treats or reduces the risk of certain diseases, such as heart disease or prostate cancer; or (b) drinking eight ounces of POM Juice is "clinically proven" to prevent, treat or reduce the risk of certain diseases, such as heart disease or prostate cancer. Even the language of the ads themselves use such qualifiers as "helps guard," "emerging science suggests," "initial scientific research" and "encouraging results." (CX0192; CX0109).

To the extent a "reduce the risk" claim can be implied from these ads, the overall net impression is not that drinking eight ounces of POM Juice "reduces the risk" of certain diseases, such as heart disease or prostate cancer, like a drug with a single target of action, but that it may help "reduce the risk," like many other whole foods, or like an especially healthy fruit or vegetable, or like a a healthy diet of fruits and vegetables and exercise "reduces the risk" of disease.

To the extent a "treat" claim can be implied from these ads (which it cannot), the overall net impression of any ad is not that POM Juice is a substitute for conventional medical treatment. (Butters, Tr. 2821-22; Appendix of Advertisements).

To the extent a "proven" claim can be implied from these ads (which it cannot), the overall net impressions of these ads are not that POM Juice is "proven" to be 100% effective in preventing, treating or reducing the risk of heart disease or prostate cancer because (1) all of the qualifying language contradicts an implied "clinically proven" interpretation, and (2) "proven" in science and to consumers means the "average person in the study benefitted," not that "everyone in the study necessarily benefitted" or that everyone will benefit like the persons who benefitted in the study. (Heber, Tr. 2011; Butters, Tr. 2893-2894; PX0361 (Sacks, Dep. at 81)).

Professor Butters concluded that POM's ads in general depend on parody, exaggeration and humor to bring their message to the potential consumer; including the following messages: 1) POM is the best pomegranate that anyone can buy; 2) POM Juice is healthy; 3) POM Juice is tasty; 4) POM Juice is arguably the best source of antioxidants of any of the comparable beverages available; 5) medical research has suggested that antioxidants combat free radicals, which are unhealthy, and may contribute to diseases of the heart, arteries, and prostate, as well as erectile dysfunction; and 6) POM also offers concentrated forms of pomegranate extract for those who wish to ingest antioxidants in even more concentrated form than pomegranate juice itself. (PX0158-0033).

Complaint Counsel presented no extrinsic evidence or expert opinion on the meaning of these ads, consumer perceptions of these ads, or consumer interpretations regarding these ads. (PX0357 (Stewart, Dep. at 49, 52))

Complaint Counsel failed to present any evidence that the claims in these ads reasonably convey that POM Juice is "clinically proven" to prevent, treat or reduce the risk of heart disease or prostate cancer.

Complaint Counsel failed to present any evidence regarding the number of exposures consumers had to these ads or any particular POM advertisement. (Mazis, Tr. 2752).

Therefore, Respondents' interpretation, which examines all the elements of the ads as whole, including, among other elements, the (1) outrageous and puffing headlines, (2) humorous visual images and (3) fact that the product is 100% fruit juice, is thus the most common-sense approach. Complaint Counsel erroneously relies on the "impact of each or a few elements" for their overall view of the net impression of the ads, (Compl. Counsel's Post-Trial Br. at 20-22), and seemingly neglect a significant element that is key to any facial or common-sense net impression analysis – that the advertisements are of products wholly-derived from pomegranates.

2. POM Juice Print Ads Made Establishment Claims Regarding Prostate Cancer

a. "Drink to Prostate Health" Print Ad (CX0260)

368. An advertisement for POM Juice, disseminated in December 2008 in *Men's Health* and *Prevention* magazines with the headline, "**Drink to prostate health,**" featured a stark image of a POM Juice bottle with logo against a bright red background (the same color as the juice). (CX0260_0002). The advertisement's body copy stated:

> Sometimes, good medicine can taste great. Case in point: P♥m Wonderful. A recently published preliminary medical study followed 46 men previously treated for prostate cancer, either with surgery or radiation. After drinking 8 ounces of P♥M Wonderful 100% Pomegranate Juice daily for at least two years, these men experienced significantly longer PSA doubling times. Want to learn more about this study? Visit pomwonderful.com/prostate. **Trust in P♥M.**

(CX0260; *see also* CX1426_00028).

Response to Finding No. 368:

Complaint Counsel misstates the evidence and the document speaks for itself. Complaint Counsel failed to present any evidence that Respondents would run these ads in the future, let alone whether it is probable they would do so. This ad cannot provide a basis for injunctive relief because (a) it ran almost four years ago; and (b) no evidence exists to show that Respondents are likely to run this ad in the future.

The fact that this ad depicts juice that is wholly-derived from the pomegranate fruit is heavily emphasized in the body copy and the visual imagery of the ad as well as on the product itself. There is a dominant image of deep, ruby red pomegranate juice in a bottle shaped like two pomegranates stacked on top of one another, the words "100% Pomegranate Juice" are clearly displayed on the face of the POM Juice bottle depicted and there is repeated textual reference to "POM Wonderful 100% Pomegranate Juice". Complaint Counsel ignores, among other elements, the overt puffery, outrageousness and humor in the headlines and imagery and the blatant fact that POM Juice is 100% fruit juice.

The fact that POM advertised in Men's Health and Prevention magazines is not damning. Men's Health and Prevention magazines cater to health-conscious consumers and have sections on beauty, shopping, health, fitness, diet and nutrition. POM's advertising in Men's Health and Prevention magazines are entirely consistent with advertising of a food product whose messaging is how a whole food product fits into a healthy lifestyle and diet program. Contrary to the marketing themes suggested by Complaint Counsel that POM marketed POM Juice as a pharmaceutical drug with a single or narrow target of action, advertising in Men's Health and Prevention Magazines do not show intent to convey that POM Juice "prevents," "treats," or "reduces the risk" of prostate cancer.

Nowhere in this ad do Respondents expressly (*i.e.*, unequivocally and directly) state that (a) POM Juice "prevents," "treats," or "reduces the risk" of prostate cancer; or (b) POM Juice is "clinically proven" to "prevent," "treat," or "reduce the risk" of prostate cancer. (CX260_0001; CX1426_0028, Exh. B). Complaint Counsel's assertion that the ad impliedly conveys the message that (a) POM Juice "prevents," "treats," or "reduces the risk" of prostate cancer, like a drug; or (b) POM Juice is "clinically proven" to "prevent," "treat," or "reduce the risk" of prostate cancer, like a drug, is not conspicuous, self-evident, or reasonably clear from the face of the ad. (CX260_0001; CX1426_0028, Exh. B). Consequently, because the above-referenced challenged implied claim may not be determined with confidence from the face of the ad, extrinsic evidence must be examined. The overall net impression of this ad is not that (a) drinking eight ounces of POM Juice prevents, treats or reduces the risk of certain diseases, such as prostate cancer, like a drug; or (b) drinking eight ounces of POM Juice is "clinically proven" to prevent, treat or reduce the risk of certain diseases, such as prostate cancer, like a drug. (CX260_0001; CX1426_0028, Exh. B).

While the ad cited some of POM's underlying research, those statements were qualified with language like, "preliminary medical study". Furthermore, competent and reliable scientific evidence supports the conclusion that the consumption of pomegranate juice supports prostate health. (PX0161; PX0353 (Heber, Dep. at 84-85)).

To the extent a "reduce the risk" claim can be implied from the ad, the overall net impression is not that drinking eight ounces of POM Juice "reduces the risk" of certain diseases, such as prostate cancer, like a drug with a single target of action, but that it may help "reduce the risk," like many other whole foods, or like an especially healthy fruit or vegetable, or like a a healthy diet of fruits and vegetables and exercise "reduces the risk" of disease. (CX260_0001; CX1426_0028, Exh. B).

To the extent a "treat" claim can be implied from this ad (which it cannot), the overall net impression of any ad is not that POM Juice is a substitute for conventional medical treatment. (Butters, Tr. 2821-22).

To the extent a "proven" claim can be implied from this ad (which it cannot), the overall net impression of this ad is not that POM Juice is "proven" to be 100% effective in preventing, treating or reducing the risk of prostate cancer because (1) all of the qualifying language contradicts an implied "clinically proven" interpretation, and (2) "proven" in science and to consumers means the "average person in the study benefitted," not that "everyone in the study necessarily benefitted" or that everyone will benefit like the persons who benefitted in the study. (Heber, Tr. 2011; Butters, Tr. 2893-2894; PX0361 (Sacks, Dep. at 81)).

Professor Butters testified that this advertisement employs humor and references an alcoholic beverage toast. (PX0350 (Butters, Dep. at 119-20)). He does not believe that any reasonable viewer could find that the advertisement communicates that it could treat, prevent, or reduce the risk of disease. (PX0350 (Butters, Dep. at 121-124)). Professor Butters testified that there may be some outliers that may interpret the ad as making a health claim but those outliers would, by definition, not be ordinary or normal. (PX0350 (Butters, Dep. at 124-25)).

Professor Butters concluded that POM's ads in general depend on parody, exaggeration and humor to bring their message to the potential consumer; including the following messages: 1) POM is the best pomegranate that anyone can buy; 2) POM Juice is healthy; 3) POM Juice is tasty; 4) POM Juice is arguably the best source of antioxidants of any of the comparable beverages available; 5) medical research has suggested that antioxidants combat free radicals, which are unhealthy, and may contribute to diseases of the heart, arteries, and prostate, as well as erectile dysfunction; and 6) POM also offers

concentrated forms of pomegranate extract for those who wish to ingest antioxidants in even more concentrated form than pomegranate juice itself. (PX0158-0033).

Ms. Leow testified that this ad was part of the "Trust in Pom" campaign and that the campaign's message was to let people know that POM Juice is healthy and is made with 100 percent pomegranate juice from California-grown pomegranates. (PX0330 (Leow, Dep. at 102-04)). Viewing the "Drink to prostate health" ad as a whole, including the interaction of the words and visual imagery, the overall net impression of the ad is that it is a humorous reference to an alcoholic toast, that POM Juice is healthy and is made with 100 percent pomegranate juice from California-grown pomegranates. (PX0350 (Butters, Dep. at 124-25); (PX0330 (Leow, Dep. at 104)).

Complaint Counsel presented no extrinsic evidence or expert opinion on this ad's meaning, consumer perceptions of this ad, or consumer interpretations regarding this ad. (PX0357 (Stewart, Dep. at 49, 52)). Complaint Counsel also failed to present any evidence (1) that the claims in this ad reasonably convey that POM Juice is "clinically proven" to prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction and failed to present any evidence (2) regarding the number of exposures consumers had to this ad or any particular POM advertisement. (Mazis, Tr. 2752).

369. In testifying about this advertisement in the *POM vs. Tropicana* lawsuit, Mr. Tupper noted that although POM tries "to have a pleasant, humorous, cute, funny voice, [in this advertisement] we're talking about some very serious published research on pomegranate juice and, in this particular case, it was a study looking at men with advanced prostate cancer. So, it's clearly a very serious topic." (CX1406 (Tupper, Trop. Tr. at 0178)).

Response to Finding No. 369:

Complaint Counsel misconstrues the testimony. Mr. Tupper testified that the research is serious, but the overall net impression of this ad is light hearted.

Professor Butters testimony supports Mr. Tuppers testimony when Professor Butters testified that this advertisement employs humor and references an alcoholic beverage toast. (PX0350 (Butters, Dep. at 119-20)). He does not believe that any reasonable viewer could find that the advertisement communicates that it could treat, prevent, or reduce the risk of disease. (PX0350 (Butters, Dep. at 121-124)). Professor Butters testified that there may be some outliers that may interpret the ad as making a health claim but those outliers would, by definition, not be ordinary or normal. (PX0350 (Butters, Dep. at 124-25)). Viewing the "Drink to prostate health" ad as a whole, including the interaction of the words and visual imagery, the overall net impression of the ad is that it is a humorous reference to an alcoholic toast, that POM Juice is healthy and is made with 100 percent pomegranate juice from California-grown pomegranates. (PX0350 (Butters, Dep. at 124-25); (PX0330 (Leow, Dep. at 104)).

370. Dr. Butters testified that the inference from this advertisement is that POM Juice may be beneficial for people who have had prostate cancer. (Butters, Tr. 2943-44).

Response to Finding No. 370:

Complaint Counsel misconstrues the testimony. Complaint Counsel omits that Professor Butters also testified that this advertisement employs humor and references an alcoholic beverage toast. (PX0350 (Butters, Dep. at 119-20)). Complaint Counsel also conveniently omits Professor Butters' testimony that he does not believe that any reasonable viewer could find that the advertisement communicates that it could treat, prevent, or reduce the risk of disease. (PX0350 (Butters, Dep. at 121-124)). Professor Butters further testified that there may be some outliers that may interpret the ad as making a health claim but those outliers would, by definition, not be ordinary or normal. (PX0350 (Butters, Dep. at 124-25)).

Professor Butters concluded that POM's ads in general depend on parody, exaggeration and humor to bring their message to the potential consumer; including the following

messages: 1) POM is the best pomegranate that anyone can buy; 2) POM Juice is healthy; 3) POM Juice is tasty; 4) POM Juice is arguably the best source of antioxidants of any of the comparable beverages available; 5) medical research has suggested that antioxidants combat free radicals, which are unhealthy, and may contribute to diseases of the heart, arteries, and prostate, as well as erectile dysfunction; and 6) POM also offers concentrated forms of pomegranate extract for those who wish to ingest antioxidants in even more concentrated form than pomegranate juice itself. (PX0158-0033).

371. This advertisement, with a description of a study on prostate cancer patients and a bold headline advising consumers to "drink to prostate health," conveys the net impression that drinking eight ounces of POM Juice daily treats prostate cancer, including by slowing PSA doubling-time. Moreover, the advertisement's reference to a specific medical study conveys the net impression that POM's benefits for prostate cancer have been proven by clinical testing. (CCFF ¶¶ 368-70).

Response to Finding No. 371:

Complaint Counsel misstates the evidence and the document speaks for itself. The fact that this ad depicts juice that is wholly-derived from the pomegranate fruit is heavily emphasized in the body copy and the visual imagery of the ad as well as on the product itself. There is a dominant image of deep, ruby red pomegranate juice in a bottle shaped like two pomegranates stacked on top of one another, the words "100% Pomegranate Juice" are clearly displayed on the face of the POM Juice bottle depicted and there is repeated textual reference to "POM Wonderful 100% Pomegranate Juice".

Nowhere in this ad do Respondents expressly (*i.e.*, unequivocally and directly) state that (a) POM Juice "prevents," "treats," or "reduces the risk" of prostate cancer; or (b) POM Juice is "clinically proven" to "prevent," "treat," or "reduce the risk" of prostate cancer. (CX260_0001; CX1426_0028, Exh. B). Complaint Counsel's assertion that the ad impliedly conveys the message that (a) POM Juice "prevents," "treats," or "reduces the risk" of prostate cancer, like a drug; or (b) POM Juice is "clinically proven" to "prevent," "treat," or "reduce the risk" of prostate cancer, like a drug, is not conspicuous,

self-evident, or reasonably clear from the face of the ad. (CX260_0001; CX1426_0028, Exh. B). Consequently, because the above-referenced challenged implied claim may not be determined with confidence from the face of the ad, extrinsic evidence must be examined. The overall net impression of this ad is not that (a) drinking eight ounces of POM Juice prevents, treats or reduces the risk of certain diseases, such as prostate cancer, like a drug; or (b) drinking eight ounces of POM Juice is "clinically proven" to prevent, treat or reduce the risk of certain diseases, such as prostate cancer, like a drug. (CX260_0001; CX1426_0028, Exh. B).

While the ad cited some of POM's underlying research, those statements were qualified with language like, "preliminary medical study". Furthermore, competent and reliable scientific evidence supports the conclusion that the consumption of pomegranate juice and pomegranate extract supports prostate health. (PX0161; PX0353 (Heber, Dep. at 84-85)).

To the extent a "reduce the risk" claim can be implied from the ad, the overall net impression is not that drinking eight ounces of POM Juice "reduces the risk" of certain diseases, such as prostate cancer, like a drug with a single target of action, but that it may help "reduce the risk," like many other whole foods, or like an especially healthy fruit or vegetable, or like a a healthy diet of fruits and vegetables and exercise "reduces the risk" of disease. (CX260_0001; CX1426_0028, Exh. B).

To the extent a "treat" claim can be implied from this ad (which it cannot), the overall net impression of any ad is not that POM Juice is a substitute for conventional medical treatment. (Butters, Tr. 2821-22).

To the extent a "proven" claim can be implied from this ad (which it cannot), the overall net impression of this ad is not that POM Juice is "proven" to be 100% effective in preventing, treating or reducing the risk of prostate cancer because (1) all of the

qualifying language contradicts an implied "clinically proven" interpretation, and (2) "proven" in science and to consumers means the "average person in the study benefitted," not that "everyone in the study necessarily benefitted" or that everyone will benefit like the persons who benefitted in the study. (Heber, Tr. 2011; Butters, Tr. 2893-2894; PX0361 (Sacks, Dep. at 81)).

Professor Butters testified that this advertisement employs humor and references an alcoholic beverage toast. (PX0350 (Butters, Dep. at 119-20)). He does not believe that any reasonable viewer could find that the advertisement communicates that it could treat, prevent, or reduce the risk of disease. (PX0350 (Butters, Dep. at 121-124)). Professor Butters testified that there may be some outliers that may interpret the ad as making a health claim but those outliers would, by definition, not be ordinary or normal. (PX0350 (Butters, Dep. at 124-25)).

Professor Butters concluded that POM's ads in general depend on parody, exaggeration and humor to bring their message to the potential consumer; including the following messages: 1) POM is the best pomegranate that anyone can buy; 2) POM Juice is healthy; 3) POM Juice is tasty; 4) POM Juice is arguably the best source of antioxidants of any of the comparable beverages available; 5) medical research has suggested that antioxidants combat free radicals, which are unhealthy, and may contribute to diseases of the heart, arteries, and prostate, as well as erectile dysfunction; and 6) POM also offers concentrated forms of pomegranate extract for those who wish to ingest antioxidants in even more concentrated form than pomegranate juice itself. (PX0158-0033).

Ms. Leow testified that this ad was part of the "Trust in Pom" campaign and that the campaign's message was to let people know that POM Juice is healthy and is made with 100 percent pomegranate juice from California-grown pomegranates. (PX0330 (Leow, Dep. at 102-04)). Viewing the "Drink to prostate health" ad as a whole, including the

interaction of the words and visual imagery, the overall net impression of the ad is that it is a humorous reference to an alcoholic toast, that POM Juice is healthy and is made with 100 percent pomegranate juice from California-grown pomegranates. (PX0350 (Butters, Dep. at 124-25); (PX0330 (Leow, Dep. at 104)).

Complaint Counsel presented no extrinsic evidence or expert opinion on this ad's meaning, consumer perceptions of this ad, or consumer interpretations regarding this ad. (PX0357 (Stewart, Dep. at 49, 52)). Complaint Counsel also failed to present any evidence (1) that the claims in this ad reasonably convey that POM Juice is "clinically proven" to prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction and failed to present any evidence (2) regarding the number of exposures consumers had to this ad or any particular POM advertisement. (Mazis, Tr. 2752).

Therefore, POM's "prostate" ad instead conveys that (1) consumption of POM Juice may lengthen PSADT in men with biochemical recurrence of PSA following treatment for prostate cancer; and (2) POM is healthy and likely good for prostate health (CX260_0001). Nowhere does POM claim it "treats" or "prevents" prostate cancer.

b. "I'm Off to Save Prostates" Print Ad (CX0274)

372. POM disseminated, in February 2009 in *Men's Fitness* magazine, a POM Juice advertisement with the headline, "**I'm off to save PROSTATES!**". The advertisement also appeared in March 2009 in *Advocate* magazine and *Men's Journal*. (CX0274_0002). It depicted a POM Juice bottle shooting off into the sky like a super hero. The advertisement's body copy stated:

> Man by man, gland by gland, The Antioxidant Superpower is 100% committed to defending healthy prostates. Powered by pure pomegranate juice . . . backed by $25 million in vigilant medical research* . . . there's no telling just how far it will go to improve prostate health in the future. *Prostate study details at http://www.pomwonderful.com/health_benefits.html.

(CX0274; *see also* CX1426_00029).

Response to Finding No. 372:

Complaint Counsel misstates the evidence and the document speaks for itself. Complaint Counsel failed to present any evidence that Respondents would run these ads in the future, let alone whether it is probable they would do so. This ad cannot provide a basis for injunctive relief because (a) it ran almost three years ago; and (b) no evidence exists to show that Respondents are likely to run this ad in the future.

The fact that this ad depicts juice that is wholly-derived from the pomegranate fruit is heavily emphasized in the body copy and the visual imagery of the ad as well as on the product itself. There is a dominant image of deep, ruby red pomegranate juice in a bottle shaped like two pomegranates stacked on top of one another, the words "100% Pomegranate Juice" are clearly displayed on the face of the POM Juice bottle depicted and there is repeated textual reference to "POM Wonderful 100% Pomegranate Juice". Complaint Counsel ignores, among other elements, the overt puffery, outrageousness and humor in the headlines and imagery and the blatant fact that POM Juice is 100% fruit juice. Additionally, Complaint Counsel acknowledges, the ads are made in a cute, cartoonish "comic book-themed animation" style (CCFF 443) that portrays the POM bottle as a superhero, and the ad taglines appear in comic style font and in dialogue bubbles. These kinds of advertisements were intended to be hyperbolic, humorous cheeky puffery, and that is not actionable. *See, e.g., Sterling Drug, Inc. v. F.T.C.,* 741 F.2d 1146, 1150 (9th Cir. 1984); *In re Thompson Medical,* 104 F.T.C. 648, 788-89 n. 6). Rather, as Dr. Butters testified, these ads were intended to be "a work of fiction" in that they are personifying the pomegranate bottle by comparing the bottle to a superhero. (Butters, Tr. 2906).

The fact that POM advertised in Men's Fitness and Men's Journal magazines is not damning. Men's Fitness and Men's Journal magazines cater to health-conscious

consumers and have sections on beauty, shopping, health, fitness, diet and nutrition. POM's advertising in Men's Fitness and Men's Journal magazines are entirely consistent with advertising of a food product whose messaging is how a whole food product fits into a healthy lifestyle and diet program. Contrary to the marketing themes suggested by Complaint Counsel that POM marketed POM Juice as a pharmaceutical drug with a single or narrow target of action, advertising in Men's Fitness and Men's Journal magazines do not show intent to convey that POM Juice "prevents," "treats," or "reduces the risk" of prostate cancer.

Nowhere in this ad do Respondents expressly (*i.e.*, unequivocally and directly) state that (a) POM Juice "prevents," "treats," or "reduces the risk" of prostate cancer; or (b) POM Juice is "clinically proven" to "prevent," "treat," or "reduce the risk" of prostate cancer. (CX260_0001; CX1426_0028, Exh. B). Complaint Counsel's assertion that the ad impliedly conveys the message that (a) POM Juice "prevents," "treats," or "reduces the risk" of prostate cancer, like a drug; or (b) POM Juice is "clinically proven" to "prevent," "treat," or "reduce the risk" of prostate cancer, like a drug, is not conspicuous, self-evident, or reasonably clear from the face of the ad. (CX260_0001; CX1426_0028, Exh. B). Consequently, because the above-referenced challenged implied claim may not be determined with confidence from the face of the ad, extrinsic evidence must be examined. The overall net impression of this ad is not that (a) drinking eight ounces of POM Juice prevents, treats or reduces the risk of certain diseases, such as prostate cancer, like a drug; or (b) drinking eight ounces of POM Juice is "clinically proven" to prevent, treat or reduce the risk of certain diseases, such as prostate cancer, like a drug. (CX260_0001; CX1426_0028, Exh. B).

While the ad cited some of POM's underlying research, those statements were qualified with language like, "vigilant medical study". Furthermore, competent and reliable scientific evidence supports the conclusion that the consumption of pomegranate juice

and pomegranate extract supports prostate health. (PX0161; PX0353 (Heber, Dep. at 84-85)).

To the extent a "reduce the risk" claim can be implied from the ad, the overall net impression is not that drinking eight ounces of POM Juice "reduces the risk" of certain diseases, such as prostate cancer, like a drug with a single target of action, but that it may help "reduce the risk," like many other whole foods, or like an especially healthy fruit or vegetable, or like a a healthy diet of fruits and vegetables and exercise "reduces the risk" of disease. (CX260_0001; CX1426_0028, Exh. B).

To the extent a "treat" claim can be implied from this ad (which it cannot), the overall net impression of any ad is not that POM Juice is a substitute for conventional medical treatment. (Butters, Tr. 2821-22).

To the extent a "proven" claim can be implied from this ad (which it cannot), the overall net impression of this ad is not that POM Juice is "proven" to be 100% effective in preventing, treating or reducing the risk of prostate cancer because (1) all of the qualifying language contradicts an implied "clinically proven" interpretation, and (2) "proven" in science and to consumers means the "average person in the study benefitted," not that "everyone in the study necessarily benefitted" or that everyone will benefit like the persons who benefitted in the study. (Heber, Tr. 2011; Butters, Tr. 2893-2894; PX0361 (Sacks, Dep. at 81)).

Complaint Counsel's expert, Professor Mazis, testified that Complaint Counsel is not challenging POM's ads for POM Juice that ran after December 2008. (Mazis, Tr. 2753-54). Accordingly, based on these representations, Complaint Counsel cannot now challenge this ad.

Professor Butters concluded that POM's ads in general depend on parody, exaggeration and humor to bring their message to the potential consumer; including the following messages: 1) POM is the best pomegranate that anyone can buy; 2) POM Juice is healthy; 3) POM Juice is tasty; 4) POM Juice is arguably the best source of antioxidants of any of the comparable beverages available; 5) medical research has suggested that antioxidants combat free radicals, which are unhealthy, and may contribute to diseases of the heart, arteries, and prostate, as well as erectile dysfunction; and 6) POM also offers concentrated forms of pomegranate extract for those who wish to ingest antioxidants in even more concentrated form than pomegranate juice itself. (PX0158-0033).

Mrs. Resnick testified that the message that was intended by the ad was that POM Juice is good for prostates. She testified that the headline, "I'm off to save PROSTATES!" would absolutely not mean that POM Juice would prevent prostate cancer. Mrs. Resnick further testified that the copy below the image means that POM Juice is backed by research and that POM Juice improves prostate health; however, the ad does not say anything about preventing prostate cancer. Mrs. Resnick explained that the intent of the ad was not to communicate to consumers that POM would treat prostate cancer; it was meant to communicate that POM Juice is good for your prostate. (L. Resnick, Tr. 217-19).

Professor Butters testified that "'I'm off to save PROSTATES!" could be interpreted by outliers, unreasonable viewers of the ad, to mean I'm going to somehow protect them or rescue them from disease but that he believes that such an interpretation is unlikely. (Butters, Tr. 2895-01). Professor Butters also testified that he concluded in his report that the use of the humor in this ad indicates to the reader that this is not serious medical advice; that this is a general suggestion that POM Juice is healthy, looking at the context of the entire ad. (Butters, Tr. 2905-06). Further, Professor Butters testified that the personification in the ad is the literal personification of the pomegranate bottle, which is

being compared "frivolously and extravagantly" to a superhero, which in itself is a work of fiction and that "the extraordinary powers" of POM Wonderful has to do with the high level of antioxidants. The copy in the ad "there's just no telling how far it will go to improve prostate health in the future," is a strong suggestion that what is going on has been undecided. Professor Butters further explained that he views the word "vigilant" as an odd word choice in the ad, because vigilant is something that refers to the superhero rather than to what you would normally say about medical research, and that keeps viewers from seeing this as any kind of a definitive medical statement. The statement does not suggest that the $25 million in vigilant medical research is anything other than what it is when you look at the web site or when you look at the footnote. (Butters, Tr. 2906-10). Professor Butters further testified that the hyperbole in the POM ads and the humor in the visual representations blocks literal interpretation of many of the headings, such as "I'm off to save prostates." These are absurd terms and will not be viewed as indicating claims. However, Professor Butters stated that the humor does not block the serious statements that are made in the text and footnotes. He testified that when you say a product is committed to defend against something, a reasonable person would not infer that the product definitely succeeds in eliminating that something. "Committed" is a word like "fight for," which does not necessarily guarantee the success of the outcome. (Butters, Tr. 2958-60).

Complaint Counsel presented no extrinsic evidence or expert opinion on this ad's meaning, consumer perceptions of this ad, or consumer interpretations regarding this ad. (PX0357 (Stewart, Dep. at 49, 52)). Complaint Counsel also failed to present any evidence (1) that the claims in this ad reasonably convey that POM Juice is "clinically proven" to prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction and (2) regarding the number of exposures consumers had to this ad or any particular POM advertisement. (Mazis, Tr. 2752).

To the extent any claim is made, the fact that POM advertised the amount of money Respondents spent on scientific research does not convey the net impression that POM Juice is "clinically proven to prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction." (RFF 2507-19; Respondents' Post-Trial Br. at 76-77.) What this "backed by" ad actually states is that Respondents spent a particular sum of money on scientific studies on POM Juice to back-up their health claims. Contrary to Complaint Counsel's implication, it is completely illogical to infer from the fact that a certain amount of money was invested in research to the conclusion that POM Juice is proven to prevent, treat or reduce the risk of disease. Again, this is another one of Complaint Counsel's ill-defined, "logical leaps" from "backed by $25 million of initial scientific research" to "backed by $25 million in research that proved POM Juice prevents, treats or reduces the risk of heart disease, prostate cancer or erectile dysfunction." Indeed, Complaint Counsel presented no evidence that consumers took away the message alleged by Complaint Counsel because Respondents' spent a certain amount of money on science and research. (RFF 28-29, 2515). Moreover, the "backed by" ads accurately and truthfully represented the dollars spent by Respondents on the totality of the science on POM Juice. (RFF 2510). Moreover, these ads are immaterial because there is no evidence that anyone bought POM Juice because they thought Respondents spent a certain amount of money in a particular area of research. Indeed, Professor Reibstein's survey showed the opposite: that no one bought POM Juice because of the amount of money spent on science. (PX0223-0006).

373. Mrs. Resnick testified that this advertisement intended to convey the message that POM was good for prostates and was backed by research to improve prostate health. She also testified that the prostate health benefits in the advertisement referred to the Pantuck Phase II Prostate Cancer Study (2006) and the basic science that had been done. (L. Resnick, Tr. 218); *see* CCFF ¶ VIII.172).

Response to Finding No. 373:

Complaint Counsel misconstrue the testimony. Mrs. Resnick's exact testimony was, "[the copy] says that it's backed by research, that we improve prostate health. We don't say anything about preventing prostate cancer." (L. Resnick, Tr. 218)

Respondents further object to the proposed finding to the extent that Complaint Counsel construe Mrs. Resnick's testimony to bolster their argument that Respondents intended to convey to consumers that the Challenged Products treat, prevent or reduce the risk of disease. Although Mrs. Resnick personally believes that consuming pomegranate juice has a powerful affect against prostate cancer (RFF 519; CX1375 (L. Resnick, Trop. Dep. at 102); CX1362 (L. Resnick, TCCC Dep. at 38)), Respondents dispute that they ever intended to convey or that the Challenged Ads do convey the claim that the Challenged Products treat, prevent or reduce the risk of heart disease, prostate cancer and erectile dysfunction or that they are "clinically proven" to do so. (RFF 496, 535, 538, 540, 545-50, 2209-11, 2280; CX1375 (L. Resnick, Trop., Dep. at 79-81)). More specifically, Lynda Resnick testified that the headline, "I'm off to save PROSTATES!" was absolutely not intended to mean that POM Juice would prevent prostate cancer. (RFF 531). Mrs. Resnick further testified that the intent of the ad was not to communicate to consumers that POM would treat prostate cancer; it was meant to communicate that POM Juice is good for your prostate or at most improves prostate health. (L. Resnick, Tr. 217-19). Nor did Mrs. Resnick intend to use Dr. Pantuck's prostate cancer study to communicate to consumers that POM Juice would treat prostate cancer. (RFF 537).

374. Mrs. Resnick has testified that "prostate health" means "keeping you safe from prostate cancer." (CX1362 (L. Resnick, TCCC Dep. at 10)).

Response to Finding No. 374:

Complaint Counsel misconstrues the testimony given by Mrs. Resnick. Mrs. Resnick did not testify that prostate health means keeping you safe from prostate cancer, but rather she testified that, "We believe, although we don't know for sure, that prostate health -- in other words, keeping you safe from prostate cancer, might be a benefit because of the dramatic results with people that are already sick." (CX1362 (L. Resnick, TCCC Dep. at 10-11)). Complaint Counsel wrongly attempts to piece together parts of testimony to convey a meaning that it does not convey. Mrs. Resnick began her statement with "We believe, although we don't know for sure that prostate health…" (CX1362 (L. Resnick, TCCC Dep. at 10)), and then she took a long pause and restated, "keeping you safe from prostate cancer, might be a benefit because of the dramatic results with people that are already sick." (CX1362 (L. Resnick, TCCC Dep. at 10-11)). Mrs. Resnick did not testify to the definition of prostate health but was simply describing that one of the benefits of drinking POM Juice was that it may be beneficial for prostate health. Complaint Counsel used pieces of Mrs. Resnick's testimony for their own self-serving purposes and, as such, misrepresented the testimony given.

In fact, Mrs. Resnick testified that the message that was intended by the ad was that POM Juice is good for prostates. She testified that the headline, "I'm off to save PROSTATES!" would absolutely not mean that POM Juice would prevent prostate cancer. Mrs. Resnick further testified that the copy below the image means that POM Juice is backed by research and that POM Juice improves prostate health; however, the ad does not say anything about preventing prostate cancer. Mrs. Resnick explained that the intent of the ad was not to communicate to consumers that POM would treat prostate cancer; it was meant to communicate that POM Juice is good for your prostates. (L. Resnick, Tr. 217-19).

375. Dr. Butters testified that "defend" could mean "resist an attack made on (someone or something) and protect from harm or danger" and that it is possible this advertisement communicates to viewers that POM Juice is protecting or defending prostates from disease. (Butters, Tr. 2899-2901).

Response to Finding No. 375:

Complaint Counsel misconstrues Dr. Butters' testimony. At trial, Complaint Counsel futilely posed the same question to Dr. Butters six different times in the hope that Dr. Butters would testify that "defend" means "protect". Despite being asked the same question repeatedly, Dr. Butters did not change his response. Each time Dr. Butters testified that "I'm off to save PROSTATES!" could be interpreted by outliers, unreasonable viewers of the ad, to mean I'm going to somehow protect them or rescue them from disease but that he believes such an interpretation is unlikely. (Butters, Tr. 2895-01). In response to Complaint Counsel's unsupported insistence that this advertisement possibly communicates to viewers that POM Juice is protecting or defending prostates from disease, Dr. Butters testifies "Among other things, yes." (Butters, Tr. 2899-2901). Complaint Counsel failed to question Dr. Butters about the more relevant and *probable* message conveyed by the ad (as detailed in Dr. Butters' report) - that the use of the humor in this ad indicates to the reader that this is not serious medical advice and that the ad is a general suggestion that POM Juice is healthy. (Butters, Tr. 2905-06).

376. This advertisement, with its references to "sav[ing]" and "defending" prostates, as well as "improve[ing] prostate health," conveys the net impression that drinking eight ounces of POM Juice daily prevents or reduces the risk of prostate cancer. Moreover, the advertisement's claim that POM Juice is "backed by $25 million in vigilant medical research," as well as a footnote referencing a "prostate study" under a URL entitled "health benefits" conveys the overall net impression that POM's benefits for prostate cancer have been proven by clinical testing. (CCFF ¶¶ 372-75).

Response to Finding No. 376:

Complaint Counsel misstates the evidence and the document speaks for itself. The fact that this ad depicts juice that is wholly-derived from the pomegranate fruit is heavily

emphasized in the body copy and the visual imagery of the ad as well as on the product itself. There is a dominant image of deep, ruby red pomegranate juice in a bottle shaped like two pomegranates stacked on top of one another, the words "100% Pomegranate Juice" are clearly displayed on the face of the POM Juice bottle depicted and there is repeated textual reference to "POM Wonderful 100% Pomegranate Juice". It is nonsensical that from the whole food aspect of the advertising that Complaint Counsel can make a giant leap to asserting that that it conveys a message that POM Juice can prevent or reduce the risk of prostate cancer.

Nowhere in this ad do Respondents expressly (*i.e.*, unequivocally and directly) state that (a) POM Juice "prevents," "treats," or "reduces the risk" of prostate cancer; or (b) POM Juice is "clinically proven" to "prevent," "treat," or "reduce the risk" of prostate cancer. (CX260_0001; CX1426_0028, Exh. B). Complaint Counsel's assertion that the ad impliedly conveys the message that (a) POM Juice "prevents," "treats," or "reduces the risk" of prostate cancer, like a drug; or (b) POM Juice is "clinically proven" to "prevent," "treat," or "reduce the risk" of prostate cancer, like a drug, is not conspicuous, self-evident, or reasonably clear from the face of the ad. (CX260_0001; CX1426_0028, Exh. B). Consequently, because the above-referenced challenged implied claim may not be determined with confidence from the face of the ad, extrinsic evidence must be examined. The overall net impression of this ad is not that (a) drinking eight ounces of POM Juice prevents, treats or reduces the risk of certain diseases, such as prostate cancer, like a drug; or (b) drinking eight ounces of POM Juice is "clinically proven" to prevent, treat or reduce the risk of certain diseases, such as prostate cancer, like a drug. (CX260_0001; CX1426_0028, Exh. B).

While the ad cited some of POM's underlying research, those statements were qualified with language like, "vigilant medical study". Furthermore, competent and reliable scientific evidence supports the conclusion that the consumption of pomegranate juice

and pomegranate extract supports prostate health. (PX0161; PX0353 (Heber, Dep. at 84-85)).

To the extent a "reduce the risk" claim can be implied from the ad, the overall net impression is not that drinking eight ounces of POM Juice "reduces the risk" of certain diseases, such as prostate cancer, like a drug with a single target of action, but that it may help "reduce the risk," like many other whole foods, or like an especially healthy fruit or vegetable, or like a a healthy diet of fruits and vegetables and exercise "reduces the risk" of disease. (CX260_0001; CX1426_0028, Exh. B). To the extent a "treat" claim can be implied from this ad (which it cannot), the overall net impression of any ad is not that POM Juice is a substitute for conventional medical treatment. (Butters, Tr. 2821-22). To the extent a "proven" claim can be implied from this ad (which it cannot), the overall net impression of this ad is not that POM Juice is "proven" to be 100% effective in preventing, treating or reducing the risk of prostate cancer because (1) all of the qualifying language contradicts an implied "clinically proven" interpretation, and (2) "proven" in science and to consumers means the "average person in the study benefitted," not that "everyone in the study necessarily benefitted" or that everyone will benefit like the persons who benefitted in the study. (Heber, Tr. 2011; Butters, Tr. 2893-2894; PX0361 (Sacks, Dep. at 81)).

Complaint Counsel's expert, Professor Mazis, testified that Complaint Counsel is not challenging POM's ads for POM Juice that ran after December 2008. (Mazis, Tr. 2753-54). Accordingly, based on these representations, Complaint Counsel cannot now challenge this ad.

Professor Butters concluded that POM's ads in general depend on parody, exaggeration and humor to bring their message to the potential consumer; including the following messages: 1) POM is the best pomegranate that anyone can buy; 2) POM Juice is healthy;

3) POM Juice is tasty; 4) POM Juice is arguably the best source of antioxidants of any of the comparable beverages available; 5) medical research has suggested that antioxidants combat free radicals, which are unhealthy, and may contribute to diseases of the heart, arteries, and prostate, as well as erectile dysfunction; and 6) POM also offers concentrated forms of pomegranate extract for those who wish to ingest antioxidants in even more concentrated form than pomegranate juice itself. (PX0158-0033).

Mrs. Resnick testified that the message that was intended by the ad was that POM Juice is good for prostates. She testified that the headline, "I'm off to save PROSTATES!" would absolutely not mean that POM Juice would prevent prostate cancer. Mrs. Resnick further testified that the copy below the image means that POM Juice is backed by research and that POM Juice improves prostate health; however, the ad does not say anything about preventing prostate cancer. Mrs. Resnick explained that the intent of the ad was not to communicate to consumers that POM would treat prostate cancer; it was meant to communicate that POM Juice is good for your prostate. (L. Resnick, Tr. 217-19).

Professor Butters testified that "'I'm off to save PROSTATES!" could be interpreted by outliers, unreasonable viewers of the ad, to mean I'm going to somehow protect them or rescue them from disease but that he believes that such an interpretation is unlikely. (Butters, Tr. 2895-01). Professor Butters also testified that he concluded in his report that the use of the humor in this ad indicates to the reader that this is not serious medical advice; that this is a general suggestion that POM Juice is healthy, looking at the context of the entire ad. (Butters, Tr. 2905-06). Further, Professor Butters testified that the personification in the ad is the literal personification of the pomegranate bottle, which is being compared "frivolously and extravagantly" to a superhero, which in itself is a work of fiction and that "the extraordinary powers" of POM Wonderful has to do with the high level of antioxidants. The copy in the ad "there's just no telling how far it will go to

improve prostate health in the future," is a strong suggestion that what is going on has been undecided. Professor Butters further explained that he views the word "vigilant" as an odd word choice in the ad, because vigilant is something that refers to the superhero rather than to what you would normally say about medical research, and that keeps viewers from seeing this as any kind of a definitive medical statement. The statement does not suggest that the $25 million in vigilant medical research is anything other than what it is when you look at the web site or when you look at the footnote. (Butters, Tr. 2906-10). Professor Butters further testified that the hyperbole in the POM ads and the humor in the visual representations blocks literal interpretation of many of the headings, such as "I'm off to save prostates." These are absurd terms and will not be viewed as indicating claims. However, Professor Butters stated that the humor does not block the serious statements that are made in the text and footnotes. He testified that when you say a product is committed to defend against something, a reasonable person would not infer that they definitely succeed in eliminating that something, that disease. "Committed" is a -- is a word like "fight for," which does not necessarily guarantee the success of the outcome. (Butters, Tr. 2958-60).

Complaint Counsel presented no extrinsic evidence or expert opinion on this ad's meaning, consumer perceptions of this ad, or consumer interpretations regarding this ad. (PX0357 (Stewart, Dep. at 49, 52)). Complaint Counsel also failed to present any evidence (1) that the claims in this ad reasonably convey that POM Juice is "clinically proven" to prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction and (2) regarding the number of exposures consumers had to this ad or any particular POM advertisement. (Mazis, Tr. 2752).

To the extent any claim is made, the fact that POM advertised the amount of money Respondents spent on scientific research does not convey the net impression that POM Juice is "clinically proven to prevent, treat or reduce the risk of heart disease, prostate

cancer or erectile dysfunction." (RFF 2507-19; Respondents' Post-Trial Br. at 76-77.) What this "backed by" ad actually states is that Respondents spent a particular sum of money on scientific studies on POM Juice to back-up their health claims. Contrary to Complaint Counsel's implication, it is completely illogical to infer from the fact that a certain amount of money was invested in research to the conclusion that POM Juice is proven to prevent, treat or reduce the risk of disease. Again, this is another one of Complaint Counsel's ill-defined, "logical leaps" from "backed by $25 million of initial scientific research" to "backed by $25 million in research that proved POM Juice prevents, treats or reduces the risk of heart disease, prostate cancer or erectile dysfunction." Indeed, Complaint Counsel presented no evidence that consumers took away the message alleged by Complaint Counsel because Respondents' spent a certain amount of money on science and research. (RFF 28-29, 2515). Moreover, the "backed by" ads accurately and truthfully represented the dollars spent by Respondents on the totality of the science on POM Juice. (RFF 2510). Moreover, these ads are immaterial because there is no evidence that anyone bought POM Juice because they thought Respondents spent a certain amount of money in a particular area of research. Indeed, Professor Reibstein's survey showed the opposite: that no one bought POM Juice because of the amount of money spent on science. (PX0223-0006).

Therefore, POM's "prostate" ad instead conveys that (1) consumption of POM Juice may lengthen PSADT in men with biochemical recurrence of PSA following treatment for prostate cancer; and (2) POM is healthy and likely good for prostate health (CX260_0001). Nowhere does POM claim it "treats" or "prevents" prostate cancer.

c. "Magazine Wrap" Print Ads (CX0314; CX0372; CX0379; CX0380)

377. POM disseminated a "magazine wrap" advertisement in Fall 2008, which included the bold headline, "**Drink to prostate health**." with an image of the POM Juice bottle with logo on the cover. (CX0314_0003).

Response to Finding No. 377:

Complaint Counsel misstates the evidence and the document speaks for itself. Complaint Counsel failed to present any definitive information regarding this ad's dissemination. Complaint Counsel also failed to present any evidence that Respondents would run this ad in the future, let alone whether it is probable they would do so. This ad cannot provide a basis for injunctive relief because (a) it ran almost four years ago; and (b) no evidence exists to show that Respondents are likely to run this ad in the future.

The fact that this ad depicts juice that is wholly-derived from the pomegranate fruit is heavily emphasized in the body copy and the visual imagery of the ad as well as on the product itself. There is a dominant image of deep, ruby red pomegranate juice in a bottle shaped like two pomegranates stacked on top of one another, and the words "100% Pomegranate Juice" are clearly displayed on the face of the POM Juice bottle depicted. Complaint Counsel fails to cite the remaining portion of the text wrap which included (1) textual reference that POM Juice is "available in your supermarket produce section" and (2) repeated textual reference to "POM Wonderful 100% Pomegranate Juice". (CX0314_0004).

Nowhere in this ad do Respondents expressly (*i.e.*, unequivocally and directly) state that (a) POM Juice "prevents," "treats," or "reduces the risk" of prostate cancer; or (b) POM Juice is "clinically proven" to "prevent," "treat," or "reduce the risk" of prostate cancer. (CX260_0001; CX1426_0028, Exh. B). Complaint Counsel's assertion that the ad impliedly conveys the message that (a) POM Juice "prevents," "treats," or "reduces the risk" of prostate cancer, like a drug; or (b) POM Juice is "clinically proven" to "prevent," "treat," or "reduce the risk" of prostate cancer, like a drug, is not conspicuous, self-evident, or reasonably clear from the face of the ad. (CX260_0001; CX1426_0028, Exh. B). Consequently, because the above-referenced challenged implied claim may not

be determined with confidence from the face of the ad, extrinsic evidence must be examined. The overall net impression of this ad is not that (a) drinking eight ounces of POM Juice prevents, treats or reduces the risk of certain diseases, such as prostate cancer, like a drug; or (b) drinking eight ounces of POM Juice is "clinically proven" to prevent, treat or reduce the risk of certain diseases, such as prostate cancer, like a drug. (CX260_0001; CX1426_0028, Exh. B).

To the extent a "reduce the risk" claim can be implied from the ad, the overall net impression is not that drinking eight ounces of POM Juice "reduces the risk" of certain diseases, such as prostate cancer, like a drug with a single target of action, but that it may help "reduce the risk," like many other whole foods, or like an especially healthy fruit or vegetable, or like a a healthy diet of fruits and vegetables and exercise "reduces the risk" of disease. (CX260_0001; CX1426_0028, Exh. B). To the extent a "treat" claim can be implied from this ad (which it cannot), the overall net impression of any ad is not that POM Juice is a substitute for conventional medical treatment. (Butters, Tr. 2821-22). To the extent a "proven" claim can be implied from this ad (which it cannot), the overall net impression of this ad is not that POM Juice is "proven" to be 100% effective in preventing, treating or reducing the risk of prostate cancer because (1) all of the qualifying language contradicts an implied "clinically proven" interpretation, and (2) "proven" in science and to consumers means the "average person in the study benefitted," not that "everyone in the study necessarily benefitted" or that everyone will benefit like the persons who benefitted in the study. (Heber, Tr. 2011; Butters, Tr. 2893-2894; PX0361 (Sacks, Dep. at 81)).

Professor Butters concluded that POM's ads in general depend on parody, exaggeration and humor to bring their message to the potential consumer; including the following messages: 1) POM is the best pomegranate that anyone can buy; 2) POM Juice is healthy; 3) POM Juice is tasty; 4) POM Juice is arguably the best source of antioxidants of any of

the comparable beverages available; 5) medical research has suggested that antioxidants combat free radicals, which are unhealthy, and may contribute to diseases of the heart, arteries, and prostate, as well as erectile dysfunction; and 6) POM also offers concentrated forms of pomegranate extract for those who wish to ingest antioxidants in even more concentrated form than pomegranate juice itself. (PX0158-0033).

Viewing the "Drink to prostate health" ad as a whole, including the interaction of the words and visual imagery, the overall net impression of the ad is that it is a humorous reference to an alcoholic toast, that POM Juice is healthy and is made with 100 percent pomegranate juice from California-grown pomegranates. (PX0350 (Butters, Dep. at 124-25); (PX0330 (Leow, Dep. at 104)).

Complaint Counsel presented no extrinsic evidence or expert opinion on this ad's meaning, consumer perceptions of this ad, or consumer interpretations regarding this ad. (PX0357 (Stewart, Dep. at 49, 52)). Complaint Counsel also failed to present any evidence (1) that the claims in this ad reasonably convey that POM Juice is "clinically proven" to prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction and (2) regarding the number of exposures consumers had to this ad or any particular POM advertisement. (Mazis, Tr. 2752).

378. Although the advertisement's body copy was titled "**P♥M Wonderful and Prostate Health**," the detailed claims below the title made clear that POM's purported benefits for prostate "health" actually referred to benefits for prostate *cancer*. The advertisement discussed only studies related to prostate cancer (rather than any other prostate health condition). The advertisement stated:

A recently published medical study involving P♥M Wonderful 100% Pomegranate Juice followed 46 men previously treated for prostate cancer either with surgery or radiation. After drinking eight ounces of P♥M Wonderful 100% Pomegranate Juice daily for at least two years, these men experienced significantly slower PSA doubling times. PSA (Prostate-Specific Antigen) is a biomarker that indicates the presence of prostate cancer. "PSA doubling time" is a measure of how long it takes for PSA levels to double. A longer doubling time may indicate slower progression of the disease.

At the beginning of the study, PSA levels doubled on average every 15 months. By the end of the study, doubling time had slowed to 54 months – nearly a four-fold improvement.

"*This is a big increase. I was surprised when I saw such an improvement in PSA numbers," said Dr. Allan Pantuck, lead author of the UCLA Study.*

In addition, in-vitro testing using blood serum from the patients who drank pomegranate juice showed a 17% increase in prostate cancer cell death and a 12% decrease in cancer cell growth.

One important note: All patients drank the same P♥M Wonderful 100% Pomegranate Juice which is available in your supermarket produce section.

(CX0314_0004).

Response to Finding No. 378:

Complaint Counsel misstates the evidence and the document speaks for itself. Complaint Counsel makes a giant leap from the headline which clearly reads "Prostate Health" to the conclusion that "health" is synonymous with "cancer" only because the word "cancer" appears in the text much later on. This is completely nonsensical. All of the information on this page is couched in qualified language and does not constitute an establishment claim regarding prostate cancer, particularly since the statements make it clear that POM's Juice should be viewed through the lens of a fruit, not a drug. Furthermore, the textual summary does not make establishment claims about prostate cancer because it does not say or imply that any of the research shows or proves a particular fact or that pomegranate juice prevents, treat, or reduces the risk of prostate cancer. Rather, the summary of the study in the copy presented is clearly qualified: the study is described as yielding "promising" results, not conclusory results and the conclusion was summarized as "emerging science suggests that diet and lifestyle may be able to significantly improve prostate health." (CX0314_0004). The summary also made it clear that "three more clinical studies are now underway to further investigate the effects of POM on prostate health." (*Id.*)

379. The magazine wrap also emphasized the danger of prostate cancer, stating: "Prostate Cancer is the most commonly diagnosed cancer in men in the United States. After lung

cancer, it's the second leading cause of cancer death in men. However, emerging science suggests that diet and lifestyle may be able to significantly improve prostate health." It went on to say: "**The Research Continues.** Results from this study were so promising that many of the original patients continued to drink pomegranate juice daily, and their PSA doubling times remained suppressed. Three more clinical studies are now underway to further investigate the effects of P♥M on prostate health." (CX0314_0004).

Response to Finding No. 379:

Once again, Complaint Counsel misstates the evidence and the document speaks for itself. Complaint Counsel makes a giant leap tying together a piece of factual information regarding the incidence of prostate cancer in men with a completely separate and distinct statement regarding research that is being conducted to observe PSA doubling times. All of the information on this page is couched in qualified language and does not constitute an establishment claim regarding prostate cancer particularly since the statements make it clear that POM's Juice should be viewed through the lens of a fruit, not a drug. Furthermore, the textual summary does not make establishment claims about prostate cancer because it does not say or imply that any of the research shows or proves a particular fact or that pomegranate juice prevents, treat, or reduces the risk of prostate cancer. Rather, the summary of the study in the copy presented is clearly qualified: the study is described as yielding "promising" results, not conclusory results and the conclusion was summarized as "emerging science suggests that diet and lifestyle may be able to significantly improve prostate health." (CX0314_0004). The summary also made it clear that "three more clinical studies are now underway to further investigate the effects of POM on prostate health." (*Id.*)

380. The magazine wrap further bolstered the efficacy claims by stating that they were "**Backed by Science.** Only P♥M is backed by $25 million in medical research conducted at the world's leading universities. Clinical studies have documented the benefits of drinking P♥M Wonderful 100% Pomegranate Juice, including improved cardiovascular and prostate health." The page on which these claims appeared was titled, "**The proof is in the P♥M**." (CX0314_0005).

Response to Finding No. 380:

Complaint Counsel's opening statement in this finding makes little sense - an efficacy claim is not made with statements regarding the amount or type of science conducted to evidence such a claim.

However, assuming aguendo that Complaint Counsel intended to allege that the magazine wrap bolstered an establishment claim, all of the information in the statement is couched in qualified language and does not constitute an establishment claim regarding prostate cancer or any other disease, particularly since the visual imagery and additional textual statements make it clear that POM's Juice should be viewed through the lens of a fruit, not a drug. Furthermore, the textual summary does not make establishment claims about prostate cancer because it does not say or imply that any of the research shows or proves a particular fact or that pomegranate juice prevents, treat, or reduces the risk of prostate cancer. Rather, the summary of the science in the textual copy is clearly qualified: The clinical studies document the "benefits" of drinking POM Juice and the results were "promising". Such benefits include "improved cardiovascular and prostate health". (CX0314_0005).

To the extent any claim is made, the fact that POM advertised the amount of money Respondents spent on scientific research does not convey the net impression that POM Juice is "clinically proven to prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction." (RFF 2507-19; Respondents' Post-Trial Br. at 76-77.) What this "backed by" ad actually states is that Respondents spent a particular sum of money on scientific studies on POM Juice to back-up their health claims. Contrary to Complaint Counsel's implication, it is completely illogical to infer from the fact that a certain amount of money was invested in research to the conclusion that POM Juice is proven to prevent, treat or reduce the risk of disease. Again, this is another one of

Complaint Counsel's ill-defined, "logical leaps" from "backed by $25 million of initial scientific research" to "backed by $25 million in research that proved POM Juice prevents, treats or reduces the risk of heart disease, prostate cancer or erectile dysfunction." Indeed, Complaint Counsel presented no evidence that consumers took away the message alleged by Complaint Counsel because Respondents' spent a certain amount of money on science and research. (RFF 28-29, 2515). Moreover, the "backed by" ads accurately and truthfully represented the dollars spent by Respondents on the totality of the science on POM Juice. (RFF 2510). Moreover, these ads are immaterial because there is no evidence that anyone bought POM Juice because they thought Respondents spent a certain amount of money in a particular area of research. Indeed, Professor Reibstein's survey showed the opposite: that no one bought POM Juice because of the amount of money spent on science. (PX0223-0006).

381. Another magazine wrap dated October 2009 depicted a POM Juice bottle with a "speech" balloon above it saying, "**Lucky I have super HEALTH POWERS!**" The inside page showed a bottle "saying" "**HOLY HEALTH! $32 million in medical research.**" Other than increasing the "**Backed by Science**" figure to $32 million, the body copy of this magazine wrap contained the very same claims regarding prostate cancer as the "Drink to prostate health" wrap. (CX0379_0002-03; *see also* CX0380; CX0372 (additional copies of similar *Time* magazine wraps dated Nov. 2009 and Dec. 2009)).

Response to Finding No. 381:

Complaint Counsel misstates the evidence and the document speaks for itself. Complaint Counsel failed to present any definitive information regarding this ad's dissemination. Complaint Counsel also failed to present any evidence that Respondents would run this ad in the future, let alone whether it is probable they would do so. This ad cannot provide a basis for injunctive relief because (a) it ran almost three years ago; and (b) no evidence exists to show that Respondents are likely to run this ad in the future.

The fact that this ad depicts juice that is wholly-derived from the pomegranate fruit is heavily emphasized in the body copy and the visual imagery of the ad as well as on the

product itself. There is a dominant image of deep, ruby red pomegranate juice in a bottle shaped like two pomegranates stacked on top of one another, and the words "100% Pomegranate Juice" are clearly displayed on the face of the POM Juice bottle depicted. Complaint Counsel ignores, among other elements, the overt puffery, outrageousness and humor in the headline and imagery and the blatant fact that POM Juice is 100% fruit juice. Furthermore, Complaint Counsel fails to cite the remaining portion of the text which included (1) a "tree to bottle" reference, which is very similar to ads that are run by Florida's Natural® Brand Orange Juice, depicting a restock of orange juice by a grocer by calling the orchard directly, wherein a farm laborer places the orange juice on the grocery shelf directly by reaching his arm out from the orchard (http://www.youtube.com/watch?v=DlA7J4rFNTM); and (2) repeated textual reference to "POM Wonderful 100% Pomegranate Juice" and juice references. (CX0379_0002-03).

Additionally, the ad emphasizes that POM Juice contains abundant naturally occurring antioxidants that may help guard your body against free radicals. For example, the "Drink and be healthy" ad references: a) "superior antioxidant[s];" b) "antioxidant superpower;" (c) "high levels of powerful antioxidants;" (d) "polyphenol antioxidants;" and 3) "free radicals." Both the whole food aspect of the advertising and the emphasis on antioxidant content, directly counter any suggestion that POM Juice is going to act like a drug, as distinguished from an especially healthy fruit or vegetable and a healthy diet.

Further, Complaint Counsel's expert, Professor Mazis, testified that Complaint Counsel is not challenging POM's ads for POM Juice that ran after December 2008. (Mazis, Tr. 2753-54). Accordingly, based on these representations, Complaint Counsel cannot now challenge this ad.

Complaint Counsel's assertion that the ad conveys the message that (a) POM Juice "prevents," "treats," or "reduces the risk" of prostate cancer; or (b) POM Juice is

"clinically proven" to "prevent," "treat," or "reduce the risk" of prostate cancer is not conspicuous, self-evident, or reasonably clear from the face of the ad. (CX0379_0003; CX0372_0003; CX380_0003). Consequently, because the above-referenced challenged implied claim may not be determined with confidence from the face of the ad, extrinsic evidence must be examined.

The overall net impression of this ad is not that (a) drinking eight ounces of POM Juice prevents, treats or reduces the risk of certain diseases, such as prostate cancer; or (b) drinking eight ounces of POM Juice is "clinically proven" to prevent, treat or reduce the risk of certain diseases, such as prostate cancer. (CX0379_0003; CX0372_0003; CX380_0003).

To the extent a "reduce the risk" claim can be implied from the ad, the overall net impression is not that drinking eight ounces of POM Juice "reduces the risk" of certain diseases, such as prostate cancer, like a drug with a single target of action, but that it may help "reduce the risk," like many other whole foods, or like an especially healthy fruit or vegetable, or like a a healthy diet of fruits and vegetables and exercise "reduces the risk" of disease. (CX0379_0003; CX0372_0003; CX380_0003).

To the extent a "treat" claim can be implied from this ad (which it cannot), the overall net impression of any ad is not that POM Juice is a substitute for conventional medical treatment. (Butters, Tr. 2821-22).

To the extent a "proven" claim can be implied from this ad (which it cannot), the overall net impression of this ad is not that POM Juice is "proven" to be 100% effective in preventing, treating or reducing the risk of prostate cancer because (1) all of the qualifying language contradicts an implied "clinically proven" interpretation, and (2) "proven" in science and to consumers means the "average person in the study benefitted," not that "everyone in the study necessarily benefitted" or that everyone will benefit like

the persons who benefitted in the study. (Heber, Tr. 2011; Butters, Tr. 2893-2894; PX0361 (Sacks, Dep. at 81)).

Complaint Counsel presented no extrinsic evidence or expert opinion on this ad's meaning, consumer perceptions of this ad, or consumer interpretations regarding this ad. (PX0357 (Stewart, Dep. at 49, 52)), and Complaint Counsel failed to present any evidence regarding the number of exposures consumers had to this ad or any particular POM advertisement. (Mazis, Tr. 2752). Finally, Complaint Counsel failed to present any evidence that the claims in this ad reasonably convey that POM Juice is "clinically proven" to prevent, treat or reduce the risk of prostate cancer.

All of the information in the ad is couched in qualified language and does not constitute an establishment claim regarding prostate cancer or other disease, particularly since the visual imagery and additional textual statements make it clear that POM Juice should be viewed through the lens of a fruit, not a drug. Furthermore, the textual summary does not make establishment claims about prostate cancer because it does not say or imply that any of the research shows or proves a particular fact or that pomegranate juice prevents, treat, or reduces the risk of prostate cancer. Rather, the summary of the science in the textual copy is clearly qualified: The clinical studies document the "benefits" of drinking POM Juice and that the results were "promising". Such benefits include "improved cardiovascular and prostate health". (CX0314_0005).

To the extent any claim is made, the fact that POM advertised the amount of money Respondents spent on scientific research does not convey the net impression that POM Juice is "clinically proven to prevent, treat or reduce the risk of prostate cancer." (RFF 2507-19; Respondents' Post-Trial Br. at 76-77.) What this "backed by" ad actually states is that Respondents spent a particular sum of money on scientific studies on POM Juice to back-up their health claims. Contrary to Complaint Counsel's implication, it is

completely illogical to infer, from the fact that a certain amount of money was invested in research, that POM Juice is proven to prevent, treat or reduce the risk of disease. Again, this is another one of Complaint Counsel's ill-defined, "logical leaps" from "backed by $32 million of initial scientific research" to "backed by $32 million in research that proved POM Juice prevents, treats or reduces the risk of prostate cancer." Indeed, Complaint Counsel presented no evidence that consumers took away the message argued by Complaint Counsel because Respondents spent a certain amount of money on science and research. (RFF 28-29, 2515). Moreover, the "backed by" ads accurately and truthfully represented the dollars spent by Respondents on the totality of the science on POM Juice. (RFF 2510). Moreover, these ads are immaterial because there is no evidence that anyone bought POM Juice because they thought Respondents spent a certain amount of money in a particular area of research. Indeed, Professor Reibstein's survey showed the opposite: that no one bought POM Juice because of the amount of money spent on science. (PX0223-0006).

Furthermore, as Complaint Counsel acknowledges, the ads are made in a cute, cartoonish "comic book-themed animation" style (CCFF 443) that portrays the POM bottle as a superhero, and the ad taglines appear in comic style font and in dialogue bubbles. These kinds of advertisements were intended to be hyperbolic, humorous cheeky puffery, and that is not actionable. *See, e.g., Sterling Drug, Inc. v. F.T.C.,* 741 F.2d 1146, 1150 (9th Cir. 1984); *In re Thompson Medical,* 104 F.T.C. 648, 788-89 n. 6). Rather, as Dr. Butters testified, these ads were intended to be "a work of fiction" in that they are personifying the pomegranate bottle by comparing the bottle to a superhero. (Butters, Tr. 2906). Therefore, this ad instead conveys that (1) consumption of POM Juice may lengthen PSADT in men with biochemical recurrence of PSA following treatment for prostate cancer; and (2) POM is healthy and likely good for prostate health (CX0379_0002-03). Nowhere does POM claim it "treats" or "prevents" prostate cancer.

382. Ms. Kuyoomjian testified that in drafting the *Time* magazine cover wrap with Mr. Tupper, she did not do any independent investigation of her own as to whether the statements about the research cited in the cover wrap were true. (CX1378 (Kuyoomjian, OS Dep. at 90, 93-94)).

Response to Finding No. 382:

The evidence is undisputed that POM has improved its advertising review process and now has more formal internal review policies in place to ensure POM's compliance with the law and to help prevent mistakes in its advertising that POM concedes have occurred. (Tupper, Tr. 962, 1041, 2993, 3003). First, POM has made changes in its advertising over the years, in part, as a result of the 2005 and 2006 NAD decisions. Mr. Tupper also testified at trial that the process POM has used to connect the science to the advertising has also changed over time. (Tupper, Tr. 2977-78). Specifically, the process is now more "formalized" and includes a "checklist of individuals who need to review and sign off on those ads, ultimately culminating in a legal review." (Tupper, Tr. 2977-78). Additionally, Mr. Resnick's stated policy as to the necessary relationship between the science advertising representations concerning specific health conditions requires that the advertising accurately represent the scientific conclusions, and the supporting science must include published clinical research. (CX1353 (Tupper, Dep. at 134); Tupper, Tr. 2979). This more formalized process involving many different individuals also acts as a guard against the occurrence of any future inadvertent mistakes in all parts of the advertising. Indeed, POM's intended goal by this new process is to "ensure that nothing falls through the cracks." (Tupper, Tr. 2977-78).

Additionally, the competency and reliability of POM's research is also ensured by Mr. Resnick's consultations with scientific experts to assess the research results and to set the future directions of POM's research program. (S. Resnick, Tr. 1859; Liker, Tr. 1892-93). Mr. Resnick is advised by multiple groups of scientific experts to assist him in the

selection and understanding of the sponsored science. (Liker, Tr. 1889-91). This is a deliberate and disciplined effort by Mr. Resnick to ensure that the integrity of the research program and the resulting science. To this end, Mr. Resnick consults with his internal advisors, attends POM's research summits, and consults with POM's scientific advisory boards in assessing the selection of the studies and to ensure that POM's research supporting the advertisements is both competent and reliable. (Liker, Tr. 1889-91). Mr. Resnick has also engaged the expertise of esteemed experts in particularized health or disease areas to ensure that POM's research in these areas (e.g., prostate) is of the highest caliber. (Liker, Tr. 1889-93). POM's advisory boards are made up by individuals such as the world-renowned cardiologist, Dr. P.K. Shah, Dr. Phillip Kantoff, who runs the Dana-Farber Cancer Institute at Harvard Medical School, and many other revered experts in the fields of prostate and cardiovascular medicine. (Liker, Tr. 1892-93; Kantoff, Tr. 3257).

The competency and reliability of POM's research is further supported by the fact that of the hundred or more studies that POM has sponsored, more than seventy of those have been vetted by esteemed individuals during the peer-review process and published in some of the most revered scientific journals in the country. (CX1353 (Tupper, Dep. at 47-49); Tupper, Tr. 2979-81); Liker, Tr. 1887-88). Respondents relied, in part, on the peer-review process, including the publication in prestigious journals as an indication that the sponsored science was both credible and reliable. (Liker, Tr. 1899-1900; *Daubert v. Merrell Dow Pharms*, 43 F.3d 1311, 1318 (9th Cir. 1995) ("That the research is accepted for publication in a reputable scientific journal after being subjected to the usual rigors of peer review is a significant indication that it is taken seriously by other scientists, i.e., that it meets at least the minimal criteria of good science.")). Complaint Counsel's insistence that Respondents knew that POM's research was flawed and did not provide sufficient support for the representations made in its advertising is unfounded. Indeed, the selection

and findings of POM's research has been vetted by experts of the highest integrity and reviewed by some of the best scientific journals in the world, ensuring the excellence, competence, and reliability of POM's research results.

Moreover, Respondents' experts testified that there is competent and reliable scientific evidence that supports the conclusion that the consumption of pomegranate juice and pomegranate extract supports prostate health, including by prolonging PSA doubling time in men with rising PSA after primary treatment for prostate cancer. (PX0161; PX0353 (Heber, Dep. at 84-85); deKernion, Tr. 3126; PX0351 (deKernion, Dep. at 41-42); Heber, Tr. 2012) (RFF 1577, 1919-1922).

Respondents' expert Dr. deKernion testified that when subjects were treated with POM Juice (Pantuck study) or POMx (Carducci study) the research showed that it slowed down the growth of the tumor cells as expressed by the longer time it took for those tumor cells to double. (deKernion, Tr. 3057). Dr. deKernion testified that that the PSA doubling time studies of Drs. Pantuck and Carducci both showed a dramatic lengthening of PSA doubling time which Dr. deKerinon opined was a valid and effective marker (i.e. surrogate) for recurrence and death from prostate cancer after radical prostatectomy. (deKernion, Tr. 3052-58). (RFF 1722). Dr. deKernion also testified that based on all of the science it is likely that POM or POMx will improve the chances of avoiding or deferring the recurrence of prostate cancer in men who have had a radical prostatectomy. (deKernion, Tr. 3061).(RFF 1774). Dr. Heber testified that POM and POMx lengthened PSA doubling time and thus at least deferred recurrence or death from prostate cancer. (Heber, Tr. 2012) (RFF 1776).

383. According to Mr. Resnick, POM's advertising did convey, through reference to the prostate research, that "the taking of pomegranate juice would affect the growth or the advance of PSA in men with prostate problems." (CX1363 (S. Resnick, TCCC Dep. at 85)).

Response to Finding No. 383:

Respondents' experts testified that there is competent and reliable scientific evidence that supports the conclusion that the consumption of pomegranate juice and pomegranate extract supports prostate health, including by prolonging PSA doubling time in men with rising PSA after primary treatment for prostate cancer. (PX0161; PX0353 (Heber, Dep. at 84-85); deKernion, Tr. 3126; PX0351 (deKernion, Dep. at 41-42); Heber, Tr. 2012) (RFF 1577, 1919-1922).

Respondents' expert Dr. deKernion testified that when subjects were treated with POM Juice (Pantuck study) or POMx (Carducci study) the research showed that it slowed down the growth of the tumor cells as expressed by the longer time it took for those tumor cells to double. (deKernion, Tr. 3057). Dr. deKernion testified that that the PSA doubling time studies of Drs. Pantuck and Carducci both showed a dramatic lengthening of PSA doubling time which Dr. deKerinon opined was a valid and effective marker (i.e. surrogate) for recurrence and death from prostate cancer after radical prostatectomy. (deKernion, Tr. 3052-58). (RFF 1722). Dr. deKernion also testified that based on all of the science it is likely that POM or POMx will improve the chances of avoiding or deferring the recurrence of prostate cancer in men who have had a radical prostatectomy. (deKernion, Tr. 3061).(RFF 1774). Dr. Heber testified that POM and POMx lengthened PSA doubling time and thus at least deferred recurrence or death from prostate cancer. (Heber, Tr. 2012) (RFF 1776).

Complaint Counsel also fail to acknowledge Mr. Resnick's testimony that the competency and reliability of POM's research is ensured by Mr. Resnick's consultations with scientific experts to assess the research results and to set the future directions of POM's research program. (S. Resnick, Tr. 1859; Liker, Tr. 1892-93). Mr. Resnick is

advised by multiple groups of scientific experts to assist him in the selection and understanding of the sponsored science. (Liker, Tr. 1889-91). This is a deliberate and disciplined effort by Mr. Resnick to ensure that the integrity of the research program and the resulting science. To this end, Mr. Resnick consults with his internal advisors, attends POM's research summits, and consults with POM's scientific advisory boards in assessing the selection of the studies and to ensure that POM's research supporting the advertisements is both competent and reliable. (Liker, Tr. 1889-91). Mr. Resnick has also engaged the expertise of esteemed experts in particularized health or disease areas to ensure that POM's research in these areas (e.g., prostate and heart) is of the highest caliber. (Liker, Tr. 1889-93). POM's advisory boards are made up by individuals such as the world-renowned cardiologist, Dr. P.K. Shah, Dr. Phillip Kantoff, who runs the Dana-Farber Cancer Institute at Harvard Medical School, and many other revered experts in the fields of prostate and cardiovascular medicine. (Liker, Tr. 1892-93; Kantoff, Tr. 3257).

The competency and reliability of POM's research is further supported by the fact that of the hundred or more studies that POM has sponsored, more than seventy of those have been vetted by esteemed individuals during the peer-review process and published in some of the most revered scientific journals in the country. (CX1353 (Tupper, Dep. at 47-49); Tupper, Tr. 2979-81); Liker, Tr. 1887-88). Respondents relied, in part, on the peer-review process, including the publication in prestigious journals as an indication that the sponsored science was both credible and reliable. (Liker, Tr. 1899-1900; *Daubert v. Merrell Dow Pharms*, 43 F.3d 1311, 1318 (9th Cir. 1995) ("That the research is accepted for publication in a reputable scientific journal after being subjected to the usual rigors of peer review is a significant indication that it is taken seriously by other scientists, i.e., that it meets at least the minimal criteria of good science.")). Complaint Counsel's insistence that Respondents knew that POM's research was flawed and did not provide sufficient

support for the representations made in its advertising is unfounded. Indeed, the selection and findings of POM's research has been vetted by experts of the highest integrity and reviewed by some of the best scientific journals in the world, ensuring the excellence, competence, and reliability of POM's research results.

384. These magazine wraps, with their detailed descriptions of studies on prostate cancer, explanation of PSADT as an indication of disease progression, and emphasis on "[d]rink[ing] to prostate health," convey the net impression that drinking eight ounces of POM Juice daily treats, prevents, or reduces the risk of prostate cancer, including by slowing PSADT. Moreover, the magazine wraps' claims that POM Juice is "backed by science," has tens of millions of dollars in medical research behind it, and has been documented by "clinical studies," convey the overall net impression that POM's benefits for prostate cancer have been proven by clinical testing. (CCFF ¶¶ 377-81).

Response to Finding No. 384:

Complaint Counsel misstates the evidence and the documents speak for themselves.

Complaint Counsel erroneously relies upon the impact of only a few, select elements for their overall view of the net impression of an ad, and seemingly neglect at least two significant elements that are key to any facial or common sense net impression analysis—that the challenged products are products wholly-derived from pomegranates, and the challenged products' effectiveness is based, at least in significant part, on the products' abundant antioxidants. The fact that the ads depict juice that is wholly-derived from the pomegranate fruit is heavily emphasized in the body copy and the visual imagery of the ad as well as on the product itself. There is a dominant image of deep, ruby red pomegranate juice in a bottle shaped like two pomegranates stacked on top of one another, the words "100% Pomegranate Juice" are clearly displayed on the face of the POM Juice bottle depicted and there is repeated textual reference to "POM Wonderful 100% Pomegranate Juice". It is nonsensical that from all these depictions of fruit juice and body copy mentioning pomegranate juice that Complaint Counsel can make a giant leap to asserting that that it conveys a message that POM Juice can prevent or reduce the risk of prostate cancer. Additionally, the ad emphasizes that POM Juice contains

abundant naturally occurring antioxidants that may help guard your body against free radicals. For example, the "Drink and be healthy" ad references: a) "superior antioxidant[s];" b) "antioxidant superpower;" (c) "high levels of powerful antioxidants;" (d) "polyphenol antioxidants;" and 3) "free radicals."

Both the whole food aspect of the advertising and the emphasis on antioxidant content, directly counter any suggestion that POM Juice is going to act like a drug, as distinguished from an especially healthy fruit or vegetable and a healthy diet.

Nowhere in these ads do Respondents expressly (*i.e.*, unequivocally and directly) state that (a) POM Juice "prevents," "treats," or "reduces the risk" of prostate cancer; or (b) POM Juice is "clinically proven" to "prevent," "treat," or "reduce the risk" of prostate cancer. (CX260_0001; CX1426_0028, Exh. B). Complaint Counsel's assertion that the ad impliedly conveys the message that (a) POM Juice "prevents," "treats," or "reduces the risk" of prostate cancer, like a drug; or (b) POM Juice is "clinically proven" to "prevent," "treat," or "reduce the risk" of prostate cancer, like a drug, is not conspicuous, self-evident, or reasonably clear from the face of the ads. (CX260_0001; CX1426_0028, Exh. B). Consequently, because the above-referenced challenged implied claim may not be determined with confidence from the face of the ads, extrinsic evidence must be examined. The overall net impression of these ads is not that (a) drinking eight ounces of POM Juice prevents, treats or reduces the risk of certain diseases, such as prostate cancer, like a drug; or (b) drinking eight ounces of POM Juice is "clinically proven" to prevent, treat or reduce the risk of certain diseases, such as prostate cancer, like a drug. (CX260_0001; CX1426_0028, Exh. B).

While the ads cited some of POM's underlying research, those statements were qualified with language like, "recently published piloy study", "emerging science" and "promising" results. Furthermore, competent and reliable scientific evidence supports the

conclusion that the consumption of pomegranate juice and pomegranate extract supports prostate health. (PX0161; PX0353 (Heber, Dep. at 84-85)).

To the extent a "reduce the risk" claim can be implied from the ads, the overall net impression is not that drinking eight ounces of POM Juice "reduces the risk" of certain diseases, such as prostate cancer, like a drug with a single target of action, but that it may help "reduce the risk," like many other whole foods, or like an especially healthy fruit or vegetable, or like a a healthy diet of fruits and vegetables and exercise "reduces the risk" of disease. (CX260_0001; CX1426_0028, Exh. B). To the extent a "treat" claim can be implied from these ads (which it cannot), the overall net impression of these ads is not that POM Juice is a substitute for conventional medical treatment. (Butters, Tr. 2821-22). And to the extent a "proven" claim can be implied from these ads (which it cannot), the overall net impression of these ads is not that POM Juice is "proven" to be 100% effective in preventing, treating or reducing the risk of prostate cancer because (1) all of the qualifying language contradicts an implied "clinically proven" interpretation, and (2) "proven" in science and to consumers means the "average person in the study benefitted," not that "everyone in the study necessarily benefitted" or that everyone will benefit like the persons who benefitted in the study. (Heber, Tr. 2011; Butters, Tr. 2893-2894; PX0361 (Sacks, Dep. at 81)).

Furthermore, Complaint Counsel's expert, Professor Mazis, testified that Complaint Counsel is not challenging POM's ads for POM Juice that ran after December 2008. (Mazis, Tr. 2753-54). Accordingly, based on these representations, Complaint Counsel cannot now challenge these ads.

Professor Butters concluded that POM's ads in general depend on parody, exaggeration and humor to bring their message to the potential consumer; including the following messages: 1) POM is the best pomegranate that anyone can buy; 2) POM Juice is healthy;

3) POM Juice is tasty; 4) POM Juice is arguably the best source of antioxidants of any of the comparable beverages available; 5) medical research has suggested that antioxidants combat free radicals, which are unhealthy, and may contribute to diseases of the heart, arteries, and prostate, as well as erectile dysfunction; and 6) POM also offers concentrated forms of pomegranate extract for those who wish to ingest antioxidants in even more concentrated form than pomegranate juice itself. (PX0158-0033).

Professor Butters testified that "'I'm off to save PROSTATES!" could be interpreted by outliers, unreasonable viewers of the ad, to mean I'm going to somehow protect them or rescue them from disease but that he believes that such an interpretation is unlikely. (Butters, Tr. 2895-01). Professor Butters also testified that he concluded in his report that the use of the humor in this ad indicates to the reader that this is not serious medical advice; that this is a general suggestion that POM Juice is healthy, looking at the context of the entire ad. (Butters, Tr. 2905-06).

Complaint Counsel presented no extrinsic evidence or expert opinion on these ads' meaning, consumer perceptions of these ads, or consumer interpretations regarding these ads. (PX0357 (Stewart, Dep. at 49, 52)). Complaint Counsel also failed to present any evidence (1) that the claims in these ads reasonably convey that POM Juice is "clinically proven" to prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction and (2) regarding the number of exposures consumers had to these ads or any particular POM advertisement. (Mazis, Tr. 2752).

To the extent any claim is made, the fact that POM advertised the amount of money Respondents spent on scientific research does not convey the net impression that POM Juice is "clinically proven to prevent, treat or reduce the risk of prostate cancer." (RFF 2507-19; Respondents' Post-Trial Br. at 76-77.) What these "backed by" ads actually states is that Respondents spent a particular sum of money on scientific studies on POM

Juice to back-up their health claims. Contrary to Complaint Counsel's implication, it is completely illogical to infer from the fact that a certain amount of money was invested in research to the conclusion that POM Juice is proven to prevent, treat or reduce the risk of disease. Again, this is another one of Complaint Counsel's ill-defined, "logical leaps" from "backed by $32 million of initial scientific research" to "backed by $32 million in research that proved POM Juice prevents, treats or reduces the risk of prostate cancer." Indeed, Complaint Counsel presented no evidence that consumers took away the message alleged by Complaint Counsel because Respondents' spent a certain amount of money on science and research. (RFF 28-29, 2515). Moreover, the "backed by" ads accurately and truthfully represented the dollars spent by Respondents on the totality of the science on POM Juice. (RFF 2510). Moreover, these ads are immaterial because there is no evidence that anyone bought POM Juice because they thought Respondents spent a certain amount of money in a particular area of research. Indeed, Professor Reibstein's survey showed the opposite: that no one bought POM Juice because of the amount of money spent on science. (PX0223-0006).

Therefore, POM's "prostate" ads instead conveys that (1) consumption of POM Juice may lengthen PSADT in men with biochemical recurrence of PSA following treatment for prostate cancer; and (2) POM is healthy and likely good for prostate health (CX260_0001). Nowhere does POM claim it "treats" or "prevents" prostate cancer.

3. POM Juice Bottle Hang Tag Made Establishment Claims Regarding Heart Disease, Prostate Cancer, and Erectile Dysfunction (CX0475 / CX1426_00027 [Compl. Ex. A])

385. POM disseminated "hang tags," which were hard paper stock tags hung around the neck of POM Juice bottles, in order to promote the product or make announcements to consumers. (L. Resnick, Tr. 264).

Response to Finding No. 385:

Respondents have no specific response.

386. One hang tag, which was disseminated on POM Juice bottles since at least September 2009, contained the bold headline "**SUPER HEALTH POWERS!**" on the outside of the tag. Inside, the hang tag stated:

100% PURE POMEGRANATE JUICE. It's 100% pure! It's heroically healthy! It's The Antioxidant Superpower, P♥M Wonderful 100% authentic pomegranate juice. Backed by $25 million in medical research. Proven to fight for cardiovascular, prostate and erectile health. Committed to keeping you healthy for a good long time!

The back of the hang tag contained a chart purporting to show that POM Juice has the most antioxidants, as compared to other beverages, and directed consumers to a page on POM's website, pomwonderful.com/compare. (CX0475; *see also* CX1426_00027).

Response to Finding No. 386:

Complaint Counsel misstates the evidence and the document speaks for itself. Complaint Counsel failed to present any evidence that Respondents would run this ad in the future, let alone whether it is probable they would do so. This ad cannot provide a basis for injunctive relief because no evidence exists to show that Respondents are likely to run this ad in the future, let alone whether it is probable they would do so.

This ad is tied to a bottle of POM Juice that is wholly-derived from the pomegranate fruit The ad emphasizes that POM Juice contains abundant naturally occurring antioxidants. For example, this ad references "antioxidant superpower". Complaint Counsel ignores, among other elements, the blatant fact that POM Juice is 100% fruit juice.

The ad does not convey the message that (a) POM Juice "prevents," "treats," or "reduces the risk" of heart disease, erectile dysfunction or prostate cancer; or (b) POM Juice is "clinically proven" to "prevent," "treat," or "reduce the risk" of heart disease or prostate cancer since this message is not conspicuous, self-evident, or reasonably clear from the face of the ad. Consequently, because no implied claim relating to prevention, treatment or reduction of risk may be determined with confidence from the face of the ad, extrinsic evidence must be examined. The overall net impression of this ad is not that (a) drinking eight ounces of POM Juice prevents, treats or reduces the risk of certain diseases, such as

heart disease or prostate cancer; or (b) drinking eight ounces of POM Juice is "clinically proven" to prevent, treat or reduce the risk of certain diseases, such as heart disease or prostate cancer.

To the extent a "reduce the risk" claim can be implied from this ad, the overall net impression is not that drinking eight ounces of POM Juice "reduces the risk" of certain diseases, such as heart disease or prostate cancer, like a drug with a single target of action, but that it may help "reduce the risk," like many other whole foods, or like an especially healthy fruit or vegetable, or like a a healthy diet of fruits and vegetables and exercise "reduces the risk" of disease.

To the extent a "treat" claim can be implied from this ad (which it cannot), the overall net impression of any ad is not that POM Juice is a substitute for conventional medical treatment. (Butters, Tr. 2821-22; Appendix of Advertisements).

To the extent a "proven" claim can be implied from this ad (which it cannot), the overall net impression of this ad is not that POM Juice is "proven" to be 100% effective in preventing, treating or reducing the risk of heart disease or prostate cancer because (1) all of the qualifying language contradicts an implied "clinically proven" interpretation, and (2) "proven" in science and to consumers means the "average person in the study benefitted," not that "everyone in the study necessarily benefitted" or that everyone will benefit like the persons who benefitted in the study. (Heber, Tr. 2011; Butters, Tr. 2893-2894; PX0361 (Sacks, Dep. at 81)).

Professor Butters concluded that POM's ads in general depend on parody, exaggeration and humor to bring their message to the potential consumer; including the following messages: 1) POM is the best pomegranate that anyone can buy; 2) POM Juice is healthy; 3) POM Juice is tasty; 4) POM Juice is arguably the best source of antioxidants of any of the comparable beverages available; 5) medical research has suggested that antioxidants

combat free radicals, which are unhealthy, and may contribute to diseases of the heart, arteries, and prostate, as well as erectile dysfunction; and 6) POM also offers concentrated forms of pomegranate extract for those who wish to ingest antioxidants in even more concentrated form than pomegranate juice itself. (PX0158-0033).

Complaint Counsel presented no extrinsic evidence or expert opinion on this ad's meaning, consumer perceptions of this ad, or consumer interpretations regarding this ad. (PX0357 (Stewart, Dep. at 49, 52))

Complaint Counsel failed to present any evidence that the claims in this ad reasonably convey that POM Juice is "clinically proven" to prevent, treat or reduce the risk of heart disease, erectile dysfunction or prostate cancer.

Complaint Counsel failed to present any evidence regarding the number of exposures consumers had to this ad or any particular POM advertisement. (Mazis, Tr. 2752).

The message that the ad actually conveys is that Respondents are committed to the science, and learning the truth about pomegranates. POM Wonderful 100% Pomegranate Juice is supported by $25 million of initial scientific research from leading universities, which has uncovered encouraging results in prostate and cardiovascular health. As Mrs. Resnick testified, the purpose of including the amount of money related to medical research in the advertising was to convey a message about the company, and its level of dedication to learning the truth about pomegranates. Mrs. Resnick testified, "[Respondents wanted] a very direct of communicating to the consumer that here was a natural food that had gone through rigorous scientific testing and that we cared enough to do this and we wanted to tell people that we had and continue to do scientific research." (L. Resnick, Tr. 251; *see also* CCFF 309, 311).

Therefore, Respondents' interpretation, which examines all the elements of the ad as whole, including, among other elements, the fact that the product is 100% fruit juice, is thus the most common-sense approach.

387. Dr. Butters testified that a reasonable reader could infer from the phrase "backed by $25 million in medical research" on the hang tag that the research has been completed and has results. (Butters, Tr. 2878).

Response to Finding No. 387:

Professor Butters also testified that because hangtags are small and will engage the concerted attention of relatively few potential purchasers, a hangtag offers limited opportunity for public communication (as compared to, newspaper ads or television commercials). (Butters, Tr. 2868-69). Professor Butters testified that the hangtag is considered a form of point-of-sale marketing and in his opinion, hangtags are less important than print advertisements. (Butters, Tr. 2869-70). Professor Butters further testified that the dominant theme of the hangtag is that POM Juice has super health powers and that the overall messaging of the hangtag reflects the tone and spirit of POM's superhero advertising campaign. Professor Butters testified that one message that is being conveyed by the hangtag is that POM Juice is extremely healthy. (Butters, Tr. 2870-73).

388. The hang tag's reference to "[p]roven to fight for cardiovascular, prostate and erectile health" and that the juice is "[b]acked by $25 million in medical research," combined with the POM Juice bottle and logo, convey the net impression that POM Juice treats, prevents, or reduces the risk of cardiovascular disease, prostate cancer, and erectile dysfunction, and that these health benefits are clinically proven. (*See* CCFF ¶¶ 386-87).

Response to Finding No. 388:

Complaint Counsel misconstrue and misrepresent the meaning of this hangtag. The fact that POM Juice is wholly-derived from the pomegranate fruit is heavily emphasized in the body copy and the visual imagery of this hangtag. This hangtag features the dominant image of deep, ruby red pomegranate juice in bottle shaped like two

pomegranates stacked on top of one another. (CX1426_0027, Exh. A). The hangtag also features a statement that POM Juice is nothing but "100% PURE POMEGRANATE JUICE". (CX1426_0027, Exh. A).

Complaint Counsel's assertion that the ad implicitly conveys the net impression that POM Juice treats, prevents, or reduces the risk of cardiovascular disease, prostate cancer, and erectile dysfunction, and that these health benefits are clinically proven is not conspicuous, self-evident, or reasonably clear from the face of the ad. (CX1426_0027, Exh. A). Consequently, because the above-referenced challenged implied claim may not be determined with confidence from the face of the ad, extrinsic evidence must be examined.

Complaint Counsel erroneously rely upon the impact of only a few, select elements for their overall view of the net impression of an ad, and seemingly neglect at least two significant elements that are key to any facial or common sense net impression analysis—that POM Juice is wholly-derived from pomegranates, and POM Juice's effectiveness is based, at least in significant part, on the products' abundant antioxidants.

Professor Butters testified that it is necessary to view the hangtag as a whole. In his opinion, the hangtag does not make any medical claims; readers would not take away that it is proven that if you drink pomegranate juice, it is going to treat cardiovascular, prostate, and erectile disease, or even give you cardiovascular, prostate, and erectile health. The hangtag only makes claims "within the framework of the superhero and the verb 'fight for,' which is not something that people are going to take as anything other than -- than hyperbolic, … It will merely 'fight for.'" (Butters, Tr. 2884-85). Professor Butters testified that the message suggested by the phrase "proven to fight for cardiovascular, prostate, and erectile health" is that you have a better cardiovascular, prostate, and erectile health -- not that POM has a cure. "Fight for" doesn't necessarily

mean that you are going to win, not does it mean that POM Juice is going to treat or cure diseases. (Butters, Tr. 2893-94). Professor Butters testified that "in describing POM Juice as extremely 'healthy,'" the hangtag merely repeats and references conventional wisdom with respect to fruit juices in general. (PX0350 (Butters, Dep. at 178-79)).

Mr. Resnick testified that POM's advertisements are not intended to convey the message that they can prevent or treat coronary heart disease. (S. Resnick, Tropicana, Dep. at 58-59). Although Mr. Resnick testified that POM believes pomegranate juice is beneficial in preventing and treating coronary heart disease, he does not want consumers to share this belief, but rather to look at their science and make up their own mind. (S. Resnick, Tropicana, Dep. at 42-43). Mr. Resnick never intended POM products to be a substitute for recommended medical treatment or anything else recommended by a doctor. (S. Resnick, Tr. 1870). Mr. Tupper testified that it is absolutely against company policy to say or suggest that POM products are a substitute for proper medical treatment. (Tupper, Tr. 3018). In responding to health-related inquires or a question about a medical condition, POM instructs its employees to tell consumers to consult with his or her physician and strongly encourage this recommendation. (CX0308; Tupper, Tr. 3019).

The overall net impression of this ad is not that POM Juice treats, prevents, or reduces the risk of cardiovascular disease, prostate cancer, and erectile dysfunction, and that these health benefits are clinically proven. (CX1426_0027, Exh. A). Even the language of the ad itself uses such qualifiers as "fight for" and "committed." (CX1426_0027, Exh. A). Instead, the "Super HEALTH POWERS!." hang-tag makes multiple efforts to convey that POM Juice is a whole food product that is wholly-derived from pomegranates, including: a) imagery of deep, ruby red pomegranate juice in a bottle shaped like two pomegranates stacked on top of one another; b) a textual reference to "100% PURE POMEGRANATE JUICE."

In addition to these efforts to convey POM Juice as whole food product that is wholly-derived from pomegranates, a consumer must go to the produce section of the grocery store in order to view the challenged hang-tag. This inevitably exposes the consumer to the clearly depicted "100% Pomegranate Juice" text on the bottle and the bottle cap, as well as the bottle shaped like two pomegranates stacked on top of one another.

Additionally, the hang-tag emphasizes that POM Juice contains abundant antioxidants. For example, the "Super HEALTH POWERS!" hang-tag references: a) "The antioxidant power of POM Wonderful" and b) an antioxidant potency comparison beverage chart.

Both the whole food aspect of the advertising and the emphasis on antioxidant content, directly counter any suggestion that POM Juice is going to act like a drug, as distinguished from a very healthy fruit or vegetable and a healthy diet.

Viewing the ad as a whole, taking into account all the various elements, including the prevalence and pervasiveness of the body copy as well as the repeated emphasis on the fact that POM Juice is a concentrated and potent source of antioxidants, it is far more logical that POM consumers would view POM Juice the way they perceive many other whole foods, like broccoli, blueberries, grapes or tomatoes, which may help prevent or improve your odds against disease, but which would not act like a drug with a single target of action against a particular disease or condition.

To the extent a "reduce the risk" claim can be implied from ad, the overall net impression is not that drinking eight ounces of POM Juice "reduces the risk" of certain diseases, such as heart disease, prostate cancer or erectile dysfunction, like a drug with a single target of action, but that it may help "reduce the risk," like many whole foods, or like an especially healthy fruit or vegetable, or like a healthy diet of fruits and vegetables and exercise "reduces the risk" of disease. (CX1426_0027, Exh. A).

To the extent a "treat" claim can be implied from this ad (which it cannot), the overall net impression of any ad is not that POM Juice is a substitute for conventional medical treatment. (Butters, Tr. 2821-22).

To the extent a "proven" claim can be implied from this ad (which it cannot), the overall impression of this ad is not that POM Juice is "proven" to be 100% effective in preventing, treating or reducing the risk of heart disease, prostate cancer or erectile dysfunction because (1) all of the qualifying language contradicts an implied "clinically proven" interpretation, and (2) "proven" in science and to consumers means the "average person in the study benefitted." "Proven" does not mean that "everyone in the study necessarily benefitted" or that everyone will benefit like the persons who benefitted in the study. (Heber, Tr. 2011; Butters, Tr. 2893-2894; PX0361 (Sacks, Dep. at 81)).

Viewing the "Super HEALTH Powers!" ad as a whole, including the interaction of the words and visual imagery, the overall net impression of this ad is that the ad is hyperbolic, POM Juice is a healthy product, and POM Juice "fights" for cardiovascular, prostate, and erectile health. (Butters, Tr. 2870-73; 2884-85; 2893-94).

Contrary to Complaint Counsel's implication, it is completely illogical to infer from the fact that a certain amount of money was invested in research to the conclusion that POM Juice is proven to prevent, treat or reduce the risk of disease. Complaint Counsel's attempts to make a "logical leaps" from "backed by $25 million of initial scientific research" to "backed by $25 million in research that proved POM Juice prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction." What the "backed by" ads actually convey is that Respondents are committed to the science and learning the truth about pomegranates. (L. Resnick, Tr. 251). Complaint Counsel presented no evidence that consumers took away the message presumed by Complaint Counsel because Respondents spent a certain amount of money on science and research.

(RFF 28-29, 2515). Moreover, the ad accurately and truthfully represented the dollars spent by Respondents on the totality of the science on POM Juice. (RFF 2510).

Even assuming *arguendo* that this ad conveys the message Complaint Counsel assigns to it, Professor Reibstein's survey effectively demonstrates that any alleged disease claims made by Respondents were not material to the purchasing decisions of POM consumers. (RFF 2623, 2630). Complaint Counsel failed to present any evidence regarding the number of exposures consumers had to this ad or any particular POM advertisement. Complaint Counsel have presented no reliable evidence to rebut Professor's Reibstein's survey findings or to show that any alleged disease claims made in POM's ads were material to the purchasing decisions of POM consumers.

Complaint Counsel presented no extrinsic evidence or expert opinion on this ad's meaning, consumer perceptions of this ad, or consumer interpretations regarding this ad. (PX0357 (Stewart, Dep. at 49, 52)). Complaint Counsel failed to present any evidence that the claims in this ad reasonably convey that the Challenged Products are "clinically proven" to treat like a drug or reduce the risk of or prevent heart disease, prostate cancer or erectile dysfunction like a drug. Complaint Counsel failed to present any evidence regarding the number of exposures consumers had to this ad or any particular POM advertisement. (Mazis, Tr. 2752).

4. POMx Pill Print Ads Made Establishment Claims Regarding Heart Disease, Prostate Cancer, and Erectile Dysfunction

389. POM disseminated numerous print advertisements for POMx Pills in 2007 through 2010. In many advertisements, the headlines differed, but the body copy was substantially similar in describing POMx's purported benefits for prostate cancer, cardiovascular disease, and erectile dysfunction, using specific clinical studies of POM Juice, purported quotes from researchers, and statements that the claims were backed by tens of millions of dollars in medical research. (*See* CCFF ¶¶397-g.441).

Response to Finding No. 389:

Respondents also object to the proposed finding to the extent that Complaint Counsel construe the cited evidence to bolster their argument that Respondents intended to convey or conveyed to consumers that the Challenged Products treat, prevent or reduce the risk of heart disease, prostate cancer and erectile dysfunction. Respondents genuinely believe in the health benefits of the Challenged Products and in the scientific integrity of POM's research (RFF 502-20). Thus, it is not surprising that POM's ads summarize some of Respondents' scientific research on the Challenged Products in the areas of cardiovascular, prostate and erectile health and talk about the healthful properties of the Challenged Products, including that the Challenged Products contain abundant antioxidants and that they are wholly derived from pomegranate fruit. (RFF 493-99, 2478-2505, 2518-44). However, the Respondents dispute that they ever intended to convey or that the Challenged Ads do convey the claim that the Challenged Products treat, prevent or reduce the risk of heart disease, prostate cancer and erectile dysfunction or that they are "clinically proven" to do so. (RFF 496, 535, 538, 540, 545-50, 2209-11, 2280; CX1375 (L. Resnick, Trop., Dep. at 79-81).

Moreover, POM never states, expressly or by implication, conspicuously on the face of any of the Challenged Ads that scientific tests "prove" that the Challenged Products "prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction," or even that they "prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction." (RFF 2209-11, 2467-68, 2506, 2517; Reply Ad Appendix; Appendix of Advertisements). Even where medical research was referenced in advertising, the ads conveyed qualified messages about the health benefits of the Challenged Products, not definitive claims that the products will treat, prevent or reduce the risk of heart disease, prostate cancer or erectile dysfunction. (RFF 2517). Throughout its advertising, POM highlights that POM Juice is a 100% juice product

wholly-derived from the pomegranate fruit, and that POMx has the same content as the pomegranate fruit itself and is 100% derived from the exact same fruit. (RFF 493-94, 2518-44; Reply Ad Appendix). Indeed, Respondents have never advertised their products as a pharmaceutical drug, nor intended to advertise their products as drugs. (RFF 495-96, 524-30). Rather, Respondents have always marketed the Challenged Products for what they intrinsically are: whole-food products. (RFF 497-99).

390. POMx print advertisements frequently included a graphic showing a POMx Pill capsule next to a POM Juice bottle, with an equal sign between them, along with statements indicating equivalence of the two products, such as "The antioxidant power of our 8 oz. juice." (*See, e.g.,* CCFF ¶¶ b.407-10, f.430).

Response to Finding No. 390:

Throughout its advertising, POM highlights that POM Juice is a 100% juice product wholly-derived from the pomegranate fruit, and that POMx has the same content as the pomegranate fruit itself and is 100% derived from the exact same fruit. (*See* RFF 494). Moreover, Respondents have never advertised their products as a pharmaceutical drug, nor intended to advertise their products as drugs. (RFF 495-96). Rather, Respondents have always marketed POM Juice and POMx Pills and POMx Liquid for what they intrinsically are: whole-food products. These facts are heavily and repeatedly emphasized throughout POM's advertising, both visually and in the body copy.

Respondents have presented ample evidence establishing that POM Juice and POMx Pills and POMx Liquid are equivalent on proving health benefits to humans and that POMx Pills and POMx Liquid have equivalent bioavaiablity as POM Juice. (RFF 920, 921). Dr. Heber testified that animal studies indicated that effect of pomegranate juice and POMx Pills on prostate cancer are equivalent. (RFF 922). Further, Dr. Carducci's study, "Safety and efficacy of pomx in men with prostate cancer: an 18-month, randomized, double-blind, dose-finding study of the effects of two (2) doses of pomegranate juice extract capsules (1 or 3 capsules/day) on rising prostate specific

antigen levels in men following initial therapy for prostate cancer," obtained a similar result when studying the effect of POMx on PSADT as obtained in Dr. Pantuck's Phase II Study. (RFF 923).

391. Mrs. Resnick was aware as early as 2006 that the Dietary Supplement Health and Education Act did not allow dietary supplement marketers to make disease claims to consumers, including through advertisements, websites, or product labels. (CX0054_0001).

Response to Finding No. 391:

Respondents object to Complaint Counsel's citation to CX0054 as it was conditionally admitted at trial. Respondents also object to this finding of fact on the basis that the statements in the document are hearsay, from a witness who did not testify at trial. CX0054_001 is an email from Staci Glovsky to Fiona Posell; Mrs. Resnick was not copied on this email. An email from a POM marketing employee to a colleague regarding comments that Mrs. Resnick purportedly made is clearly hearsay; such an email merely reflects the author's view or interpretation of their discussion with Mrs. Resnick. Further, Ms. Posell, the recipient of the email, testified that she did not even recall this email. (Posell, Tr. 394-95).

Complaint Counsel cannot attempt to attribute knowledge that the Dietary Supplement Health and Education Act did not allow dietary supplement marketers to make disease claims to consumers to Mrs. Resnick based on this email. In fact, the author's testimony supports the exact opposite conclusion. Ms. Glovsky testified that she doubted that she discussed the Dietary Supplement Health and Education Act with Mrs. Resnick. From what she could recall about the discussion, Ms. Glovsky indicated that it was likely that she raised the limitations on making disease claims in advertising in communicating with Ms. Posell, not that Mrs. Resnick raised such concerns with Ms. Glovsky. (Glovsky, Dep. at 41-44)).

392. Charlene Rainey, a regulatory consultant who assisted POM in submitting a new dietary ingredient application to FDA, reviewed a draft brochure for POMx in 2007. (Dreher, Tr. 541-42). In a January 2007 email providing her feedback on the brochure, Rainey cautioned, "Mentions of diseases: In labeling (which includes supporting materials such as the brochure), FDA does not allow statements that *claim or imply that the product may help to diagnose, treat, cure or prevent any disease*, unless the statement is authorized by FDA." (CX0094_0001 (emphasis added)). Further emphasizing this point, Rainey wrote, "[l]abeling claims need to be limited to what are called 'structure/function claims,' which are statements about the ability of a product to maintain a healthy structure or function of the body, *without implying disease prevention or treatment*." (CX0094_0001 (emphasis added)). Rainey specifically warned:

Therefore, the brochure and other supporting materials should be limited to statements such as "cardiovascular support," "helps maintain prostate health," etc.

Examples of words or phrases that FDA would object to:

- Inflammatory stress
- Cardiovascular disease, heart disease, atherosclerosis, etc.
- Hypertension, high blood pressure, etc.
- Cancer
- Plaque build-up
- Thickening of artery walls
- Ischemia

(CX0094_0001).

Response to Finding No. 392:

Respondents object to Complaint Counsel's citation to CX0094 as it was conditionally admitted at trial. Respondents also object to this finding of fact on the basis that the statements in the document are hearsay, from a witness who did not testify at trial.

393. POM's internal documents show that when POM introduced POMx Pills, the company was concerned about using studies that were done on POM Juice to support claims for POMx Pills. (CX0073_0002 ("Please note that juice claims cannot simply be transferred to POMx claims. Please see the attached . . . starter list of claims. Note that all claims are based on clinical studies for the POMx material.")). Nonetheless, a 2007 press release for POMx Pills described the product as a supplement that "[j]ust like [POM Juice] . . . promote[s] heart and prostate health." (CX0115_0001).

Response to Finding No. 393:

Respondents object to Complaint Counsel's citation to CX0073_0002 as it was conditionally admitted at trial. Respondents also object to this finding of fact on the basis that the statements in the document are hearsay, from a witness who did not testify at trial.

Respondents aver that competent and reliable scientific evidence supports the conclusion that the consumption of pomegranate juice and pomegranate extract supports prostrate health and the conclusion that the same mechanism in the *in vitro* studies, the animal studies and in the Pantuck and Carducci human studies also showed with a high degree of probability that the Challenged Products inhibit the clinical development of prostate cancer cells in men who have not been diagnosed with prostate cancer. (RFF 1577-1578).

After reviewing Respondents' body of cardiovascular research, Dr. Heber concluded that the Respondents' science showed that POM Juice and POMx Pills and POMx Liquid are likely to cause a significant improvement in cardiovascular health and help to reduce the risk of cardiovascular disease. (RFF 131 (Heber, Tr. 2012)). Further, Dr. Heber testified "that the scientific community believes that the research done by Dr. Ornish and Dr. Aviram and Dr. Davidson on the basis of the basic science does provide a significant scientific agreement" that pomegranate helps to reduce the risk of heart disease. (RFF 582 (Heber, Tr. 2081)). David Heber, MD, PhD, Professor Medicine and Director, UCLA Center for Human Nutrition, provided additional commentary on POMx as it relates to prostate cancer. "Basic studies indicate that the effects of POMx and POM Wonderful pomegranate juice on prostate cancer are the same. The most abundant and most active ingredients in pomegranate juice are also found in POMx." (CX0065 (Press Release –

POMx, a Highly Concentrated Form of Healthy Pomegranate Antioxidants, Becomes Available to Consumers for the First Time)).

Respondents' scientific research on cardiovascular health demonstrates that POM Juice, POMx Pills and POMx Liquid have beneficial effects on arterial plaque, blood pressure and blood flow. (RFF 1064-1146). With respect to POMx Pills and POMx Liquid in particular, Respondents detailed the findings of eight scientific studies that document the beneficial effects of POMx Pills and POMx Liquid on cardiovascular health. (CX0053; PX0057; PX0056; PX0008; PX0017; PX0038; PX0139; PX0127; RFF 831-840, 924, 930-957, 1100). Respondents dispute that they have made any establishment claims for POMx Pills and POMx Liquid.

394. POM's internal research assessments in February and July 2007 also noted "research gaps" in assessing the potency and efficacy of POMx Pills or Liquid versus POM Juice for cardiovascular disease and prostate cancer in humans. One document noted a "key question" for human studies in both diseases was whether POMx was as effective as POM Juice. (CX0100_0001; CX0132_0001).

Response to Finding No. 394:

Respondents have detailed how POM Juice and POMx Pills and POMx Liquid are equivalent on proving health benefits to humans and that POMx Pills and POMx Liquid have equivalent bioavaiablity as POM Juice. (RFF 920, 921). Dr. Heber found no difference in the antioxidant effect between POM Juice and POMx products in laboratory studies he conducted. (RFF 925). Professor Stampfer did not dispute Dr. Heber's findings. (RFF 215-216, 818-819). Respondents have provided ample evidence to demonstrate that POMx Pills and POMx Liquid are bioequivalent to POM Juice and that POMx Pills and POMx Liquid provide similar health benefits as POM Juice provides. (RFF 915-951).

395. As late as January 2009, Dr. Aviram stated that "I feel that it is important to learn more about the relationships between POM (PJ, and the pill, which, unlike PJ, we know very little on it from a mechanistical point of view[.])" (CX1060_0001; CX1358 (Aviram, Dep. at 48)). At his deposition in March 2011, Dr. Aviram admitted that "very little was

done with POMx" and that he could not confidently say POMx would work the same as POM Juice before testing it. (CX1358 (Aviram, Dep. at 48).

Response to Finding No. 395:

Complaint Counsel fail to consider the whole of Dr. Aviram's testimony regarding POMx Pills and POMx Liquid. Dr. Aviram also testified that several studies were done, such as the Rock study, on POMx showing similarity to POM Juice in amount of polyphenol antioxidants. (CX1358 (Aviram, Dep. at 51-52; 45-46)).

Respondents have detailed how POM Juice and POMx Pills and POMx Liquid are equivalent on proving health benefits to humans and that POMx Pills and POMx Liquid have equivalent bioavaiablity as POM Juice. (RFF 920, 921).

396. POMx print advertisements also frequently included a graphic showing a POMx Pill bottle next to a pomegranate fruit. Finally, POMx print advertisements frequently included a graphic of a caduceus, a symbol often associated with medicine or medical treatment. (*See*, *e.g.*, CCFF ¶¶ 397-98, b.407-10; *see also* Butters, Tr. 2944).

Response to Finding No. 396:

Throughout its advertising, POM highlights that POM Juice is a 100% juice product wholly-derived from the pomegranate fruit, and that POMx has the same content as the pomegranate fruit itself and is 100% derived from the exact same fruit. (*See* RFF 494). Moreover, even if POMx print advertisements included a graphic of a caduceus, this does not establish that Respondents advertised their products as a pharmaceutical drug, or intended to advertise their products as drugs. Respondents have never advertised their products as a pharmaceutical drug, or intended to advertise their products as drugs. (RFF 495-96). Rather, Respondents have always marketed POM Juice and POMx Pills and POMx Liquid for what they intrinsically are: whole-food products. These facts are heavily and repeatedly emphasized throughout POM's advertising, both visually and in the body copy.

b. "One small pill for mankind" / "Science, not fiction" Print Ads (CX0120 / CX0122)

397. As early as 2007, POM disseminated print advertisements introducing POMx Pills. One such advertisement, which ran in *Fortune* magazine in May 2007, included an image of a POMx Pill bottle over a bold headline, "**One small pill for mankind.**" Directly underneath the headline, in smaller but still bold font, the advertisement included a quote from a *New York Times* article dated July 4, 2006: "**Findings from a small study suggest that pomegranate juice may one day prove an effective weapon against prostate cancer.**" (CX0120).

Response to Finding No. 397:

Complaint Counsel failed to present any other definitive information regarding this ad's dissemination. Complaint Counsel failed to present any evidence that Respondents would run this ad in the future, let alone whether it is probable they would do so.

398. POM disseminated a very similar POMx advertisement in June 2007 in *Discover* and *Scientific American* magazines. (CX0122_0002). This advertisement included the same images of the POMx Pill bottle, POM Juice bottle, and caduceus. The headline of this advertisement read, "**Science, not fiction.**" and the subheadline read, "**Made from the only pomegranates backed by $20 million in medical research.**" (CX0122).

Response to Finding No. 398:

Complaint Counsel failed to present any other definitive information regarding this ad's dissemination. Complaint Counsel failed to present any evidence that Respondents would run this ad in the future, let alone whether it is probable they would do so.

The message that the ad actually conveys is that Respondents are committed to the science, and learning the truth about pomegranates. POM Wonderful 100% Pomegranate Juice is supported by $20 million of scientific research from leading universities, which has uncovered encouraging results in prostate and cardiovascular health. As Mrs. Resnick testified, the purpose of including the amount of money related to medical research in the advertising was to convey a message about the company, and its level of dedication to learning the truth about pomegranates. Mrs. Resnick testified, "[Respondents wanted] a very direct of communicating to the consumer that here was a

natural food that had gone through rigorous scientific testing and that we cared enough to do this and we wanted to tell people that we had and continue to do scientific research." (L. Resnick, Tr. 251; *see also* CCFF 309, 311).

399. The body copy of the "Science, not fiction" advertisement was otherwise almost identical to the "One small pill for mankind" advertisement.

Response to Finding No. 399:

Complaint Counsel failed to present any other definitive information regarding this ad's dissemination. Complaint Counsel failed to present any evidence that Respondents would run this ad in the future, let alone whether it is probable they would do so.

The message that the ad actually conveys is that Respondents are committed to the science, and learning the truth about pomegranates. POM Wonderful 100% Pomegranate Juice is supported by $20 million of scientific research from leading universities, which has uncovered encouraging results in prostate and cardiovascular health. As Mrs. Resnick testified, the purpose of including the amount of money related to medical research in the advertising was to convey a message about the company, and its level of dedication to learning the truth about pomegranates. Mrs. Resnick testified, "[Respondents wanted] a very direct of communicating to the consumer that here was a natural food that had gone through rigorous scientific testing and that we cared enough to do this and we wanted to tell people that we had and continue to do scientific research." (L. Resnick, Tr. 251; *see also* CCFF 309, 311).

400. Both advertisements expressly stated that taking one POMx Pill was the equivalent of drinking eight ounces of POM Juice: "Introducing P♥Mx – a highly concentrated, incredibly powerful blend of all-natural polyphenol antioxidants made from the very same pomegranates in **P♥M Wonderful 100% Pomegranate Juice**. . . . So now you can get all the antioxidant power of an 8oz glass of juice in the convenience of a calorie-free capsule." This paragraph appeared next to an image of a POM Juice bottle. The advertisements also included the tag line "**P♥M IN A PILL**" in bold font near the bottom of the page. (CX0120; CX0122).

Response to Finding No. 400:

Complaint Counsel misconstrue and misrepresent the meaning of these ads. The "One small pill" and "Science, not fiction" ads do not expressly state that taking one POMx Pill was the equivalent of drinking eight ounces of POM Juice. The clear language of the ads states that POMx Pills are made from the same pomegranates as POM Juice and state that "you can get all the antioxidant power of an 8oz glass of juice." Respondents have previously detailed how POM Juice and POMx Pills and POMx Liquid are equivalent on proving health benefits to humans and that POMx Pills and POMx Liquid have equivalent bioavaiablity as POM Juice. (RFF 920, 921). Dr. Heber found no difference in the antioxidant effect between POM Juice and POMx products in laboratory studies he conducted. (RFF 925). Professor Stampfer did not dispute Dr. Heber's findings. (RFF 215-216, 818-819). Also, Dr. Aviram testified that several studies and that there is good deal of data on POMx which shows similarity to POM Juice and that a POMx Pill has the same amount of polyphenol antioxidants as eight ounces of POM Juice. (CX1358 (Aviram, Dep. at 51-52; 45-46)). Respondents have provided ample evidence to demonstrate that POMx Pills and POMx Liquid are bioequivalent to POM Juice and that POMx Pills and POMx Liquid provide similar health benefits as POM Juice provides. (RFF 915-951).

401. The advertisements went on to state:

> Ready to take on free radicals? Put up your P♥Mx and fight them with a mighty 1000 mg capsule – that's more concentrated pomegranate polyphenol antioxidants than any other 100% pomegranate supplement. An initial UCLA medical study on P♥M Wonderful 100% Pomegranate Juice showed hopeful results for men with prostate cancer. And preliminary human research suggests that our California-grown pomegranate juice also promotes heart health. Take your antioxidants into your own hands.
>
> Footnotes in the advertisements, which appeared next to a caduceus, referred consumers to two of POM's web pages, **pomwonderful.com/cancer.html** and **pomwonderful.com/heart_health.html**. (CX0120).

Response to Finding No. 401:

Complaint Counsel misstates the evidence and the document speaks for itself. Complaint Counsel failed to present any evidence that Respondents would run this ad in the future, let alone whether it is probable they would do so. This ad cannot provide a basis for injunctive relief because no evidence exists to show that Respondents are likely to run this ad in the future.

The fact that this ad depicts juice that is wholly-derived from the pomegranate fruit is heavily emphasized in the body copy and the visual imagery of the ad as well as on the product itself. There is an image of deep, ruby red pomegranate juice in a bottle shaped like two pomegranates stacked on top of one another, the words "100% Pomegranate Juice" are clearly displayed on the face of the POM Juice bottle depicted and there is textual reference to "POM Wonderful 100% Pomegranate Juice". The ad emphasizes that POM Juice contains abundant naturally occurring antioxidants that may help guard your body against free radicals. For example, this ad references: a) "antioxidant superpower" and b) "free radicals." Complaint Counsel ignores, among other elements, the blatant fact that POMx Pills are made from the same pomegranates as POM Juice..

The ad does not convey the message that (a) POMx Pills "prevents," "treats," or "reduces the risk" of heart disease or prostate cancer; or (b) POMx Pills are "clinically proven" to "prevent," "treat," or "reduce the risk" of heart disease or prostate cancer since this message is not conspicuous, self-evident, or reasonably clear from the face of the ad. Consequently, because no implied claim relating to prevention, treatment or reduction of risk may be determined with confidence from the face of the ad, extrinsic evidence must be examined. The overall net impression of this ad is not that (a) taking one POMx Pill prevents, treats or reduces the risk of certain diseases, such as heart disease or prostate cancer; or (b) taking one POMx Pill is "clinically proven" to prevent,

treat or reduce the risk of certain diseases, such as heart disease or prostate cancer. Even the language of the ad itself uses such qualifiers as "initial medical study", "preliminary human research" and "hopeful results." (CX0120).

To the extent a "reduce the risk" claim can be implied from this ad, the overall net impression is not that taking one POMx Pill "reduces the risk" of certain diseases, such as heart disease or prostate cancer, like a drug with a single target of action, but that it may help "reduce the risk," like many other whole foods, or like an especially healthy fruit or vegetable, or like a healthy diet of fruits and vegetables and exercise "reduces the risk" of disease.

To the extent a "treat" claim can be implied from this ad (which it cannot), the overall net impression of any ad is not that POMx Pills are a substitute for conventional medical treatment. (Butters, Tr. 2821-22; Appendix of Advertisements).

To the extent a "proven" claim can be implied from this ad (which it cannot), the overall net impression of this ad is not that POMx Pills are "proven" to be 100% effective in preventing, treating or reducing the risk of heart disease or prostate cancer because (1) all of the qualifying language contradicts an implied "clinically proven" interpretation, and (2) "proven" in science and to consumers means the "average person in the study benefitted," not that "everyone in the study necessarily benefitted" or that everyone will benefit like the persons who benefitted in the study. (Heber, Tr. 2011; Butters, Tr. 2893-2894; PX0361 (Sacks, Dep. at 81)).

Complaint Counsel presented no extrinsic evidence or expert opinion on this ad's meaning, consumer perceptions of this ad, or consumer interpretations regarding this ad. (PX0357 (Stewart, Dep. at 49, 52))

Complaint Counsel failed to present any evidence that the claims in this ad reasonably convey that POMx Pills are "clinically proven" to prevent, treat or reduce the risk of heart disease or prostate cancer.

Complaint Counsel failed to present any evidence regarding the number of exposures consumers had to this ad or any particular POM advertisement. (Mazis, Tr. 2752).

402. In August 2006, shortly after the Pantuck Phase II Prostate Cancer Study (2006) was published, Dr. Pantuck complained to Respondents that the information they intended to disseminate about his study, including information on POM's website, was "marketing" and that the claims troubled him. Dr. Pantuck told Dr. Liker in an email, which was forwarded to Mr. Tupper and Mrs. Resnick, that "I am not sure what it means to say PJ [POM Juice] shows 'promise for prostate cancer.' I think the lay interpretation will be that it shows promise for the treatment of prostate cancer. I am very concerned that my legitimacy will be affected by displaying my name in such a manner[.]" (CX0072_0001; *see also* CCFF ¶ X.F.691).

Response to Finding No. 402:

Complaint Counsel attempt to rely on an email written by Dr. Allan Pantuck as evidence that POM intentionally disregarded warnings by outside parties that there were problems with POM's advertising. (CX0072). First, Dr. Pantuck's statements have no bearing on this case. Second, Complaint Counsel intentionally distort the meaning of the emails by cherry-picking statements from the documents to artificially construct a story about warning and intent. Significantly, no testimony supports their inferences here. In August 2006, POM drafted a press that adopted quotes made by Dr. Pantuck in articles featured on WebMD and in the New York Times in July 2006. (CX0071). The title of the August 2006 draft press release was "Wonderful variety pomegranate juice shows promise for prostate cancer." (CX0071_0001). That press release was the basis for the August 2006 email discussion between Dr. Liker and Dr. Pantuck cited to by Complaint Counsel. (CX0071_0001; CX0072). Indeed, Complaint Counsel misconstrue the meaning of the statements made by Dr. Pantuck in the August 2006 email. (CX0072). Dr. Pantuck was not concerned with POM's marketing claims or the

further publicizing of his study generally. (CX0072_0001). Dr. Pantuck, in fact, never raised any issue with more aggressive quotes in an article featured on WebMD that were attributed to him. In the WebMD article, "Pomegranate Slows Prostate Cancer," Dr. Pantuck made the following statements: "The juice seems to be working[.]; "Pantuck says that pomegranate juice may allow 65-to 70-year old men treated for prostate cancer to outlive their risk of dying from their cancer." (*available at* http://www.webmd.com/prostate-cancer/news/20060705/pomegranate-slows-prostate-cancer).

Dr. Pantuck also did not take issue with the following description of his study in a 2006 New York Times Article, also referenced in the email: "Findings from a small study suggest that pomegranate juice may one day prove an effective weapon against prostate cancer." (CX0071_0001; *available at* http://www.nytimes.com/2006/07/04/health/04test.html?scp=1&sq=testing:%20linking%20pomegranates%20to%20prostate%20health&st=cse). Dr. Pantuck was not concerned about the claims POM was making about his research—he was concerned about POM's use of his quotes *on POM's website*. He therefore writes, "I am very concerned that my legitimacy will be affected by displaying my name in such a manner: am I a spokesperson for the company, am I independent from the company? I was just quoted in Newsweek saying that POM was not using the study merely to sell juice, now I am on their website making claims?" (CX0072_0001). Thus, the main concern expressed by Dr. Pantuck in this email exchange was that he did not want to be considered a spokesperson for POM, which is what he thought consumers would take away from the website, because doing so might affect his credibility as an objective researcher. (CX0072_0001). Consequently, Mrs. Resnick's statement that Dr. Pantuck was "not a marketing person" makes absolute sense when her statement is put into this correct context—Mrs. Resnick did not think consumers would take away that he would

be deemed a "spokesperson" for the Company. (L. Resnick, Tr. 212). His concern was not about a disagreement with the substantive statements he made in the articles that were thereafter copied on the press release.

403. POM was also aware of Dr. Pantuck's view, expressed in an interview in October 2006 after the study was published, that he was "not at the point where [he] would say that everyone who has prostate cancer or who is at risk for prostate cancer should be drinking pomegranate juice." The article, in the Center for Science in the Public Interest's *Nutrition Action Newsletter*, was forwarded to Mr. Tupper and Mrs. Resnick. (CX0087_0001, 0004).

Response to Finding No. 403:

Respondents object to the term "aware" on the basis that it is vague and ambiguous as to its meaning. Respondents further dispute this proposed finding as it mischaracterizes the record evidence.

Dr. Pantuck stated that there are categories of patients with whom he has discussed the benefits of pomegranate juice. (CX1341 (Pantuck, Dep. at 270-271)). In addition, Dr. Pantuck publicly commented, "In older men 65 to 70, who have been treated for prostate cancer, we can give them pomegranate juice and it may be possible for them to outlive their risk of dying from their cancer." He also commented, "The juice seems to be working." (RFF 1918). Dr. Heber also testified that in meetings with Respondents also attended by Dr. Pantuck, that the there was substantial agreement on the body of evidence that the Challenged Products could help to prevent prostate cancer in the correct setting. (Heber, Tr. 2157-58). (RFF 1911, 1914). Dr. Heber further testified that prevent would not mean absolutely prevent not a substitute for a pharmaceutical prevention. (RFF 1915).

404. Nevertheless, even though POM was aware of Dr. Pantuck's concerns about overselling the scope of his study, POM continued to cite his study and claim it provided "hopeful results for men with prostate cancer" in advertisements in 2007, and made references to a website with the URL "pomwonderful.com/cancer.html." (CCFF ¶¶ 397-401; Tupper, Tr. 1004-05).

Response to Finding No. 404:

Complaint Counsel misrepresents the nature of Dr. Pantuck's concern regarding POM's use of his study. Dr. Pantuck was not concerned about the claims POM was making about his research—he was concerned about POM's use of his quotes *on POM's website*. He therefore writes, "I am very concerned that my legitimacy will be affected by displaying my name in such a manner: am I a spokesperson for the company, am I independent from the company? I was just quoted in Newsweek saying that POM was not using the study merely to sell juice, now I am on their website making claims?" (CX0072_0001). Thus, the main concern expressed by Dr. Pantuck in this email exchange was that he did not want to be considered a spokesperson for POM, which is what he thought consumers would take away from the website, because doing so might affect his credibility as an objective researcher. (CX0072_0001). His concern was not about a disagreement with the substantive statements he made in the articles that were thereafter copied on the press release.

405. The imagery and text of these POMx advertisements, particularly in light of POM's stated intention to target consumers who sought to prevent diseases, including prostate cancer, *see* CCFF ¶¶ C.2.304, C.2.307, convey the net impression that taking one POMx Pill daily treats, prevents, or reduces the risk of prostate cancer and that those health benefits are clinically proven. Because the advertisements specifically note that the study was done on the POM Juice, and that one POMx Pill is equivalent to eight ounces of POM Juice, they also convey the net impression that drinking eight ounces of POM Juice daily treats, prevents, or reduces the risk of prostate cancer and that those health benefits are clinically proven. (CCFF ¶¶ 397-401).

Response to Finding No. 405:

Complaint Counsel misconstrue and misrepresent the meaning of these ads. Respondents dispute the contention that POM's stated intention was to target consumers who sought to prevent diseases. The audience for POM products includes men and women, spanning all levels of age and income, who want to take an active approach to health, via good nutrition, to live vibrant and healthy lives. (Tupper, Tr. 3017-18). POM consumers

understand that POMx Pills, POMx Liquid and POM Juice are 100 percent derived from a fruit (which is a fact heavily emphasized in POM's advertising), and no reasonable consumer would reasonably take away the message from Respondents' advertising that POMx Pills, POMx Liquid or POM Juice can treat their diseases or that they should disregard conventional medical treatment if they were to consume POMx Pills, POMx Liquid or POM Juice. (Butters Tr. 2817-18). Instead, POM consumers view Respondents' advertising through the lens that POMx Pills, POMx Liquid and POM Juice are wholly derived from pomegranates and perceive POMx Pills, POMx Liquid and POM Juice the way they perceive any other whole food, like broccoli or blueberries, which may help or improve your odds against disease. (Butters Tr. 2817-18).

Complaint Counsel's assertion that the ads implicitly convey the message convey the net impression that taking one POMx Pill daily or drinking eight ounces of POM Juice daily treats, prevents, or reduces the risk of prostate cancer and that those health benefits are clinically proven is not conspicuous, self-evident, or reasonably clear from the face of the ad. (CX0122_0001). Consequently, because the above-referenced challenged implied claim may not be determined with confidence from the face of the ad, extrinsic evidence must be examined.

Complaint Counsel erroneously rely upon the impact of only a few, select elements for their overall view of the net impression of an ad, and seemingly neglect at least two significant elements that are key to any facial or common sense net impression analysis—that POMx Pills, POMx Liquid and POM Juice are products wholly-derived from pomegranates, and POMx Pills, POMx Liquid and POM Juice's effectiveness is based, at least in significant part, on the products' abundant antioxidants.

The overall net impression of this ad is not that taking one POMx Pill daily or drinking eight ounces of POM Juice daily treats, prevents, or reduces the risk of prostate cancer

and that those health benefits are clinically proven (CX0122_0001). Even the language of the ads themselves use such qualifiers as "initial UCLA medical study," "hopeful results," "fight," "preliminary studies" and "promising results." (CX0122_0001). Instead, the "One small pill for mankind" and the "Science, not fiction" ads make multiple efforts to convey that POMx is a whole food product that is wholly-derived from pomegranates, including: a) pervasive imagery of the POMx bottle shaped like a pomegranate; b) visual imagery of deep, ruby red pomegranate juice in a bottle shaped like two pomegranates stacked on top of one another; c) repeated textual references to "POM Wonderful 100% Pomegranate Juice"; d) statements touting that POMx is "made from the very same pomegranates as POM Wonderful 100% Pomegranate Juice." and e) Reference to the fact that challenged products are from pomegranates grown in California.

Additionally, the ad emphasizes that POMx contains abundant antioxidants. For example, the "One small pill for mankind." ad references: a) the "incredibly powerful blend of all-natural polyphenol antioxidants" in POMx; b) that "now you can get all the antioxidant power of an 8oz glass of juice in the convenience of a calorie-free capsule;" and c) that a POMx Pill has "more concentrated pomegranate polyphenol antioxidants than any other 100% pomegranate supplement".

Both the whole food aspect of the advertising and the emphasis on antioxidant content, directly counter any suggestion that POMx is going to act like a drug, as distinguished from a very healthy fruit or vegetable and a healthy diet. The ad emphasizes that the POMx Pill has nutritional benefits equivalent to the nutritional benefits of 8 oz of POM Juice, not more.

To the extent a "reduce the risk" claim can be implied from these ads, the overall net impression is not that taking one POMx Pill or drinking eight ounces of POM Juice per

day "reduces the risk" of certain diseases, such as prostate cancer, like a drug with a single target of action, but that it may help "reduce the risk," like many whole foods, or like an especially healthy fruit or vegetable, or like a healthy diet of fruits and vegetables and exercise "reduces the risk" of disease. (CX0122_0001).

To the extent a "treat" claim can be implied from this ad (which it cannot), the overall net impression of any ad is not that POMx Pills or POM Juice is a substitute for conventional medical treatment. (Butters, Tr. 2821-22).

To the extent a "proven" claim can be implied from this ad (which it cannot), the overall impression of these ads is not that POMx Pills and POM Juice are "proven" to be 100% effective in preventing, treating or reducing the risk of prostate cancer because (1) all of the qualifying language contradicts an implied "clinically proven" interpretation, and (2) "proven" in science and to consumers means the "average person in the study benefitted." "Proven" does not mean that "everyone in the study necessarily benefitted" or that everyone will benefit like the persons who benefitted in the study. (Heber, Tr. 2011; Butters, Tr. 2893-2894; PX0361 (Sacks, Dep. at 81)).

Professor Butters testified that the "Science, not fiction" is a parody or pun on "science fiction" that constitutes a humorous introduction to the ad. (PX0350 (Butters, Dep. at 140)). With respect to the "One small pill for mankind" ad, Professor Butters testified that this ad is humorous and is an "irreverent re-appropriation" of what was said by the first man on the moon. (PX0350 (Butters, Dep. at 141)). Mr. Tupper testified that the "One small pill for mankind" ad indicated that there were "hopeful results for men with prostate cancer." (Tupper, Tr. 1004).

Viewing the "Science, not fiction" ad as a whole, including the interaction of the words and visual imagery, the overall net impression of this ad is that the headline is humorous and that there were hopeful results regarding testing of POM Juice for men with prostate

cancer. (PX0350 (Butters, Dep. at 140); (PX0158-0033)). Viewing the "One pill for mankind" ad as a whole, including the interaction of the words and visual imagery, the overall net impression of this ad is that the headline is humorous and that there are hopeful results regarding testing of POM Juice for men with prostate cancer. (PX0350 (Butters, Dep. at 141); (CX1364 (Tupper, Dep. at 1004)).

Even assuming *arguendo* that this ad conveys the message Complaint Counsel assigns to it, Professor Reibstein's survey effectively demonstrates that any alleged disease claims made by Respondents were not material to the purchasing decisions of POM consumers. (RFF 2623, 2630). Complaint Counsel failed to present any evidence regarding the number of exposures consumers had to this ad or any particular POM advertisement. Complaint Counsel have presented no reliable evidence to rebut Professor's Reibstein's survey findings or to show that any alleged disease claims made in POM's ads were material to the purchasing decisions of POM consumers.

Complaint Counsel presented no extrinsic evidence or expert opinion on this ad's meaning, consumer perceptions of this ad, or consumer interpretations regarding this ad. (PX0357 (Stewart, Dep. at 49, 52)). Complaint Counsel failed to present any evidence that the claims in this ad reasonably convey that POMx Pills, POMx Liquid and POM Juice are "clinically proven" to prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction. Complaint Counsel failed to present any evidence regarding the number of exposures consumers had to this ad or any particular POM advertisement. (Mazis, Tr. 2752).

c. "The power of P♥M, in one little pill"/ "The Antioxidant Superpill"/ "Science, not fiction" Print Ads (CX0169 / CX0180 / CX0279)

406. In 2008 and 2009, POM continued to disseminate POMx advertisements, with additional, detailed copy describing the POMx Pill's purported health benefits, usually citing scientific journal articles to bolster the claims. (*See* CCFF ¶¶ 407-11).

Response to Finding No. 406:

Respondents object to this finding of fact on the basis that it is vague and ambiguous.

407. For example, one advertisement disseminated in January 2008 in the *New York Times* with the headline, "**The power of P♥M, in one little pill.**" included several different bold subheadlines, "**Antioxidant Superpill**," "**Peace of Mind in a Pill**," "**Safe and Natural**," "**Backed by Science**," and "**One a Day, For Life**." The advertisement also included images of a POMx Pills bottle next to a POM Juice bottle with an equal sign in between, a caduceus, and a POMx Pills bottle next to a pomegranate fruit. (CX0169).

Response to Finding No. 407:

Complaint Counsel failed to present any other definitive information regarding this ad's dissemination. Moreover, Complaint Counsel have presented no evidence that it is probable or likely that Respondents would run this type of ad again. Because this ad ran over five years ago and there is no evidence that Respondents are likely to run this ad in the future, the ad provides no basis for injunctive relief.

408. As another example, in February 2008, POM disseminated in the *Los Angeles Times* a similar print advertisement for POMx Pills headlined, "**The antioxidant superpill.**" (CX0180).

Response to Finding No. 408:

Complaint Counsel failed to present any other definitive information regarding this ad's dissemination. Complaint Counsel failed to present any evidence that Respondents would run this ad in the future, let alone whether it is probable they would do so.

409. A POMx Pills print advertisement with the headline, "**Science, not fiction.**" and with similar claims was disseminated in *Popular Science* magazine in March 2009. (CX0279).

Response to Finding No. 409:

Complaint Counsel failed to present any other definitive information regarding this ad's dissemination. Complaint Counsel failed to present any evidence that Respondents would run this ad in the future, let alone whether it is probable they would do so.

410. The body copy for the "The Power of POM" advertisement described the purported effects of POM Juice in prostate cancer and coronary heart patients:

> POMx is made from the only pomegranates supported by $23 million in medical research. . . . An initial UCLA MEDICAL STUDY on POM Wonderful 100% Pomegranate Juice found *hopeful results for prostate health*. "Pomegranate juice delays PSA doubling time in humans," according to AJ Pantuck, et al, in Clinical Cancer Research, 2006. Two additional preliminary studies on our juice showed *promising results for heart health*. "Pomegranate juice improves myocardial perfusion in coronary heart patients," per D. Ornish, et al, in the American Journal of Cardiology, 2005. "Pomegranate juice pilot research suggests anti-atherosclerosis benefits," according to M. Aviram, et al, in Clinical Nutrition, 2004.
>
> (CX0169).

Response to Finding No. 410:

Respondents object to this finding of fact on the basis that it misstates the evidence and the document speaks for itself. Complaint Counsel quotes only part of the ad's copy on in this finding. The message that the ad actually conveys is that Respondents are committed to the science, and learning the truth about pomegranates. POM Wonderful 100% Pomegranate Juice is supported by $23 million of initial scientific research from leading universities, which has uncovered encouraging results in prostate and cardiovascular health. As Mrs. Resnick testified, the purpose of including the amount of money related to medical research in the advertising was to convey a message about the company, and its level of dedication to learning the truth about pomegranates. Mrs. Resnick testified, "[Respondents wanted] a very direct of communicating to the consumer that here was a natural food that had gone through rigorous scientific testing and that we cared enough to do this and we wanted to tell people that we had and continue to do scientific research." (L. Resnick, Tr. 251; *see also* CCFF 309, 311).

411. Similarly, "The Antioxidant Superpill" print advertisement stated:

> POMx is made from the only pomegranates backed by $23 million in medical research, the same pomegranates we use to make our POM Wonderful 100% Pomegranate Juice. An initial UCLA MEDICAL STUDY on POM Wonderful 100% Pomegranate Juice found *hopeful results for prostate health*. The study reports "statistically significant prolongation of PSA doubling times," according to Dr. Allen [*sic*] J. Pantuck in Clinical

Cancer Research, 2006. Two additional preliminary studies on our juice showed *promising results for heart health*. "Stress-induced ischemia decreased in the pomegranate group," Dr. Dean Ornish reported in the American Journal of Cardiology, 2005. "Pomegranate juice consumption resulted in a significant IMT reduction by up to 30% after one year," said Dr. Michael Aviram, referring to reduced arterial plaque in Clinical Nutrition, 2004.

(CX0180; *see also* CX0279 (similar body copy but stating "backed by $25 million in medical research")).

Response to Finding No. 411:

Respondents object to this finding of fact on the basis that it misstates the evidence and the document speaks for itself. Complaint Counsel quote only part of the ad's copy in this finding. The message that the ad actually conveys is that Respondents are committed to the science, and learning the truth about pomegranates. POM Wonderful 100% Pomegranate Juice is supported by $23 million of initial scientific research from leading universities, which has uncovered encouraging results in prostate and cardiovascular health. As Mrs. Resnick testified, the purpose of including the amount of money related to medical research in the advertising was to convey a message about the company, and its level of dedication to learning the truth about pomegranates. Mrs. Resnick testified, "[Respondents wanted] a very direct of communicating to the consumer that here was a natural food that had gone through rigorous scientific testing and that we cared enough to do this and we wanted to tell people that we had and continue to do scientific research." (L. Resnick, Tr. 251; *see also* CCFF 309, 311).

412. The clear implication of these claims, along with the images and text indicating equivalence between POMx Pills and POM Juice, is that the studies on POM Juice also support the same health benefits of POMx Pills. (CCFF ¶¶ 406-11).

Response to Finding No. 412:

Respondents have previously detailed how POM Juice and POMx Pills and POMx Liquid are equivalent on providing health benefits to humans and that POMx Pills and POMx Liquid have equivalent bioavaiablity as POM Juice. (RFF 920, 921). Dr. Heber found

no difference in the antioxidant effect between POM Juice and POMx products in laboratory studies he conducted. (RFF 925). Professor Stampfer did not dispute Dr. Heber's findings. (RFF 215-216, 818-819). Also, Dr. Aviram testified that several studies and that there is good deal of data on POMx which shows similarity to POM Juice and that a POMx Pill has the same amount of polyphenol antioxidants as eight ounces of POM Juice. (CX1358 (Aviram, Dep. at 51-52; 45-46)). Respondents have provided ample evidence to demonstrate that POMx Pills and POMx Liquid are bioequivalent to POM Juice and that POMx Pills and POMx Liquid provide similar health benefits as POM Juice provides. (RFF 915-951).

413. Moreover, although Respondents did not use the specific terms "heart disease" or "prostate cancer," Dr. Butters testified that speakers of American English would interpret the phrases "heart health" and "prostate health" that were used in the advertisements to mean a condition of not being diseased. (Butters, Tr. 2851).

Response to Finding No. 413:

Respondents have no specific response.

414. These advertisements (CX0169, CX0180, and CX0279) convey the net impression that taking one POMx Pill daily treats, prevents, or reduces the risk of cardiovascular disease and prostate cancer, and that those health benefits are clinically proven. Because the advertisements specifically note that the studies were done on POM Juice, and that one POMx Pill is equivalent to eight ounces of POM Juice, they also convey the net impression that drinking eight ounces of POM Juice daily treats, prevents, or reduces the risk of cardiovascular disease and prostate cancer, and that those health benefits are clinically proven. (CCFF ¶¶ 406-13).

Response to Finding No. 414:

Respondents object to Complaint Counsel's citation to CX0169, CX0180, and CX0279 as they were conditionally admitted at trial. Complaint Counsel misconstrue and misrepresent the meaning of these ads. The fact that the POMX Pills are wholly-derived from the pomegranate fruit is heavily emphasized in the body copy and the visual imagery of these ads as well as on the products themselves. These ads depict prevalent visual imagery of one or several deep, ruby red pomegranates; dominant images of deep,

ruby red pomegranate juice in bottle shaped like two pomegranates stacked on top of one another; the pervasive image of POMx Pill bottle shaped like a pomegranate fruit; repeated textual reference to "POM Wonderful 100% Pomegranate Juice;"statements that POMx is "made from the very same pomegranates as POM Wonderful 100% Pomegranate Juice;" and also reference the fact that the Challenged Products are from pomegranates grown in California: "California-grown pomegranate juice," "California-grown" with visual image of pomegranate tree or "California-grown, Wonderful variety pomegranates. (CX0169, CX0180, and CX0279).

Nowhere in these ads do Respondents expressly (*i.e.*, unequivocally and directly) state that (a) taking one POMx Pill daily or drinking eight ounces of POM Juice daily "prevents," "treats," or "reduces the risk" of heart disease or prostate cancer; or (b) taking one POMx Pill daily or drinking eight ounces of POM Juice daily is "clinically proven" to "prevent," "treat," or "reduce the risk" of cardiovascular disease or prostate cancer. (CX0169, CX0180, and CX0279).

Complaint Counsel's assertion that these ads convey the message that (a) taking one POMx Pill daily or drinking eight ounces of POM Juice daily "prevents," "treats," or "reduces the risk" of cardiovascular disease and prostate cancer; or (b) taking one POMx Pill daily or drinking eight ounces of POM Juice daily is "clinically proven" to "prevent," "treat," or "reduce the risk" of cardiovascular disease and prostate cancer is not conspicuous, self-evident, or reasonably clear from the face of the ads. (CX0279_0001). Consequently, because the above-referenced challenged implied claim may not be determined with confidence from the face of the ads, extrinsic evidence must be examined.

Complaint Counsel erroneously rely upon the impact of only a few, select elements for their overall view of the net impression of an ad, and seemingly neglect at least two

significant elements that are key to any facial or common sense net impression analysis—that POMx Pills, POMx liquid and POM Juice are products wholly-derived from pomegranates, and POMx Pills, POMx liquid and POM Juice's effectiveness is based, at least in significant part, on the products' abundant antioxidants.

The overall net impression of these ads is not that taking one POMx Pill daily or drinking eight ounces of POM Juice daily prevents, treats or reduces the risk of certain diseases, such as cardiovascular disease or prostate cancer; or (b) taking one POMx Pill daily or drinking eight ounces of POM Juice daily is "clinically proven" to prevent, treat or reduce the risk of certain diseases, such as cardiovascular disease or prostate cancer. (CX0279_0001). Even the language of the ads themselves uses such qualifiers as "initial UCLA Medical Study," "hopeful results," "fight," "preliminary studies," and "promising results." (CX0169, CX0180, and CX0279). Instead, the "The power of POM, in one little pill." advertisement makes multiple efforts to convey that POMx is a whole food product that is wholly-derived from pomegranates, including: a) pervasive imagery of the POMx bottle shaped like a pomegranate; b) visual imagery of deep, ruby red pomegranate juice in a bottle shaped like two pomegranates stacked on top of one another; c) imagery of a ruby red pomegranate; d) Statements touting that POMx is "made from the very same pomegranates as POM Wonderful 100% Pomegranate Juice"; e) Repeated textual references to "POM Wonderful 100% Pomegranate Juice; f) a mention that "POMx is made from pure pomegranates"; and g) an image and text referencing the fact that the challenged products are from pomegranates grown in California.

Additionally, the ad emphasizes that POMx contains abundant antioxidants. For example, the "The power of POM, in one little pill." ad references: a) POMx as an "Antioxidant Superpill"; b) a statement that a POMx Pill provides "more concentrated antioxidants than any other pomegranate antioxidant supplement;" c) that "POMx is a

highly concentrated powerful blend of polyphenol antioxidants;" and d) that "POM Wonderful pomegranate antioxidants neutralize free radicals."

Both the whole food aspect of the advertising and the emphasis on antioxidant content, directly counter any suggestion that POMx is going to act like a drug, as distinguished from a very healthy fruit or vegetable and a healthy diet. The ad emphasizes that the POMx Pill has nutritional benefits equivalent to the nutritional benefits of 8oz POM Juice, not more.

Viewing the ad as a whole, taking into account all the various elements, including the prevalence and pervasiveness of these "whole-food" graphics, in the form of a pomegranate image and the POMx and POM Juice bottles, and body copy as well as the repeated emphasis on the fact that POMx is a concentrated and potent source of antioxidants, it is far more logical that POM consumers would view POMx the way they perceive many other whole foods, like broccoli, blueberries, grapes or tomatoes, which may help prevent or improve your odds against disease, but which would not act like a drug with a single target of action against a particular disease or condition.

To the extent a "reduce the risk" claim can be implied from these ads, the overall net impression is not that taking one POMx Pill daily or drinking eight ounces of POM Juice daily "reduces the risk" of certain diseases, such as heart disease or prostate cancer, like a drug with a single target of action, but that it may help "reduce the risk," like many whole foods, or like an especially healthy fruit or vegetable, or like a healthy diet of fruits and vegetables and exercise "reduces the risk" of disease. (CX0169, CX0180, and CX0279).

To the extent a "treat" claim can be implied from these ads (which it cannot), the overall net impression of these ads is not that POMx Pills or POM Juice is a substitute for conventional medical treatment. (Butters, Tr. 2821-22).

To the extent a "proven" claim can be implied from these ads (which it cannot), the overall impression of these ads is not that POMx Pills and POM Juice are "proven" to be 100% effective in preventing, treating or reducing the risk of heart disease or prostate cancer because (1) all of the qualifying language contradicts an implied "clinically proven" interpretation, and (2) "proven" in science and to consumers means the "average person in the study benefitted." "Proven" does not mean that "everyone in the study necessarily benefitted" or that everyone will benefit like the persons who benefitted in the study. (Heber, Tr. 2011; Butters, Tr. 2893-2894; PX0361 (Sacks, Dep. at 81)).

Also, Mr. Resnick testified that POM's advertisements are not intended to convey the message that they can prevent or treat coronary heart disease. (S. Resnick, Tropicana, Dep. at 58-59). Although Mr. Resnick testified that POM believes pomegranate juice is beneficial in preventing and treating coronary heart disease, he does not want consumers to share this belief, but rather to look at their science and make up their own mind. (S. Resnick, Tropicana, Dep. at 42-43). Mr. Resnick never intended POM products to be a substitute for recommended medical treatment or anything else recommended by a doctor. (S. Resnick, Tr. 1870). Mr. Tupper testified that it is absolutely against company policy to say or suggest that POM products are a substitute for proper medical treatment. (Tupper, Tr. 3018). In responding to health-related inquires or a question about a medical condition, POM instructs its employees to tell consumers to consult with his or her physician and strongly encourage this recommendation. (CX0308; Tupper, Tr. 3019).

Even assuming *arguendo* that this ad conveys the message Complaint Counsel assigns to it, Professor Reibstein's survey effectively demonstrates that any alleged disease claims made by Respondents were not material to the purchasing decisions of POM consumers. (RFF 2623, 2630). Complaint Counsel failed to present any evidence regarding the number of exposures consumers had to this ad or any particular POM advertisement.

Complaint Counsel have presented no reliable evidence to rebut Professor's Reibstein's survey findings or to show that any alleged disease claims made in POM's ads were material to the purchasing decisions of POM consumers.

Complaint Counsel presented no extrinsic evidence or expert opinion on the meaning of these ads, consumer perceptions of these ads, or consumer interpretations regarding these ads. (PX0357 (Stewart, Dep. at 49, 52)). Complaint Counsel failed to present any evidence that the claims in these ads reasonably convey that POMx Pills, POMx liquid or POM Juice are "clinically proven" to prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction.

Complaint Counsel failed to present any evidence regarding the number of exposures consumers had to these ads or any particular POM advertisement. (Mazis, Tr. 2752).

d. "Live Long Enough to Watch Your 401(k) Recover" / "Your New Health Care Plan" / "Healthy, ~~Wealthy~~, and Wise" / "The First Bottle You Should Open in 2010" Print Ads (CX0280 / CX0328 / CX0331 / CX0337)

415. POM continued to disseminate POMx print advertisements from 2009 into 2010. For example, four print advertisements headlined "**LIVE LONG ENOUGH TO WATCH YOUR 401(K) RECOVER,**" "**YOUR NEW HEALTH CARE PLAN. (NO TOWN HALL MEETING REQUIRED.),**" "**HEALTHY. ~~WEALTHY.~~ AND WISE (2 OUT OF 3 IN THIS ECONOMY AIN'T BAD.)**," and "**THE FIRST BOTTLE YOU SHOULD OPEN IN 2010**" all contained slightly different subheadlines, but the images and body copy were very similar or identical. (CX0280; CX0328; CX0331; CX0337). These advertisements stated:

Emerging science suggests that antioxidants are critically important to maintaining good health because they protect you from free radicals, which can damage your body. Taking one P♥Mx pill a day will help protect you from free radicals and keep you at your healthy best.

***

P♥Mx – an ultra-potent antioxidant extract made from the same pomegranates as P♥M Wonderful 100% Pomegranate Juice – is the most potent natural antioxidant supplement available. Each 1000 mg P♥Mx pill has the antioxidant power of a full glass of P♥M Wonderful 100% Pomegranate Juice.

***

P♥Mx is made from the only pomegranates backed by $25 million in medical research at the world's leading universities. Not only has this research documented the unique and superior antioxidant power of pomegranates, it has revealed promising results for prostate and cardiovascular health.

***

Our P♥Mx pills are made from the same pomegranates we use to make our P♥M Wonderful 100% Pomegranate Juice, on which each of the following medical studies was conducted.

An initial UCLA study on our juice found hopeful results for prostate health, reporting "statistically significant prolongation of PSA doubling times," according to Dr. Allen *[sic]* J. Pantuck in *Clinical Cancer Research*, '06.

Two additional preliminary studies on our juice showed promising results for heart health. "Stress-induced ischemia (restricted blood flow to the heart) decreased in the pomegranate group," Dr. Dean Ornish reported in the *American Journal of Cardiology*, '05.

"Pomegranate juice consumption resulted in significant reduction in IMT (thickness of arterial plaque) by up to 30% after one year," said Dr. Michael Aviram, *Clinical Nutrition*, '04.

The advertisements contained the same images as in other POMx print ads, including the graphic equating one POMx Pill to an eight-ounce bottle of POM Juice and the POMx Pill bottle next to a pomegranate fruit. They additionally contain an image showing a pill capsule with pomegranate fruits inside. (CX0280 (disseminated at least 70 times in various publications from March to November 2009); CX0328 (*Washington Post*, November 2009); CX0331 (disseminated at least 99 times in various publications from September to October 2009); CX0337 (*New York Times*, January 2010)).

Response to Finding No. 415:

Respondents object to Complaint Counsel's citation to CX0280, CX0328, and CX0331 as they were conditionally admitted at trial. Respondents object to this finding of fact on the basis that it misstates the evidence and the documents speak for themselves. Complaint Counsel quote only part of the ad's copy in this finding. Further, Complaint Counsel also fail to cite any testimony or evidence in support of their finding concerning how many times CX0280, CX0328, and CX0331 were disseminated.

416. The "Live Long Enough to Watch Your 401(k) Recover" advertisement stated that POMx was "backed by $25 million in medical research at the world's leading universities," while the other three advertisements stated POMx was backed by $32 million. (*Compare* CX0280 *with* CX0328, CX0331, CX0337).

Response to Finding No. 416:

Respondents object to this finding of fact on the basis that it misstates the evidence and the document speaks for itself. The "Live Long Enough to Watch Your 401(k) Recover" advertisement actually states that "POMx is made from the only pomegranates backed by $25 million in medical research at the world's leading universities," and the other three advertisements state that "POMx is made from the only pomegranates backed by $32 million in medical research at the world's leading universities". (CX0280, CX0328, CX0331, CX0337). The message that the ads actually conveys is that Respondents are committed to the science, and learning the truth about pomegranates. POM Wonderful 100% Pomegranate Juice is supported by millions of dollars of initial scientific research from leading universities, which has uncovered encouraging results in prostate, erectile and cardiovascular health. As Mrs. Resnick testified, the purpose of including the amount of money related to medical research in the advertising was to convey a message about the company, and its level of dedication to learning the truth about pomegranates. Mrs. Resnick testified, "[Respondents wanted] a very direct of communicating to the consumer that here was a natural food that had gone through rigorous scientific testing and that we cared enough to do this and we wanted to tell people that we had and continue to do scientific research." (L. Resnick, Tr. 251; *see also* CCFF 309, 311).

417. As with the POMx advertisements referenced in CCFF ¶¶ b.407-09, POM used the terms "heart health" and "prostate health," which Dr. Butters testified meant a condition free of disease. (CCFF ¶b.413).

Response to Finding No. 417:

Respondents object to this finding of fact on the basis that it is vague and ambiguous. Furthermore, Complaint Counsel misconstrue Professor Butters' testimony.

418. The advertisements (CX0280; CX0328; CX0331; CX0337) convey the net impression that taking one POMx Pill daily treats, prevents, or reduces the risk of cardiovascular

disease and prostate cancer, and that those health benefits are clinically proven. Because the advertisements specifically note that the studies were done on POM Juice, and that one POMx Pill is equivalent to eight ounces of POM Juice, they also convey the net impression that drinking eight ounces of POM Juice daily treats, prevents, or reduces the risk of cardiovascular disease and prostate cancer, and that those health benefits are clinically proven. (CCFF ¶¶ 415-17).

Response to Finding No. 418:

Respondents object to Complaint Counsel's citation to CX0280; CX0328; CX0331 as they were conditionally admitted at trial. Complaint Counsel misconstrue and misrepresent the meaning of these ads. The fact that the POMX Pills are wholly-derived from the pomegranate fruit is heavily emphasized in the body copy and the visual imagery of these ads as well as on the products themselves. These ads depict prevalent visual imagery of one or several deep, ruby red pomegranates; dominant images of deep, ruby red pomegranate juice in bottle shaped like two pomegranates stacked on top of one another; the pervasive image of POMx Pill bottle shaped like a pomegranate fruit; repeated textual reference to "POM Wonderful 100% Pomegranate Juice;"and statements that POMx is "made from the very same pomegranates as POM Wonderful 100% Pomegranate Juice". (CX0280; CX0328; CX0331; CX0337). Complaint Counsel ignore the (1) outrageousness of the headline, (2) puffery in the headlines and sub-headlines and (3) fact the product is 100% fruit derived.

Nowhere in these ads do Respondents expressly (*i.e.*, unequivocally and directly) state that (a) taking one POMx Pill daily or drinking eight ounces of POM Juice daily "prevents," "treats," or "reduces the risk" of heart disease or prostate cancer; or (b) taking one POMx Pill daily or drinking eight ounces of POM Juice daily is "clinically proven" to "prevent," "treat," or "reduce the risk" of cardiovascular disease or prostate cancer. (CX0280; CX0328; CX0331; CX0337).

Complaint Counsel's assertion that these ads convey the message that (a) taking one POMx Pill daily or drinking eight ounces of POM Juice daily "prevents," "treats," or

"reduces the risk" of cardiovascular disease and prostate cancer; or (b) taking one POMx Pill daily or drinking eight ounces of POM Juice daily is "clinically proven" to "prevent," "treat," or "reduce the risk" of cardiovascular disease and prostate cancer is not conspicuous, self-evident, or reasonably clear from the face of the ads. (CX0279_0001). Consequently, because the above-referenced challenged implied claim may not be determined with confidence from the face of the ads, extrinsic evidence must be examined.

Complaint Counsel erroneously rely upon the impact of only a few, select elements for their overall view of the net impression of an ad, and seemingly neglect at least two significant elements that are key to any facial or common sense net impression analysis—that the Challenged Products are products wholly-derived from pomegranates, and the Challenged Products' effectiveness is based, at least in significant part, on the products' abundant antioxidants.

The overall net impression of these ads is not that taking one POMx Pill daily or drinking eight ounces of POM Juice daily prevents, treats or reduces the risk of certain diseases, such as cardiovascular disease or prostate cancer; or (b) taking one POMx Pill daily or drinking eight ounces of POM Juice daily is "clinically proven" to prevent, treat or reduce the risk of certain diseases, such as cardiovascular disease or prostate cancer. (CX0279_0001). Even the language of the ads themselves uses such qualifiers as "initial UCLA Medical Study," "hopeful results," "fight," "preliminary studies," and "promising results." (CX0280; CX0328; CX0331; CX0337). Instead, the advertisements (CX0280; CX0328; CX0331; CX0337) make multiple efforts to convey that POMx is a whole food product that is wholly-derived from pomegranates, including: a) pervasive imagery of the POMx bottle shaped like a pomegranate; b) visual imagery of deep, ruby red pomegranate juice in a bottle shaped like two pomegranates stacked on top of one another; c) multiple images of pomegranates, one of which features pomegranates

spilling out of a pill capsule; d) repeated textual references to "POM Wonderful 100% Pomegranate Juice; and e) statements touting that POMx is "made from the same pomegranates as POM Wonderful 100% Pomegranate Juice."

Additionally, the ads emphasize that POMx contains abundant antioxidants. For example, the ads reference: a) that "taking one POMx pill a day will help protect you from free radicals;" b) POMx as "an ultra-potent antioxidant extract;" c) POMx as "The Antioxidant Superpill;" and d) the "unique and superior antioxidant power of pomegranates."

Both the whole food aspect of the advertising and the emphasis on antioxidant content, directly counter any suggestion that POMx is going to act like a drug, as distinguished from a very healthy fruit or vegetable and a healthy diet. The ads emphasize that the POMx Pill has nutritional benefits equivalent to the nutritional benefits of 8 oz of POM Juice, not more.

Viewing the ads as a whole, taking into account all the various elements, including the prevalence and pervasiveness of these "whole-food" graphics, in the form of pomegranates and the POMx and POM Juice bottles, and body copy as well as the repeated emphasis on the fact that POMx is a concentrated and potent source of antioxidants, it is far more logical that POM consumers would view POMx the way they perceive any other whole food, like broccoli, blueberries, grapes or tomatoes, which may help prevent or improve your odds against disease, but which would not act like a drug with a single target of action against a particular disease or condition.

To the extent a "reduce the risk" claim can be implied from these ads, the overall net impression is not that taking one POMx Pill daily or drinking eight ounces of POM Juice daily "reduces the risk" of certain diseases, such as heart disease or prostate cancer, like a drug with a single target of action, but that it may help "reduce the risk," like many whole

foods, or like an especially healthy fruit or vegetable, or like a healthy diet of fruits and vegetables and exercise "reduces the risk" of disease. (CX0280; CX0328; CX0331; CX0337).

To the extent a "treat" claim can be implied from these ads (which it cannot), the overall net impression of these ads is not that POMx Pills or POM Juice is a substitute for conventional medical treatment. (Butters, Tr. 2821-22).

To the extent a "proven" claim can be implied from these ads (which it cannot), the overall impression of these ads is not that POMx Pills and POM Juice are "proven" to be 100% effective in preventing, treating or reducing the risk of heart disease or prostate cancer because (1) all of the qualifying language contradicts an implied "clinically proven" interpretation, and (2) "proven" in science and to consumers means the "average person in the study benefitted." "Proven" does not mean that "everyone in the study necessarily benefitted" or that everyone will benefit like the persons who benefitted in the study. (Heber, Tr. 2011; Butters, Tr. 2893-2894; PX0361 (Sacks, Dep. at 81)).

With respect to CX0280, Professor Butters testified that this headline of this ad is not irreverent but "kind of joking" and "gallows humor"; the ad is a "joking reference to a very serious issue." (PX0350 (Butters, Dep. at 141)). Viewing the "Live Long Enough To Watch Your 401(k) Recover" ad as a whole, including the interaction of the words and visual imagery, the overall net impression of the ad is that it is a humorous ad and that POM Juice is healthy. (PX0350 (Butters, Dep. at 141); (PX0158-0033)).

With respect to CX0328, Mr. Tupper testified that this advertisement references the healthcare reform debate that was going on at the time the ad was released. He further testified that the language in the ad, "no town hall meeting required," is also a reference to the health care reform debate. (Tupper, Tr. 969). Professor Butters describes this advertisement as a "joking reference to a very serious matter." (PX0350 (Butters, Dep. at

142)). Viewing the "Your New Health Care Plan" ad as a whole, including the interaction of the words and visual imagery, the overall net impression of the ad is that it is a humorous ad that references the debate on health care reform that was taking place when the ad ran and that POMx Pills are healthy. (PX0350 (Butters, Dep. at 135); (PX0158-0033))).

Regarding CX0331, Professor Butters describes the headline of this ad as "light hearted," "kind of a joke," and "a bit of, if not self parody, at least confession of the high price of POM products." He further testified that this advertisement tells the consumer that the POM "products are not cheap, but they're really good." (PX0350 (Butters, Dep. at 135)). Viewing the "Healthy, Wealthy & Wise" ad as a whole, including the interaction of the words and visual imagery, the overall net impression of the ad is that it is a humorous ad and that POMx Pills are healthy. (PX0350 (Butters, Dep. at 135); (PX0158-0033))).

In examining, CX0337, Professor Butters testified that this ad employs parody; it is a parody on "the self-importance of POMx itself," that POMx Pills "should be the first bottle you open" and that POMx Pills are "as important as champagne on New Year's." (PX0350 (Butters, Dep. at 141)). Viewing the "The First Bottle You Should Open In 2010" ad as a whole, including the interaction of the words and visual imagery, the overall net impression of the ad is that it is a humorous ad and that POMx Pills are healthy. (PX0350 (Butters, Dep. at 141); (PX0158-0033)).

Also, Mr. Resnick testified that POM's advertisements are not intended to convey the message that they can prevent or treat coronary heart disease. (S. Resnick, Tropicana, Dep. at 58-59). Although Mr. Resnick testified that POM believes pomegranate juice is beneficial in preventing and treating coronary heart disease, he does not want consumers to share this belief, but rather to look at their science and make up their own mind. (S. Resnick, Tropicana, Dep. at 42-43). Mr. Resnick never intended POM products to be a

substitute for recommended medical treatment or anything else recommended by a doctor. (S. Resnick, Tr. 1870). Mr. Tupper testified that it is absolutely against company policy to say or suggest that POM products are a substitute for proper medical treatment. (Tupper, Tr. 3018). In responding to health-related inquires or a question about a medical condition, POM instructs its employees to tell consumers to consult with his or her physician and strongly encourage this recommendation. (CX0308; Tupper, Tr. 3019).

Even assuming *arguendo* that this ad conveys the message Complaint Counsel assigns to it, Professor Reibstein's survey effectively demonstrates that any alleged disease claims made by Respondents were not material to the purchasing decisions of POM consumers. (RFF 2623, 2630). Complaint Counsel failed to present any evidence regarding the number of exposures consumers had to this ad or any particular POM advertisement. Complaint Counsel have presented no reliable evidence to rebut Professor's Reibstein's survey findings or to show that any alleged disease claims made in POM's ads were material to the purchasing decisions of POM consumers.

Complaint Counsel presented no extrinsic evidence or expert opinion on the meaning of these ads, consumer perceptions of these ads, or consumer interpretations regarding these ads. (PX0357 (Stewart, Dep. at 49, 52)). Complaint Counsel failed to present any evidence that the claims in these ads reasonably convey that the Challenged Products are "clinically proven" to prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction.

Complaint Counsel failed to present any evidence regarding the number of exposures consumers had to these ads or any particular POM advertisement. (Mazis, Tr. 2752).

e. "Take Out a Life Insurance Supplement" / "24 Scientific Studies" Print Ads (CX0342 / CX0348 / CX0350 / CX0353)

419. POMx disseminated print advertisements headlined, "**TAKE OUT A LIFE INSURANCE SUPPLEMENT**" and "**24 SCIENTIFIC STUDIES NOW IN ONE EASY-TO-SWALLOW PILL**," which included similar images and text as the advertisements described in CCFF ¶ 415. However, the body copy in these advertisements referred only to the Pantuck and Ornish studies, and omitted the Aviram study:

An initial UCLA study on POM Wonderful 100% Pomegranate Juice found hopeful results for prostate health, reporting "statistically significant prolongation of PSA doubling times," according to Dr. Allen [*sic*] J. Pantuck in *Clinical Cancer Research*, 2006. Additional preliminary study on our juice showed promising results for heart health. "Stress-induced ischemia (restricted blood flow to the heart) decreased in the pomegranate group," Dr. Dean Ornish reported in the *American Journal of Cardiology*, 2005.

(CX0342_0001 (disseminated at least three times in various publications in February and March 2010); CX0348_0001 (*Men's Health* magazine and *Popular Science* magazine, April 2010)). POM disseminated additional, very similar advertisements, but which cited $34 million in research, instead of $32 million. (CX0350_0001 (*Time* magazine, April 2010]); CX0353_0001 (disseminated at least six times in various media including the *New York Times* and *Men's Health* magazine in June and September 2010)).

Response to Finding No. 419:

Respondents object to Complaint Counsel's citation to CX0348, CX0350, and CX0353 as they were conditionally admitted at trial. Respondents object to this finding of fact on the basis that it misstates the evidence and the documents speak for themselves. Complaint Counsel quote only part of the ad's copy in this finding. Further, Complaint Counsel also fail to cite any testimony or evidence in support of their finding concerning how many times CX0280, CX0328, and CX0331 were disseminated.

420. POM admits that it had continued to run advertisements promoting the 30% reduction in arterial plaque purportedly shown by the Aviram CIMT/BP Study (2004) (*see, e.g.*, CCFF ¶¶b.410, c.415), even after it was aware, as early as 2006, of the inconsistent results of the Davidson CIMT Study (2009) that showed, at most, a 5% decrease in arterial plaque in some patients measured at an interim point in the study. (Tupper, Tr. 965-966.)

Response to Finding No. 420:

Complaint Counsel's attempt to demonstrate that Dr. Davidson's CIMT Study (2009) contradicts Dr. Aviram's CIMT/BP (2004) study lacks merit. Dr. Aviram's and Dr. Davidson's studies are apples and oranges: both used the same surrogate (CIMT) in a different group of patients. (RFF 1565; Heber, Tr. 1975-76). In Dr. Aviram's study, the subjects had thickened plaque, whereas, in Dr. Davidson's study, his patients had less plaque to the point where it was not significant. (RFF 1561; Heber, Tr. 1975-76; 1983-84). Dr. Davidson's protocol actually excluded people with significant stenosis or plaque from his study. (RFF 1564; Heber, Tr. 1819). As a result, Dr. Aviram's and Dr. Davidson's studies are two different studies, with one group of patients who have very significant disease and the other group where it was just at risk. (RFF 1565; Heber, Tr. 1983-84). The finding of a smaller result in the at-risk group than in the carotid artery stenosis group therefore, is not that surprising. (RFF 1567; Heber, Tr. 1983-84).

Dr. Davidson testified that his findings do not contradict and are consistent with previous studies conducted by Dr. Aviram, Dr. Ornish, and other researchers. (RFF 1569; CX1336 (Davidson, Dep. at 227-229)).

421. The Davidson CIMT Study (2009), with its negative results, was finally published in late 2009, and only in mid to late 2010 did POM's advertisements finally omit reference to the results of the Aviram CIMT/BP Study (2004), as in the advertisement cited above. (CCFF ¶ 419).

Response to Finding No. 421:

Respondents also object to the word "negative" as vague and ambiguous and argumentative. The evidence does not support Complaint Counsel's argument that the results of Dr. Davidson's CIMT study is "negative." At 12 months, the data from Dr. Davidson's study showed a statistically significant reduction in CIMT in the group consuming pomegranate juice versus the placebo group in composite measurements, but

statistical significance between the two groups was not demonstrated at 18 months. (CX1065; CX 1336 (Davidson, Dep. at 55)). However, in a post-hoc analysis of the study, Dr. Davidson noted that patients with the highest risk factors of coronary heart disease, in fact, did experience a benefit as compared to the placebo group. (CX1065). Indeed, this analysis showed that the higher risk patients in the pomegranate juice group had significantly less anterior wall and/or composite CIMT progression versus control subjects. (CX1065). Thus, the evidence does not support Complaint Counsel's argument that the results of Dr. Davidson's CIMT study is "negative."

Respondents also object to the term "finally" as vague, ambiguous, and argumentative. POM did not use the results of the Davidson study in its advertising until 2009 because of the delay in its publication. Respondents received the results of Dr. Davidson's CIMT study in 2006, but Dr. Davidson and the Respondents decided to have the data re-read by a blinded independent group because both Dr. Davidson and POM's internal science team were confused by the results. (Liker, Tr. 1895-96; CX1350 (Liker, Dep. at 146, 149-50, 163-64)). Mr. Resnick also wanted to make sure that if POM's advertising shared the study's results that it, in fact, accurately reflected the true benefit from the Challenged Products. (Liker, Tr. 1895-96; CX1350 (Liker, Dep. at 146, 149-50, 163-64)). Furthermore, POM did not advertise the unpublished results between 2006 and 2009 because doing so would have interfered with Dr. Davidson's ability to get the results published in a scientific journal. (CX1065). The re-reading of the results caused a delay in the publication of Dr. Davidson's study until 2009. Upon publication of Dr. Davidson's study in the American Journal of Cardiology, POM did share Dr. Davidson's published work.

Respondents further object to Complaint Counsel's inference POM omitted reference to the Aviram 2004 because it believes that the study did not constitute competent and reliable support for POM's heart health representations. In fact, Dr. Aviram's study

found a 30% reduction in arterial plaque of individuals who consumed pomegranate juice daily for one year. (RFF 1118). Specifically, the authors wrote: "We thus conclude that, as previously shown in atherosclerotic mice, also in humans pomegranate juice consumption (by patients with carotid artery stenosis) possess anti-atherosclerotic properties, as it substantially decreased serum oxidative stress and, in parallel, reduced common carotid intima-media thickness." (CX0611-0009). Thus, Dr. Aviram's study constitutes competent and reliable evidence that the consumption of POM Juice is beneficial to cardiovascular health by, among other things, reducing arterial plaque and lowering blood pressure. (CX0611; Heber, Tr. 1962-64).

422. Dr. Butters testified that a viewer of the "24 Scientific Studies" advertisement would find it reasonable to believe that the headline is accurate and that there must be 24 scientific studies on POMx. (Butters, Tr. 2940).

Response to Finding No. 422:

Respondents have no specific response.

423. Mrs. Resnick testified that she would have seen the POMx advertisement in CX0348 and that she would have approved specific elements of the advertisement, including the headline "24 Scientific Studies Now in One Easy-to-Swallow Pill," the image of the pill equaling eight ounces of POM Juice, and the image of the pomegranates pouring out of the pill. (L. Resnick, Tr. 249-51).

Response to Finding No. 423:

Respondents object to the proposed finding to the extent that Complaint Counsel construe the cited evidence to bolster their argument that Respondents intended to convey or conveyed to consumers that the Challenged Products treat, prevent or reduce the risk of heart disease, prostate cancer and erectile dysfunction. Although Respondents genuinely believe in the health benefits of the Challenged Products and in the scientific integrity of POM's research (RFF 502-20), the Respondents dispute that they ever intended to convey or that the Challenged Ads do convey the claim that the Challenged Products treat, prevent or reduce the risk of heart disease, prostate cancer and erectile dysfunction

or that they are "clinically proven" to do so. (RFF 496, 535, 538, 540, 545-50, 2209-11, 2280; CX1375 (L. Resnick, Trop., Dep. at 79-81).

424. These advertisements (CX0342, CX0348, CX0350, and CX0353), by using terms such as "life insurance," citing specific studies, and referencing support by a significant dollar amount of medical research conducted, convey the net impression that taking one POMx Pill daily treats, prevents, or reduces the risk of cardiovascular disease and prostate cancer, and that those health benefits are clinically proven. Because the advertisements specifically note that the studies were done on the POM Juice, and that one POMx Pill is equivalent to eight ounces of POM Juice, they also convey the net impression that drinking 8 ounces of POM Juice daily treats, prevents, or reduces the risk of cardiovascular disease and prostate cancer, and that those health benefits are clinically proven. (CCFF ¶¶ 419, 422).

Response to Finding No. 424:

Respondents object to Complaint Counsel's citation to CX0348, CX0350, and CX0353 as they were conditionally admitted at trial. Complaint Counsel misconstrue and misrepresent the meaning of these ads. The fact that the POMX Pills are wholly-derived from the pomegranate fruit is heavily emphasized in the body copy and the visual imagery of these ads as well as on the products themselves. These ads depict prevalent visual imagery of one or several deep, ruby red pomegranates; dominant images of deep, ruby red pomegranate juice in bottle shaped like two pomegranates stacked on top of one another; the pervasive image of POMx Pill bottle shaped like a pomegranate fruit; repeated textual reference to "POM Wonderful 100% Pomegranate Juice;"and statements that POMx is "made from the very same pomegranates as POM Wonderful 100% Pomegranate Juice". (CX0342, CX0348, CX0350, and CX0353). Complaint Counsel ignore the (1) outrageousness of the headline, (2) puffery in the headlines and sub-headlines and (3) fact the product is 100% fruit derived.

The fact that POM advertised in *Men's Health* is not damning. *Men's Health* magazine caters to health-conscious consumers and has sections on beauty, shopping, health, fitness, diet and nutrition. POM's advertising in *Men's Health* is entirely consistent with advertising of a food product whose messaging is how a whole food product fits into a

healthy lifestyle and diet program. Contrary to the marketing themes suggested by Complaint Counsel that POM marketed POM Juice as a pharmaceutical drug with a single or narrow target of action, advertising in *Men's Health* does not show intent to convey that POM Juice "prevents," "treats," or "reduces the risk" of heart disease or prostate cancer.

Nowhere in these ads do Respondents expressly (*i.e.*, unequivocally and directly) state that (a) taking one POMx Pill daily or drinking eight ounces of POM Juice daily "prevents," "treats," or "reduces the risk" of heart disease or prostate cancer; or (b) taking one POMx Pill daily or drinking eight ounces of POM Juice daily is "clinically proven" to "prevent," "treat," or "reduce the risk" of cardiovascular disease or prostate cancer. (CX0342, CX0348, CX0350, and CX0353).

Complaint Counsel's assertion that these ads convey the message that (a) taking one POMx Pill daily or drinking eight ounces of POM Juice daily "prevents," "treats," or "reduces the risk" of cardiovascular disease and prostate cancer; or (b) taking one POMx Pill daily or drinking eight ounces of POM Juice daily is "clinically proven" to "prevent," "treat," or "reduce the risk" of cardiovascular disease and prostate cancer is not conspicuous, self-evident, or reasonably clear from the face of the ads. (CX0279_0001). Consequently, because the above-referenced challenged implied claim may not be determined with confidence from the face of the ads, extrinsic evidence must be examined.

Complaint Counsel erroneously rely upon the impact of only a few, select elements for their overall view of the net impression of an ad, and seemingly neglect at least two significant elements that are key to any facial or common sense net impression analysis—that POMx Pills, POMx Liquid and POM Juice are products wholly-derived from

pomegranates, and POMx Pills, POMx Liquid and POM Juice's effectiveness is based, at least in significant part, on the products' abundant antioxidants.

The overall net impression of these ads is not that taking one POMx Pill daily or drinking eight ounces of POM Juice daily prevents, treats or reduces the risk of certain diseases, such as cardiovascular disease or prostate cancer; or (b) taking one POMx Pill daily or drinking eight ounces of POM Juice daily is "clinically proven" to prevent, treat or reduce the risk of certain diseases, such as cardiovascular disease or prostate cancer. (CX0279_0001). Even the language of the ads themselves uses such qualifiers as "initial UCLA Medical Study," "hopeful results," "fight," "preliminary studies," and "promising results (CX0342, CX0348, CX0350, and CX0353).

The ads make multiple efforts to convey that POMx is a whole food product that is wholly-derived from pomegranates, including: a) pervasive imagery of the POMx bottle shaped like a pomegranate; b) visual imagery of deep, ruby red pomegranate juice in a bottle shaped like two pomegranates stacked on top of one another; c) multiple images of pomegranates, one of which features pomegranates spilling out of a pill capsule; d) repeated textual references to "POM Wonderful 100% Pomegranate Juice"; and e) statements touting that POMx is "made from the same pomegranates used to make POM Wonderful 100% Pomegranate Juice."

Additionally, the ads emphasize that POMx contains abundant antioxidants. For example, the ads reference: a) that "taking one POMx pill a day will help protect you from free radicals;" b) POMx as "an ultra-potent antioxidant extract;" c) to POMx as "The Antioxidant Superpill;" and d) the "unique and superior antioxidant power of pomegranates."

Both the whole food aspect of the advertising and the emphasis on antioxidant content, directly counter any suggestion that POMx is going to act like a drug, as distinguished

from a very healthy fruit or vegetable and a healthy diet. The ads emphasize that the POMx Pill has nutritional benefits equivalent to the nutritional benefits of 8 oz of POM Juice, not more.

Viewing the ads as a whole, taking into account all the various elements, including the prevalence and pervasiveness of these "whole-food" graphics, in the form of pomegranates and the POMx and POM Juice bottles, and body copy as well as the repeated emphasis on the fact that POMx is a concentrated and potent source of antioxidants, it is far more logical that POM consumers would view POMx the way they perceive any other whole food, like broccoli, blueberries, grapes or tomatoes, which may help prevent or improve your odds against disease, but which would not act like a drug with a single target of action against a particular disease or condition.

To the extent a "reduce the risk" claim can be implied from these ads, the overall net impression is not that taking one POMx Pill daily or drinking eight ounces of POM Juice daily "reduces the risk" of certain diseases, such as heart disease or prostate cancer, like a drug with a single target of action, but that it may help "reduce the risk," like many whole foods, or like an especially healthy fruit or vegetable, or like a healthy diet of fruits and vegetables and exercise "reduces the risk" of disease. (CX0342, CX0348, CX0350, and CX0353).

To the extent a "treat" claim can be implied from these ads (which it cannot), the overall net impression of these ads is not that POMx Pills or POM Juice is a substitute for conventional medical treatment. (Butters, Tr. 2821-22).

To the extent a "proven" claim can be implied from these ads (which it cannot), the overall impression of these ads is not that POMx Pills and POM Juice are "proven" to be 100% effective in preventing, treating or reducing the risk of heart disease or prostate cancer because (1) all of the qualifying language contradicts an implied "clinically

proven" interpretation, and (2) ""proven" in science and to consumers means the "average person in the study benefitted." "Proven" does not mean that "everyone in the study necessarily benefitted" or that everyone will benefit like the persons who benefitted in the study. (Heber, Tr. 2011; Butters, Tr. 2893-2894; PX0361 (Sacks, Dep. at 81)).

Contrary to Complaint Counsel's implication, it is completely illogical to infer from the fact that a certain amount of money was invested in research to the conclusion that POMx Pills, POMx Liquid or POM Juice are proven to prevent, treat or reduce the risk of disease. Complaint Counsel's attempts to make a "logical leaps" from "supported by $32 million of initial scientific research from leading universities, which has uncovered encouraging results in prostate and cardiovascular health" to supported by $32 million in research that proved POMx Pills, POMx Liquid and POM Juice prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction. What the "backed by" ads actually convey is that Respondents are committed to the science and learning the truth about pomegranates. (L. Resnick, Tr. 251). Complaint Counsel presented no evidence that consumers took away the message presumed by Complaint Counsel because Respondents spent a certain amount of money on science and research. (RFF 28-29, 2515). Moreover, the ad accurately and truthfully represented the dollars spent by Respondents on the totality of the science on POMx Pills, POMx Liquid and POM Juice. (RFF 2510).

With respect to CX0342 and CX0353, Professor Butters testified that these ads employ humor as it is a "joking reference to death." (PX0350 (Butters, Dep. at 141)). Viewing the "Take Out A Life Insurance Supplement" ads as a whole, including the interaction of the words and visual imagery, the overall net impression of the ads is that they are humorous ads and that POMx Pills are healthy. (PX0350 (Butters, Dep. at 141); (PX0158-0033)).

In reviewing CX0348 and CX0350, Professor Butters testified that these advertisements convey "the sense that pomegranate juice is healthy and that pomegranate juice contains the same antioxidants that are found in the POMx super pill, the antioxidant super pill." (Butters, Tr. 2939). Professor Butters also testified that these ads also communicate that one of the benefits of POMx Pills is that they may help with prostate health. Professor Butters does not believe that it is reasonable for viewers to equate hopeful results for prostate health to mean hopeful results for preventing prostate cancer though. (Butters, Tr. 2940-43). Further, Professor Butters testified that the ads never state that POMx will treat a disease and that reasonable consumers cannot infer from this advertisement that POMx Pills treat disease, prevent or reduce the risk of prostate cancer or heart disease, like a drug, as distinguished from the way a healthy diet of fruits and vegetables and exercise maintain health and reduce the risk of disease. (PX0350 (Butters, Dep. at 139)). Professor Butters also testified that the advertisements could not communicate to reasonable consumers or more than just outliers that scientific studies document that POMx Pills treat, prevent or reduce the risk of prostate cancer or heart disease like a drug may. (PX0350 (Butters, Dep. at 137-38)). Viewing the "24 Scientific Studies" ads as a whole, including the interaction of the words and visual imagery, the overall net impression of the ads is that POMx Pills are healthy and that they may help with prostate health. (PX0350 (Butters, Dep. at 141); (PX0158-0033)).

Also, Mr. Resnick testified that POM's advertisements are not intended to convey the message that they can prevent or treat coronary heart disease. (S. Resnick, Tropicana, Dep. at 58-59). Although Mr. Resnick testified that POM believes pomegranate juice is beneficial in preventing and treating coronary heart disease, he does not want consumers to share this belief, but rather to look at their science and make up their own mind. (S. Resnick, Tropicana, Dep. at 42-43). Mr. Resnick never intended POM products to be a substitute for recommended medical treatment or anything else recommended by a

doctor. (S. Resnick, Tr. 1870). Mr. Tupper testified that it is absolutely against company policy to say or suggest that POM products are a substitute for proper medical treatment. (Tupper, Tr. 3018). In responding to health-related inquires or a question about a medical condition, POM instructs its employees to tell consumers to consult with his or her physician and strongly encourage this recommendation. (CX0308; Tupper, Tr. 3019).

Even assuming *arguendo* that these ads conveys the message Complaint Counsel assigns to them, Professor Reibstein's survey effectively demonstrates that any alleged disease claims made by Respondents were not material to the purchasing decisions of POM consumers. (RFF 2623, 2630). Complaint Counsel failed to present any evidence regarding the number of exposures consumers had to these ads or any particular POM advertisement. Complaint Counsel have presented no reliable evidence to rebut Professor's Reibstein's survey findings or to show that any alleged disease claims made in POM's ads were material to the purchasing decisions of POM consumers.

Complaint Counsel presented no extrinsic evidence or expert opinion on the meaning of these ads, consumer perceptions of these ads, or consumer interpretations regarding these ads. (PX0357 (Stewart, Dep. at 49, 52)). Complaint Counsel failed to present any evidence that the claims in these ads reasonably convey that the Challenged Products are "clinically proven" to prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction.

Complaint Counsel failed to present any evidence regarding the number of exposures consumers had to these ads or any particular POM advertisement. (Mazis, Tr. 2752).

f. "The Only Antioxidant Supplement Rated X" Print Ads (CX0351 / CX0355)

425. POM disseminated POMx print advertisements headlined, "**THE ONLY ANTIOXIDANT SUPPLEMENT RATED X**," in male-oriented magazines such as *Advocate* and *Playboy*. The advertisements used subheadlines presumably intended to

appeal to male readers, such as "Always use protection," "P♥Mx. Super-potent. Like you." "$32 million in research. We're not just playing doctor." and "Is that P♥Mx in your pocket?" However, the body copy was substantially similar to prior POMx print advertisements, with the addition of several claims that POM Juice and therefore, POMx, improves erectile function:

POMx is made from the only pomegranates backed by $32 million in medical research at the world's leading universities. Not only has this research documented the unique and superior antioxidant power of pomegranates, it has revealed promising results for erectile, prostate and cardiovascular health.

***

Our P♥Mx pills are made from the same pomegranates we use to make our P♥M Wonderful 100% Pomegranate Juice, on which each of the following medical studies was conducted.

In a preliminary study on erectile function, men who consumed POM Juice reported a 50% greater likelihood of improved erections as compared to placebo. "As a powerful antioxidant, enhancing the actions of nitric oxide in vascular endothelial cells, POM has potential in the management of ED. . . further studies are warranted." *International Journal of Impotence Research*, '07.

An initial UCLA study on our juice found hopeful results for prostate health, reporting "statistically significant prolongation of PSA doubling times," *Clinical Cancer Research*, '06.

A preliminary study on our juice showed promising results for heart health. "Stress-induced ischemia (restricted blood flow to the heart) decreased in the pomegranate group," *American Journal of Cardiology*, '05.

(CX0351_0001 (*Advocate* magazine, June 2010); CX0355_0001 (*Playboy* magazine, July 2010)). The *Playboy* advertisement cited a figure of $34 million in medical research. (CX0355).

Response to Finding No. 425:

Respondents object to Complaint Counsel's citation to CX0351, and CX0355 as they were conditionally admitted at trial. Respondents object to this finding of fact on the basis that it misstates the evidence and the documents speak for themselves. Complaint Counsel quote only part of the ad's copy in this finding. Also, Complaint Counsel erroneously assert that the *Advocate* is a "male-oriented" magazine. On the contrary, it is the leading national gay and lesbian news magazine, which by definition includes a large percentage of women. (http://www. advocate.com).

426. Respondents' expert, Dr. Butters, testified that speakers of American English would interpret the phrase "erectile function" to relate to the ability of men to achieve and maintain erections and that erectile function and the absence of erectile dysfunction are closely related. (Butters, Tr. 2851).

Response to Finding No. 426:

Erectile function relates to the erectile mechanism that the penis uses to get an erection. (PX0352 (Goldstein, Dep. at 148-149). Erectile function is distinguished from erectile dysfunction, which is the consistent or persistent inability to obtain and/or sustain an erection adequate for sexual intercourse. (RFF 2051; PX0189-0008-0009).

427. Dr. Butters also stated in his report and testified at trial that this advertisement conveys that preliminary initial studies suggest that pomegranate extract, a strong source of antioxidants, could help alleviate erectile dysfunction. (Butters, Tr. 2943).

Response to Finding No. 427:

Respondents have no specific response.

428. Mrs. Resnick admits she approved the headline for the POMx print advertisement headlined "The only antioxidant supplement rated X" that appeared in *Playboy* magazine. (L. Resnick, Tr. 266).

Response to Finding No. 428:

Respondents dispute the misrepresentation of Mrs. Resnick's testimony regarding what magazine the advertisement appeared in. In fact, Mrs. Resnick testified that it would make sense that with this headline, this ad ran in *Playboy* magazine, however, she stated she did not know whether it was true or not if the ad ran in *Playboy* magazine. (L. Resnick, Tr. 266).

429. The advertisements (CX0351 and CX0355) convey the net impression that taking one POMx Pill daily treats, prevents, or reduces the risk of cardiovascular disease, prostate cancer, and erectile dysfunction, and that those health benefits are clinically proven. Because the advertisements specifically note that the studies were done on the juice, and that one pill is equivalent to eight ounces of POM Juice, they also convey the net impression that drinking eight ounces of POM Juice daily treats, prevents, or reduces the risk of cardiovascular disease, prostate cancer, and erectile dysfunction, and that those health benefits are clinically proven. (CCFF ¶¶ 425-27).

Response to Finding No. 429:

Complaint Counsel misconstrue and misrepresent the meaning of these ads. The fact that the POMX Pills are wholly-derived from the pomegranate fruit is heavily emphasized in the body copy and the visual imagery of these ads as well as on the products themselves. These ads depict prevalent visual imagery of one or several deep, ruby red pomegranates; dominant images of deep, ruby red pomegranate juice in bottle shaped like two pomegranates stacked on top of one another; the pervasive image of POMx Pill bottle shaped like a pomegranate fruit; repeated textual reference to "POM Wonderful 100% Pomegranate Juice"; and statements that POMx is "made from the same pomegranates as POM Wonderful 100% Pomegranate Juice". (CX0351 and CX0355). Complaint Counsel ignore the (1) outrageousness of the headline, (2) puffery in the headlines and sub-headlines and (3) fact the product is 100% fruit derived.

Nowhere in these ads do Respondents expressly (*i.e.*, unequivocally and directly) state that (a) taking one POMx Pill daily or drinking eight ounces of POM Juice daily "prevents," "treats," or "reduces the risk" of heart disease, prostate cancer or erectile dysfunction; or (b) taking one POMx Pill daily or drinking eight ounces of POM Juice daily is "clinically proven" to "prevent," "treat," or "reduce the risk" of heart disease, prostate cancer or erectile dysfunction. (CX0351 and CX0355).

Complaint Counsel's assertion that these ads convey the message that (a) taking one POMx Pill daily or drinking eight ounces of POM Juice daily "prevents," "treats," or "reduces the risk" of heart disease, prostate cancer or erectile dysfunction; or (b) taking one POMx Pill daily or drinking eight ounces of POM Juice daily is "clinically proven" to "prevent," "treat," or "reduce the risk" of heart disease, prostate cancer or erectile dysfunction is not conspicuous, self-evident, or reasonably clear from the face of the ads. (CX0279_0001). Consequently, because the above-referenced challenged implied

claim may not be determined with confidence from the face of the ads, extrinsic evidence must be examined.

Complaint Counsel erroneously rely upon the impact of only a few, select elements for their overall view of the net impression of an ad, and seemingly neglect at least two significant elements that are key to any facial or common sense net impression analysis—that POMx Pills, POMx Liquid and POM Juice are products wholly-derived from pomegranates, and POMx Pills, POMx Liquid and POM Juice's effectiveness is based, at least in significant part, on the products' abundant antioxidants.

The overall net impression of these ads is not that taking one POMx Pill daily or drinking eight ounces of POM Juice daily prevents, treats or reduces the risk of certain diseases, such as heart disease, prostate cancer or erectile dysfunction; or (b) taking one POMx Pill daily or drinking eight ounces of POM Juice daily is "clinically proven" to prevent, treat or reduce the risk of certain diseases, such as heart disease, prostate cancer or erectile dysfunction. (CX0279_0001). Even the language of the ads themselves uses such qualifiers as "initial UCLA Medical Study," "hopeful results," "fight," "preliminary studies," and "promising results." (CX0351 and CX0355). The "The Only Antioxidant Supplement Rated X" advertisement makes multiple efforts to convey that POMx is a whole food product that is wholly-derived from pomegranates, including: a) pervasive imagery of the POMx bottle shaped like a pomegranate; b) visual imagery of deep, ruby red pomegranate juice in a bottle shaped like two pomegranates stacked on top of one another; c) an image of pomegranates spilling out of a pill capsule; d) repeated textual references to "POM Wonderful 100% Pomegranate Juice; and e) statements touting that POMx is "made from the same pomegranates used to make POM Wonderful 100% Pomegranate Juice."

Additionally, the ad emphasizes that POMx contains abundant antioxidants. For example, the "The Only Antioxidant Supplement Rated X" ad references: a) that "taking one POMx pill a day will help protect you from free radicals;" b) POMx as "an ultra-potent antioxidant extract;" c) to POMx as "The Antioxidant Superpill;" d) the "unique and superior antioxidant power of pomegranates; and e) a study stating "As a powerful antioxidant, enhancing the actions of nitric oxide in vascular endothelial cells, POM has potential in the management of ED."

Both the whole food aspect of the advertising and the emphasis on antioxidant content, directly counter any suggestion that POMx is going to act like a drug, as distinguished from a very healthy fruit or vegetable and a healthy diet. The ad emphasizes that the POMx Pill has nutritional benefits equivalent to the nutritional benefits of 8 oz of POM Juice, not more.

Viewing the ad as a whole, taking into account all the various elements, including the prevalence and pervasiveness of these "whole-food" graphics, in the form of pomegranates and the POMx and POM Juice bottles, and body copy as well as the repeated emphasis on the fact that POMx is a concentrated and potent source of antioxidants, it is far more logical that POM consumers would view POMx the way they perceive many other whole foods, like broccoli, blueberries, grapes or tomatoes, which may help prevent or improve your odds against disease, but which would not act like a drug with a single target of action against a particular disease or condition.

To the extent a "reduce the risk" claim can be implied from these ads, the overall net impression is not that taking one POMx Pill daily or drinking eight ounces of POM Juice daily "reduces the risk" of certain diseases, such as heart disease, prostate cancer or erectile dysfunction, like a drug with a single target of action, but that it may help "reduce the risk," like many whole foods, or like an especially healthy fruit or vegetable, or like a

healthy diet of fruits and vegetables and exercise "reduces the risk" of disease. (CX0351 and CX0355).

To the extent a "treat" claim can be implied from these ads (which it cannot), the overall net impression of these ads is not that POMx Pills or POM Juice is a substitute for conventional medical treatment. (Butters, Tr. 2821-22).

To the extent a "proven" claim can be implied from these ads (which it cannot), the overall impression of these ads is not that POMx Pills and POM Juice are "proven" to be 100% effective in preventing, treating or reducing the risk of heart disease, prostate cancer or erectile dysfunction because (1) all of the qualifying language contradicts an implied "clinically proven" interpretation, and (2) "proven" in science and to consumers means the "average person in the study benefitted." "Proven" does not mean that "everyone in the study necessarily benefitted" or that everyone will benefit like the persons who benefitted in the study. (Heber, Tr. 2011; Butters, Tr. 2893-2894; PX0361 (Sacks, Dep. at 81)).

Contrary to Complaint Counsel's implication, it is completely illogical to infer from the fact that a certain amount of money was invested in research to the conclusion that POMx Pills, POMx Liquid and POM Juice are proven to prevent, treat or reduce the risk of disease. Complaint Counsel's attempts to make a "logical leaps" from "supported by $32 million of initial scientific research from leading universities, which has uncovered encouraging results in prostate and cardiovascular health" to supported by $32 million in research that proved POMx Pills, POMx Liquid and POM Juice prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction. What the "backed by" ads actually convey is that Respondents are committed to the science and learning the truth about pomegranates. (L. Resnick, Tr. 251). Complaint Counsel presented no evidence that consumers took away the message presumed by Complaint Counsel

because Respondents spent a certain amount of money on science and research. (RFF 28-29, 2515). Moreover, the ad accurately and truthfully represented the dollars spent by Respondents on the totality of the science on POMx Pills, POMx Liquid and POM Juice. (RFF 2510).

With respect to CX0351 and CX0355, Mrs. Resnick testified the purpose of these ads was "just meant to give you a chuckle." (L. Resnick, Tr. 266-67). Professor Butters' testified that part of his conclusion in his report regarding this POMx Pills ad was that "preliminary initial studies suggest that pomegranate extract, a strong source of antioxidants, could help alleviate erectile dysfunction." (Butters, Tr. 2943). Viewing the "The Only Antioxidant Supplement Rated X" ads as a whole, including the interaction of the words and visual imagery, the overall net impression of the ads is that they are humorous ads, that POMx Pills are healthy and that they may help with erectile dysfunction. ((L. Resnick, Tr. 266-67); (PX0350 (Butters, Dep. at 141); (PX0158-0033)). First, the advertisement was meant to be humorous and to give the reader a "chuckle" as evidenced by the overt puffery and outrageous sub-headlines in the ad. (*E.g.*, "Always Use Protection," "POMx Super-potent. Like you," and "Is that POMx in your pocket?")." (CX0351 and CX0355). Second, the ad emphasizes from the beginning the "emerging science" on free radicals "important to maintaining health. (CX0351; CX0355). The ad emphasizes, heavily, the connections between POM Juice and POMx Pills, noting that POMx Pills are made from the same pomegranates as the juice, and that therefore, this is a 100% derived pomegranate product. (CX0351; CX0355). Third, when the advertisement addresses erectile health, it does so by solely accurately describing, summarizing and even quoting the qualified results or outcomes of the specific scientific research contained in the journal-published Forest/Padma-Nathan RCT Study. (CX0351; CX0355). Accurately summarizing and quoting the highly qualified results of a published scientific study about preliminary and potential benefits cannot

logically convey, as Complaint Counsel argue, the net impression that POMx Pills, POMx Liquid and POM Juice treat, prevent, or reduce the risk of erectile dysfunction, or that they are clinically proven to do so without qualification.

Also, Mr. Resnick testified that POM's advertisements are not intended to convey the message that they can prevent or treat coronary heart disease. (S. Resnick, Tropicana, Dep. at 58-59). Although Mr. Resnick testified that POM believes pomegranate juice is beneficial in preventing and treating coronary heart disease, he does not want consumers to share this belief, but rather to look at their science and make up their own mind. (S. Resnick, Tropicana, Dep. at 42-43). Mr. Resnick never intended POM products to be a substitute for recommended medical treatment or anything else recommended by a doctor. (S. Resnick, Tr. 1870). Mr. Tupper testified that it is absolutely against company policy to say or suggest that POM products are a substitute for proper medical treatment. (Tupper, Tr. 3018). In responding to health-related inquires or a question about a medical condition, POM instructs its employees to tell consumers to consult with his or her physician and strongly encourage this recommendation. (CX0308; Tupper, Tr. 3019).

Even assuming *arguendo* that these ads conveys the message Complaint Counsel assigns to them, Professor Reibstein's survey effectively demonstrates that any alleged disease claims made by Respondents were not material to the purchasing decisions of POM consumers. (RFF 2623, 2630). Complaint Counsel failed to present any evidence regarding the number of exposures consumers had to these ads or any particular POM advertisement. Complaint Counsel have presented no reliable evidence to rebut Professor's Reibstein's survey findings or to show that any alleged disease claims made in POM's ads were material to the purchasing decisions of POM consumers.

Complaint Counsel presented no extrinsic evidence or expert opinion on the meaning of these ads, consumer perceptions of these ads, or consumer interpretations regarding these ads. (PX0357 (Stewart, Dep. at 49, 52)). Complaint Counsel failed to present any evidence that the claims in these ads reasonably convey that POMx Pills, POMx Liquid and POM Juice are "clinically proven" to prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction.

Complaint Counsel failed to present any evidence regarding the number of exposures consumers had to these ads or any particular POM advertisement. (Mazis, Tr. 2752).

g. POMx "Antioxidant Superpill" Package Insert (CX1426_00038 [Compl. Ex. I])

430. A package insert for POMx, disseminated in June 2007, displayed the image of a POMx Pill bottle over the bold headline, "**Antioxidant Superpill**." It went on to state, "P♥Mx is a highly concentrated, incredibly powerful blend of all-natural polyphenol antioxidants made from the very same pomegranates in POM Wonderful 100% Pomegranate Juice." It also used the tag line, "The Power of P♥M. Now in one little pill." and included an image of an eight ounce POM Juice bottle with an equals sign next to a POMx Pill. (CX1426_00039 [Compl. Ex. I, p. 2]).

Response to Finding No. 430:

Complaint Counsel failed to present any definitive information regarding this ad's dissemination. Complaint Counsel failed to present any evidence that Respondents would run this ad in the future, let alone whether it is probable they would do so.

431. The package insert quoted Dr. Aviram as saying, "POM Wonderful Pomegranate Juice has been proven to promote cardiovascular health, and we believe that POMx may have the same health benefits." (CX1426_00042 [Compl. Ex. I, p. 5]). Next to an illustration of a heart was the following text:

In two groundbreaking preliminary studies, patients who drank POM Wonderful 100% Pomegranate Juice experienced impressive cardiovascular results. A pilot study at the Rambam Medical Center in Israel included 19 patients with atherosclerosis (clogged arteries). After a year, arterial plaque decreased 30% for those patients who consumed 8 oz of POM Wonderful 100% Pomegranate Juice daily.

[footnote omitted]

An additional study at the University of California, San Francisco included 45 patients with impaired blood flow to the heart. Patients who consumed 8 oz of POM Wonderful 100% Pomegranate Juice daily for three months experienced a 17% improvement in blood flow. Initial studies on POMx share similar promise for heart health, and our research continues.

(CX1426_00042 [Compl. Ex. I, p. 5]).

Response to Finding No. 431:

Respondents object to this finding of fact on the basis that the document speaks for itself.

Complaint Counsel quote only part of the ad's copy in this finding.

432. The same 2007 package insert for POMx made claims about prostate cancer, including:

Prostate health.

Prostate cancer is the most commonly diagnosed cancer among men in the United States and the second-leading cause of cancer death in men after lung cancer. [footnote omitted]

Time pill.

Stable levels of prostate-specific antigens (or PSA levels) are critical for men with prostate cancer. Patients with quick PSA doubling times are more likely to die from their cancer. [footnote omitted] According to a UCLA study of 46 men age 65 to 70 with advanced prostate cancer, drinking an 8oz glass of POM Wonderful 100% Pomegranate Juice every day slowed their PSA doubling time by nearly 350%. [footnote omitted]

83% of those who participated in the study showed a significant decrease in their cancer regrowth rate. [footnote omitted]

(CX1426_00041 [Compl. Ex. I, p. 4]).

Response to Finding No. 432:

Respondents object to this finding of fact on the basis that the document speaks for itself.

Complaint Counsel quote only part of the ad's copy in this finding.

433. Mrs. Resnick testified that she was very involved in developing the POMx brochure when it was first produced, and that the information under "Prostate Health" on fourth page of the package insert was in fact discussing prostate cancer. (L. Resnick, Tr. 246; CX1426_00041 [Compl. Ex. I, p. 4]).

Response to Finding No. 433:

Respondents state that this assertion is imprecise and does not create a full picture of Mrs. Resnick's testimony and the POMx brochure. Page 4 of the CX1426, Exh. I clearly and accurately describes and summarizes the results of the Pantuck Study (2006) that studied 46 men "age 65 or 70 with advanced prostate cancer" who drank pomegranate juice every day. (*See* RFF 2484-87).

434. The net impression from the POMx package insert, including the detailed description of several studies, is that eight ounces of POM Juice or one POMx Pill taken daily, prevents, treats, or reduces the risk of heart disease, including by decreasing arterial plaque, or improving blood flow to the heart; that eight ounces of POM Juice or 1 POMx Pill taken daily prevents, treats, or reduces the risk of prostate cancer, including by prolonging PSA doubling time; and that these benefits for heart disease and prostate cancer are clinically proven. (*See* CCFF ¶¶ 430-32).

Response to Finding No. 434:

Complaint Counsel misconstrue and misrepresent the meaning of these ads. The fact that the POMX Pills are wholly-derived from the pomegranate fruit is heavily emphasized in the body copy and the visual imagery of these ads as well as on the products themselves. These ads depict prevalent visual imagery of one or several deep, ruby red pomegranates; dominant images of deep, ruby red pomegranate juice in bottle shaped like two pomegranates stacked on top of one another; the pervasive image of POMx Pill bottle shaped like a pomegranate fruit; repeated textual reference to "POM Wonderful 100% Pomegranate Juice;"and statements that POMx is "made from the same pomegranates as POM Wonderful 100% Pomegranate Juice". (CX1426, Exh. I).

Nowhere in this ad do Respondents expressly (*i.e.*, unequivocally and directly) state that (a) taking one POMx Pill per day "prevents," "treats," or "reduces the risk" of heart disease or prostate cancer; or (b) taking one POMx Pill per day is "clinically proven" to "prevent," "treat," or "reduce the risk" of heart disease or prostate cancer. (CX01426_0038-0042, Exh. I)

Complaint Counsel's assertion that the ad implicitly conveys the message that (a) taking one POMx Pill per day "prevents," "treats," or "reduces the risk" of heart disease or prostate cancer; or (b) taking one POMx Pill per day is "clinically proven" to "prevent," "treat," or "reduce the risk" of heart disease or prostate cancer is not conspicuous, self-evident, or reasonably clear from the face of the ad. (CX1426_0038-0042, Exh. I). Consequently, because the above-referenced challenged implied claim may not be determined with confidence from the face of the ad, extrinsic evidence must be examined.

Complaint Counsel erroneously rely upon the impact of only a few, select elements for their overall view of the net impression of an ad, and seemingly neglect at least two significant elements that are key to any facial or common sense net impression analysis—that the Challenged Products are products wholly-derived from pomegranates, and the Challenged Products' effectiveness is based, at least in significant part, on the products' abundant antioxidants.

The overall net impression of this ad is not that not that taking one POMx Pill per day prevents, treats or reduces the risk of certain diseases, such as heart disease or prostate cancer; or (b) taking one POMx Pill per day is "clinically proven" to prevent, treat or reduce the risk of certain diseases, such as heart disease or prostate cancer. (CX1426_0038-0042, Exh. I). Even the language of the ad itself uses such qualifiers as "emerging science," may be linked," helping to prevent," "can lead," "can disrupt," "findings from a small study suggest," "may one day prove," "potential ability," "basic studies indicate," and "may have the same effect." (CX1426_0038-0042, Exh. I).

The "Antioxidant Superpill" advertisement makes multiple efforts to convey that POMx is a whole food product that is wholly-derived from pomegranates, including: a) pervasive imagery of the POMx bottle shaped like a pomegranate; b) visual imagery of

deep, ruby red pomegranate juice in a bottle shaped like two pomegranates stacked on top of one another; c) an image of a ruby red pomegranate; d) Repeated textual references to "POM Wonderful 100% Pomegranate Juice; e) Statements touting that POMx is "made from the very same pomegranates used to make POM Wonderful 100% Pomegranate Juice;" f) that "POMx is made from pomegranates only—nothing else."

Additionally, the ad emphasizes that POMx contains abundant antioxidants. For example, the "Antioxidant Superpill" ad references: a) that "POMx is a "highly concentrated, incredibly powerful blend of all-natural polyphenol antioxidants;" b) that "now you can get all the antioxidant power of an 8oz glass of juice in the convenience of a calorie-free capsule;" c) that POMx has "more polyphenol antioxidants than any other pomegranate antioxidant supplement;" d) that POMx has "1000mg of natural pomegranate polyphenol extract in every pill;" and e) that POMx "guards your body from free radicals."

Both the whole food aspect of the advertising and the emphasis on antioxidant content, directly counter any suggestion that POMx is going to act like a drug, as distinguished from a very healthy fruit or vegetable and a healthy diet. The ad emphasizes that the POMx Pill has nutritional benefits equivalent to the nutritional benefits of 8 oz of POM Juice, not more.

Viewing the ad as a whole, taking into account all the various elements, including the prevalence and pervasiveness of these "whole-food" graphics, in the form of pomegranates and the POMx and POM Juice bottles, and body copy as well as the repeated emphasis on the fact that POMx is a concentrated and potent source of antioxidants, it is far more logical that POM consumers would view POMx the way they perceive many other whole foods, like broccoli, blueberries, grapes or tomatoes, which may help prevent or improve your odds against disease, but which would not act like a drug with a single target of action against a particular disease or condition.

To the extent a "reduce the risk" claim can be implied from this ad, the overall net impression is not that taking one POMx Pill per day "reduces the risk" of certain diseases, such as heart disease or prostate cancer, like a drug with a single target of action, but that it may help "reduce the risk," like many whole foods, or like an especially healthy fruit or vegetable, or like a healthy diet of fruits and vegetables and exercise "reduces the risk" of disease. (CX1426_0038-0042, Exh. I).

To the extent a "treat" claim can be implied from this ad (which it cannot), the overall net impression of any ad is not that POMx Pills are a substitute for conventional medical treatment. (Butters, Tr. 2821-22).

To the extent a "proven" claim can be implied from this ad (which it cannot), the overall impression of this ad is not that POMx Pills are "proven" to be 100% effective in preventing, treating or reducing the risk of heart disease or prostate cancer because (1) all of the qualifying language contradicts an implied "clinically proven" interpretation, and (2) "proven" in science and to consumers means the "average person in the study benefitted." "Proven" does not mean that "everyone in the study necessarily benefitted" or that everyone will benefit like the persons who benefitted in the study. (Heber, Tr. 2011; Butters, Tr. 2893-2894; PX0361 (Sacks, Dep. at 81)).

Also, Mr. Resnick testified that POM's advertisements are not intended to convey the message that they can prevent or treat coronary heart disease. (S. Resnick, Tropicana, Dep. at 58-59). Although Mr. Resnick testified that POM believes pomegranate juice is beneficial in preventing and treating coronary heart disease, he does not want consumers to share this belief, but rather to look at their science and make up their own mind. (S. Resnick, Tropicana, Dep. at 42-43). Mr. Resnick never intended POM products to be a substitute for recommended medical treatment or anything else recommended by a doctor. (S. Resnick, Tr. 1870). Mr. Tupper testified that it is absolutely against company

policy to say or suggest that POM products are a substitute for proper medical treatment. (Tupper, Tr. 3018). In responding to health-related inquires or a question about a medical condition, POM instructs its employees to tell consumers to consult with his or her physician and strongly encourage this recommendation. (CX0308; Tupper, Tr. 3019).

Even assuming *arguendo* that this ad conveys the message Complaint Counsel assign to it, Professor Reibstein's survey effectively demonstrates that any alleged disease claims made by Respondents were not material to the purchasing decisions of POM consumers. (RFF 2623, 2630). Complaint Counsel failed to present any evidence regarding the number of exposures consumers had to this ad or any particular POM advertisement. Complaint Counsel have presented no reliable evidence to rebut Professor's Reibstein's survey findings or to show that any alleged disease claims made in POM's ads were material to the purchasing decisions of POM consumers.

Complaint Counsel presented no extrinsic evidence or expert opinion on this ad's meaning, consumer perceptions of this ad, or consumer interpretations regarding this ad. (PX0357 (Stewart, Dep. at 49, 52)).

Complaint Counsel failed to present any evidence that the claims in this ad reasonably convey that the Challenged Products are "clinically proven" to prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction.

Complaint Counsel failed to present any evidence regarding the number of exposures consumers had to this ad or any particular POM advertisement. (Mazis, Tr. 2752).

h. POMx Heart and Prostate Newsletters (CX1426_00046 [Compl. Ex. M] / CX1426_00049 [Compl. Ex. N])

435. A POMx newsletter dated "Summer '07" and labeled "Volume 1, Issue 1: FOR YOUR HEART," claimed "NEW RESEARCH OFFERS FURTHER PROOF OF THE HEART-HEALTHY BENEFITS OF POM WONDERFUL JUICE." (CX1426_0004-48 [Compl. Ex. M, pp. 1-3]).

Response to Finding No. 435:

Complaint Counsel failed to present any other definitive information regarding this newsletter's dissemination. Complaint Counsel failed to present any evidence that Respondents would run this newsletter in the future, let alone whether it is probable they would do so. This newsletter cannot provide a basis for injunctive relief because (a) it ran over five years ago; and (b) no evidence exists to show that Respondents are likely to run this ad in the future.

436. The newsletter begins with the bolded heading "**What's New in the Lab by Dr. Mark Dreher**" followed by a photograph of Dr. Dreher next to his title:

Mark Dreher, PhD

Chief Science Officer

POM Wonderful, LLC

The newsletter opens with, "Hi, I'm Dr. Mark Dreher, Chief Science Officer at POM, and your guide to continuing new research on the benefits of POMx and POM Wonderful pomegranates as they relate to your health." (CX1426_00046-47 [Compl. Ex. M, pp. 1-2]).

Response to Finding No. 436:

Respondents object to the proposed finding to the extent that Complaint Counsel construe the cited evidence to bolster their argument that Respondents intended to convey or conveyed to consumers that the Challenged Products treat, prevent or reduce the risk of heart disease, prostate cancer and erectile dysfunction. Although Respondents genuinely believe in the health benefits of the Challenged Products and in the scientific integrity of POM's research (RFF 502-20), the Respondents dispute that they ever intended to convey or that the Challenged Ads do convey the claim that the Challenged Products treat, prevent or reduce the risk of heart disease, prostate cancer and erectile dysfunction or that they are "clinically proven" to do so. (RFF 496, 535, 538, 540, 545-50, 2209-11, 2280; CX1375 (L. Resnick, Trop., Dep. at 79-81).

437. The heart benefits were described as:

30% DECREASE IN ARTERIAL PLAQUE

After one year of a pilot study conducted at the Technion Institute in Israel involving 19 patients with atherosclerosis (clogged arteries), those patients who consumed 8 oz of POM Wonderful 100% Pomegranate Juice daily saw a 30% decrease in arterial plaque.

17% IMPROVED BLOOD FLOW

A recent study at the University of California, San Francisco (UCSF) included 45 patients with impaired blood flow to the heart. Patients who consumed 8 oz of POM Wonderful 100% Pomegranate Juice daily for three months experienced 17% improved blood flow. Those who drank a placebo experienced an 18% decline.

PROMOTES HEALTHY BLOOD VESSELS

An in vitro study at the University of California, Los Angeles (UCLA) showed that pomegranate juice uniquely possesses enough antioxidant activity to protect nitric oxide (an important biochemical that helps maintain healthy blood vessels for proper blood flow) against oxidative destruction thereby enhancing its biological activity. In other words, pomegranate juice by protecting nitric oxide promotes healthy blood flow.

(CX1426_00048 [Compl. Ex. M, p. 3]).

Response to Finding No. 437:

Respondents object to the proposed finding to the extent that Complaint Counsel construe the cited evidence to bolster their argument that Respondents intended to convey or conveyed to consumers that the Challenged Products treat, prevent or reduce the risk of heart disease, prostate cancer and erectile dysfunction. Although Respondents genuinely believe in the health benefits of the Challenged Products and in the scientific integrity of POM's research (RFF 502-20), the Respondents dispute that they ever intended to convey or that the Challenged Ads do convey the claim that the Challenged Products treat, prevent or reduce the risk of heart disease, prostate cancer and erectile dysfunction or that they are "clinically proven" to do so. (RFF 496, 535, 538, 540, 545-50, 2209-11, 2280; CX1375 (L. Resnick, Trop., Dep. at 79-81).

438. A text box within the newsletter equated the effects of POM Juice and POMx, stating, "In his 2006 POMx study, Dr. Michael Aviram, one of the world's pre-eminent cardiovascular researchers from the Technion Institute in Israel, remarked that '*POMx is as potent an antioxidant as pomegranate juice and just like pomegranate juice, POMx may promote cardiovascular health.*'" (CX1426_00048 [Compl. Ex. M, p. 3])).

Response to Finding No. 438:

Respondents have previously detailed how POM Juice and POMx Pills and POMx Liquid are equivalent on proving health benefits to humans and that POMx Pills and POMx Liquid have equivalent bioavaiablity as POM Juice. (RFF 920, 921). Dr. Heber found no difference in the antioxidant effect between POM Juice and POMx products in laboratory studies he conducted. (RFF 925). Professor Stampfer did not dispute Dr. Heber's findings. (RFF 215-216, 818-819). Also, Dr. Aviram testified that several studies and that there is good deal of data on POMx which shows similarity to POM Juice and that a POMx Pill has the same amount of polyphenol antioxidants as eight ounces of POM Juice. (CX1358 (Aviram, Dep. at 51-52; 45-46)). Respondents have provided ample evidence to demonstrate that POMx Pills and POMx Liquid are bioequivalent to POM Juice and that POMx Pills and POMx Liquid provide similar health benefits as POM Juice provides. (RFF 915-951).

439. Another newsletter dated "Fall '07" and labeled "Volume 1, Issue 2: PROSTATE HEALTH," also begins with the bolded heading "**What's New in the Lab by Dr. Mark Dreher**" followed by an photograph of Dr. Dreher next to his title:

Mark Dreher, PhD

Chief Science Officer

POM Wonderful, LLC

In this newsletter, Dr. Dreher is quoted as saying, "Research studies like the ones discussed in this newsletter and conducted by UCLA "my alma mater" serve to validate the many reasons I am proud to be affiliated with POM Wonderful and POMx." (CX1426_00050 [Compl. Ex. N, p. 2]).

Response to Finding No. 439:

Respondents dispute this finding of fact to the extent it insinuates that the research studies conducted by UCLA are not competent and reliable because Dr. Dreher is an alum of one of the highest rated medical institutions in the United States and previously worked for POM. (Liker, Tr. 1888).

Further, Respondents ass that: Dr. Dreher does not believe that there is anything false or misleading about the newsletters that were the basis for his settlement agreement with the FTC. (Dreher, Tr. 588). Dr. Dreher believes in the science supporting the health benefits of pomegranates despite the FTC's accusations against him. (Dreher, Tr. 588).

440. This newsletter stated:

Prostate Cancer Affects 1 Out of Every 6 Men

Prostate cancer is the second leading cause of cancer related death in men in the United States according to the National Cancer Institute. Prostate cancer incidence rates rose dramatically in the late 1980's with improved detection and diagnosis through widespread use of prostate-specific antigen (PSA) testing.

***

What's New in the Lab by Dr. Mark Dreher

***

POM Wonderful 100% Pomegranate Juice and POMx are backed by a $25 million dollar investment in world-class scientific research. This includes ten clinical studies published in top peer-reviewed medical journals that document the pomegranate's antioxidant health benefits such as heart and prostate health.

***

In fact, studies funded by POM represent the vast majority of human medical research ever conducted on pomegranates.

***

NEW POMEGRANATE RESEARCH OFFERS HOPE TO PROSTATE CANCER PATIENTS

A preliminary UCLA medical study involving POM Wonderful 100% Pomegranate Juice revealed promising news. 46 men who had been treated for prostate cancer with surgery or radiation were given 8oz *[sic]* of POM Wonderful 100% Pomegranate Juice to drink daily.

A majority of the patients experienced a significantly extended PSA doubling time. Doubling time is an indicator of prostate cancer progression – extended doubling time may indicate slower disease progression.

Before the study, the mean doubling time was 15 months. After drinking 8oz *[sic]* of pomegranate juice daily for two years, the mean PSA doubling time increased to 54 months. Testing on patient blood serum showed a 12% decrease in cancer cell proliferation and a 17% increase in cancer cell death (apoptosis).

In another study, in vitro laboratory testing at UCLA showed that POMx significantly decreased human prostate cancer cell growth and increased cancer cell death. (CX1426_00050-51 [Compl. Ex. N, p. 2-3]).

Response to Finding No. 440:

Respondents add the following facts to Complaint Counsel's proposed finding: Dr. Dreher does not believe that there is anything false or misleading about the newsletters that were the basis for his settlement agreement with the FTC. (Dreher, Tr. 588). Dr. Dreher believes in the science supporting the health benefits of pomegranates despite the FTC's accusations against him. (Dreher, Tr. 588). Additionally, Respondents refer the Court to the Appendix of Advertisements 605-618.

441. The net impression from the heart newsletter, including the detailed description of several studies, is that eight ounces of POM Juice or one POMx Pill taken daily, prevents, treats, or reduces the risk of heart disease, including by decreasing arterial plaque, or improving blood flow to the heart, and that these benefits are clinically proven. (*See* CCFF ¶¶ 435-38). The net impression from the prostate newsletter is that eight ounces of POM Juice or one POMx Pill taken daily prevents, treats, or reduces the risk of prostate cancer, including by prolonging PSA doubling time; and that these benefits are clinically proven. (*See* CCFF ¶¶ 439-40).

Response to Finding No. 441:

Complaint Counsel misconstrue and misrepresent the meaning of these ads. Nowhere in Dreher Heart Newsletter do Respondents expressly (*i.e.*, unequivocally and directly) state that (a) taking one POMx Pill per day "prevents," "treats," or "reduces the risk" of heart disease; or (b) taking one POMx Pill per day is "clinically proven" to "prevent," "treat," or "reduce the risk" of heart disease. (CX01426_0046-0048, Exh. M).

Complaint Counsel's assertion that the ad implicitly conveys the message that (a) taking one POMx Pill per day "prevents," "treats," or "reduces the risk" of heart disease; or (b) taking one POMx Pill per day is "clinically proven" to "prevent," "treat," or "reduce the risk" of heart disease is conveyed in this newsletter is not conspicuous, self-evident, or reasonably clear from the face of it. (CX01426_0046-0048, Exh. M). Consequently,

because the above-referenced challenged implied claim may not be determined with confidence from the face of the newsletter, extrinsic evidence must be examined.

Complaint Counsel erroneously rely upon the impact of only a few, select elements for their overall view of the net impression of the newsletter, and seemingly neglect at least two significant elements that are key to any facial or common sense net impression analysis—that the Challenged Products are products wholly-derived from pomegranates, and the Challenged Products' effectiveness is based, at least in significant part, on the products' abundant antioxidants.

The overall net impression of this Dreher Heart Newsletter is not that not that taking one POMx Pill per day prevents, treats or reduces the risk of certain diseases, such as heart disease or prostate cancer; or (b) taking one POMx Pill per day is "clinically proven" to prevent, treat or reduce the risk of certain diseases, such as heart disease or prostate cancer. (CX1426_0046-0048, Exh. M). Even the language of the ad itself uses such qualifiers as "pipeline of research suggesting," "initial findings," "can lead," "may help," "pilot study," "initial scientific research," "encouraging results," "aim," "promotes" and "promising information." (CX1426_0046-0048, Exh. M).

The "Dreher Heart Newsletter" makes multiple efforts to convey that POMx is a whole food product that is wholly-derived from pomegranates, including: a) repeated textual references to "POM Wonderful 100% Pomegranate Juice; and b) Each dose of POMx contains the same amount of antioxidant polyphenols found in 8oz of POM Wonderful 100% pomegranate juice.

Additionally, the newsletter emphasizes that POMx contains abundant antioxidants. For example, the "Dreher Heart Newsletter" ad references: a) that "antioxidants neutralize free radicals, helping to prevent the cell and tissue damage that can lead to disease;" and

b) “Pomegranates contain polyphenols—powerful antioxidants that are important as part of a balanced diet.”

Both the whole food aspect of the newsletter and the emphasis on antioxidant content, directly counter any suggestion that POMx is going to act like a drug, as distinguished from a very healthy fruit or vegetable and a healthy diet. The newsletter emphasizes that the POMx Pill has nutritional benefits equivalent to the nutritional benefits of 8 oz of POM Juice, not more.

Viewing the newsletter as a whole, taking into account all the various elements, including the body copy as well as the repeated emphasis on the fact that POMx is a concentrated and potent source of antioxidants, it is far more logical that POM consumers would view POMx the way they perceive many other whole foods, like broccoli, blueberries, grapes or tomatoes, which may help prevent or improve your odds against disease, but which would not act like a drug with a single target of action against a particular disease or condition.

To the extent a “may reduce the risk” or “reduce the risk” claim can be implied from this newsletter, the overall net impression is not that taking one POMx Pill per day “reduces the risk” of heart disease, like a drug with a single target of action, but that it may help “reduce the risk,” like many whole foods, or like an especially healthy fruit or vegetable, or like a healthy diet of fruits and vegetables and exercise “reduces the risk” of disease. (CX1426_0046-0048, Exh. M).

To the extent a “treat” claim can be implied from this newsletter (which it cannot), the overall net impression of any ad is <u>not</u> that POMx Pills are a substitute for conventional medical treatment. (Butters, Tr. 2821-22).

To the extent a "proven" claim can be implied from this newsletter (which it cannot), the overall impression of this ad is not that POMx Pills are "proven" to be 100% effective in preventing, treating or reducing the risk of heart disease because (1) all of the qualifying language contradicts an implied "clinically proven" interpretation, and (2) "proven" in science and to consumers means the "average person in the study benefitted." "Proven" does not mean that "everyone in the study necessarily benefitted" or that everyone will benefit like the persons who benefitted in the study. (Heber, Tr. 2011; Butters, Tr. 2893-2894; PX0361 (Sacks, Dep. at 81)).

Also, Mr. Resnick testified that POM's advertisements are not intended to convey the message that they can prevent or treat coronary heart disease. (S. Resnick, Tropicana, Dep. at 58-59). Although Mr. Resnick testified that POM believes pomegranate juice is beneficial in preventing and treating coronary heart disease, he does not want consumers to share this belief, but rather to look at their science and make up their own mind. (S. Resnick, Tropicana, Dep. at 42-43). Mr. Resnick never intended POM products to be a substitute for recommended medical treatment or anything else recommended by a doctor. (S. Resnick, Tr. 1870). Mr. Tupper testified that it is absolutely against company policy to say or suggest that POM products are a substitute for proper medical treatment. (Tupper, Tr. 3018). In responding to health-related inquires or a question about a medical condition, POM instructs its employees to tell consumers to consult with his or her physician and strongly encourage this recommendation. (CX0308; Tupper, Tr. 3019).

Even assuming *arguendo* that this Newsletter conveys the message Complaint Counsel assign to it, Professor Reibstein's survey effectively demonstrates that any alleged disease claims made by Respondents were not material to the purchasing decisions of POM consumers. (RFF 2623, 2630). Complaint Counsel failed to present any evidence regarding the number of exposures consumers had to this ad or any particular POM

advertisement. Complaint Counsel have presented no reliable evidence to rebut Professor's Reibstein's survey findings or to show that any alleged disease claims made in POM's ads were material to the purchasing decisions of POM consumers.

Complaint Counsel presented no extrinsic evidence or expert opinion on this newsletter's meaning, consumer perceptions of this newsletter, or consumer interpretations regarding this newsletter. (PX0357 (Stewart, Dep. at 49, 52)).

Complaint Counsel failed to present any evidence that the claims in this newsletter reasonably convey that the Challenged Products are "clinically proven" to prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction.

Complaint Counsel failed to present any evidence regarding the number of exposures consumers had to this newsletter or any particular POM advertisement. (Mazis, Tr. 2752).

With respect to the Dreher Prostate Newsletter, nowhere in this newsletter do Respondents expressly (*i.e.*, unequivocally and directly) state that (a) taking one POMx Pill per day "prevents," "treats," or "reduces the risk" of prostate cancer; or (b) taking one POMx Pill per day is "clinically proven" to "prevent," "treat," or "reduce the risk" of prostate cancer. (CX01426_0049-0051, Exh. N).

Complaint Counsel's assertion that the Newsletter conveys the message that (a) taking one POMx Pill per day "prevents," "treats," or "reduces the risk" of prostate cancer; or (b) taking one POMx Pill per day is "clinically proven" to "prevent," "treat," or "reduce the risk" of prostate cancer is conveyed in this newsletter is not conspicuous, self-evident, or reasonably clear from the face of it. (CX1426_0049-0051, Exh. N).

Consequently, because the above-referenced challenged implied claim may not be determined with confidence from the face of the newsletter, extrinsic evidence must be examined.

Complaint Counsel erroneously rely upon the impact of only a few, select elements for their overall view of the net impression of the newsletter, and seemingly neglect at least two significant elements that are key to any facial or common sense net impression analysis—that the Challenged Products are products wholly-derived from pomegranates, and the Challenged Products' effectiveness is based, at least in significant part, on the products' abundant antioxidants.

The overall net impression of this Dreher Prostate Newsletter is not that not that taking one POMx Pill per day prevents, treats or reduces the risk of certain diseases, such as prostate cancer; or (b) taking one POMx Pill per day is "clinically proven" to prevent, treat or reduce the risk of certain diseases, such as prostate cancer. (CX1426_0049-0051, Exh. N). Even the language of the ad itself uses such qualifiers as "preliminary UCLA medical study," "promising news," "aim," "may indicate," "promising results," "preliminary studies," "potential," "initial scientific research," "encouraging results and information." (CX1426_0049-0051, Exh. N).

The "Dreher Prostate Newsletter" makes multiple efforts to convey that POMx is a whole food product that is wholly-derived from pomegranates, including repeated textual references to "POM Wonderful 100% Pomegranate Juice."

The whole food aspect of the newsletter directly counters any suggestion that POMx is going to act like a drug, as distinguished from a very healthy fruit or vegetable and a healthy diet. The newsletter emphasizes that the POMx Pill has nutritional benefits equivalent to the nutritional benefits of 8 oz of POM Juice, not more.

Viewing the newsletter as a whole, taking into account all the various elements, including the body copy as well as the repeated emphasis on the fact that POMx is a concentrated and potent source of antioxidants, it is far more logical that POM consumers would view POMx the way they perceive many other whole foods, like broccoli, blueberries, grapes or tomatoes, which may help prevent or improve your odds against disease, but which would not act like a drug with a single target of action against a particular disease or condition.

To the extent a "reduce the risk" or "may reduce the risk" claim can be implied from this newsletter, the overall net impression is not that taking one POMx Pill per day "reduces the risk" of certain diseases, such as prostate cancer, like a drug with a single target of action, but that it may help "reduce the risk," like many whole foods, or like an especially healthy fruit or vegetable, or like a healthy diet of fruits and vegetables and exercise "reduces the risk" of disease. (CX1426_0049-0051, Exh. N).

To the extent a "treat" claim can be implied from this ad (which it cannot), the overall net impression of any newsletter is not that POMx Pills are a substitute for conventional medical treatment. (Butters, Tr. 2821-22).

To the extent a "proven" claim can be implied from this newsletter (which it cannot), the overall impression of this newsletter is not that POMx Pills are "proven" to be 100% effective in preventing, treating or reducing the risk of prostate cancer because (1) all of the qualifying language contradicts an implied "clinically proven" interpretation, and (2) "proven" in science and to consumers means the "average person in the study benefitted." "Proven" does not mean that "everyone in the study necessarily benefitted" or that everyone will benefit like the persons who benefitted in the study. (Heber, Tr. 2011; Butters, Tr. 2893-2894; PX0361 (Sacks, Dep. at 81)).

Complaint Counsel presented no extrinsic evidence or expert opinion on this newsletter's meaning, consumer perceptions of this newsletter, or consumer interpretations regarding this newsletter. (PX0357 (Stewart, Dep. at 49, 52)).

Complaint Counsel failed to present any evidence that the claims in this newsletter reasonably convey that the Challenged Products are "clinically proven" to prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction.

Complaint Counsel failed to present any evidence regarding the number of exposures consumers had to this newsletter or any particular POM advertisement. (Mazis, Tr. 2752).

E. Health Claims in Internet Advertising

442. POM's websites include pomwonderful.com, pomegranatetruth.com, and pompills.com. (JX0003 ¶ B.11; Rushton, Tr. 1354-55; Leow, Tr. 433).

Response to Finding No. 442:

It is undisputed that POM's websites include pomwonderful.com, pomegranatetruth.com, and pompills.com; however, POM did not make any unauthorized health claims in these websites. Furthermore, Respondents object to Complaint Counsel's Proposed Findings of Fact Nos. 442-540 on the ground that, although Complaint Counsel gave Respondents CX0473 earlier in this litigation, it was not until Complaint Counsel filed its Proposed Findings of Fact and Conclusions of Law that Respondents on January 11, 2012 were made aware of exactly what Complaint Counsel's complaints were concerning pomwonderful.com, pompills.com, and pomegranatetruth.com. Thus, POM was prevented from presenting all of the evidence they could have presented to refute Complaint Counsel's contentions concerning POM's websites, which is essentially trial by ambush. Moreover, to the extent that POM's websites include advertisements or entries that were disseminated after August 2009, these advertisements are not relevant to

any determination in this case as conceded during the testimony of Complaint Counsel's expert Professor Mazis. According to Professor Mazis, the Commission is only challenging POM's website entries that were disseminated in the fourteen months before the execution of Professor David Reibstein's Survey ("Reibstein Survey") (October 2010). (PX0296 at 0010; Mazis, Tr. 2753-54). Additionally, these ads are immaterial because there is no evidence that anyone bought POM Juice because they thought Respondents spent a certain amount of money in a particular area of research, or based on any of POM's ads. (Mazis, Tr. 2743). . Indeed, Professor Reibstein's survey showed the opposite: that no one bought POM Juice because of the amount of money spent on science. (PX0223-0006). Finally, these ads are substantiated by rigorous, competent and reliable scientific evidence. (Reply Ad Appendix; RFF 1206-11, 1777-83, 2094-2119, 2217-18).

2. Pomwonderful.com Made Establishment Claims Regarding Heart Disease, Prostate Cancer, and Erectile Dysfunction

443. In April 2009, the pomwonderful.com homepage featured a large comic book-themed animation depicting the POM Juice bottle announcing, "**Risk your health in this economy!?! NEVER!**" and the copy "**The Antioxidant Superpower. Learn about POM's promising health benefits**." (CX0473 (Compl. Ex. E-2 at 00:04)). The homepage also featured a similarly styled animation, with the POM Juice bottle warning, "**HURRY! Prostates everywhere are in danger!**" in the first frame and then in the second, "**I'm off to save PROSTATES!**" (CX0473 (Compl. Ex. E-4 at 00:05)). A prominent hyperlink led to the "Health Benefits" section of the website. (CX0473 (Compl. Ex. E-2 at 00:15)).

Response to Finding No. 443:

It is undisputed that, in April 2009, the pomwonderful.com website (not necessarily its homepage) included a version of the ad with the tagline, "Risk your health in this economy? NEVER!"; a version of the ad with the tagline, "Hurry! Prostates everywhere are in danger!"; and a version of the ad with the tagline, "I'm off to save PROSTATES!" These advertisements do not make establishment claims about any particular disease. An establishment claim is one that makes "statements to the effect that scientific tests

establish that a product works." *Removatron Int'l Corp. v. F.T.C.*, 884 F.2d 1489, 1492 n.3 (1st Cir. 1989). "Common examples include statements such as 'tests prove,' 'doctors recommend,' or 'studies show,'" *F.T.C. v. Direct Mktg. Concepts, Inc.*, 569 F. Supp. 2d 285 (D. Mass. 2008) (citations omitted); put differently, "[a]n establishment claim is one that says, in substance, that 'tests or studies prove' a certain fact." *Gillette Co. v. Norelco Consumer Prods. Co.*, 946 F. Supp. 115, 121 (D. Mass. 1996) (emphasis added). As the taglines make clear, neither of these ads state, expressly or impliedly, that POM's pomegranate juice is clinically proven to treat, prevent, or reduce the risk of prostate cancer. Viewing all the elements of each of the ads as a whole, including the (1) outrageous and puffing headlines; (2) humorous visual imagery; (3) that the deep burgundy POM Juice bottle resembles two stacked pomegranates; and (4) that the face of the POM Juice bottle contained the words "100% Pomegranate Juice." Rather, the ads convey general health messages, such as the Challenged Products are good for your health generally and / or promote a healthy prostate. (Compl. Ex. E-2 at 00:15). Furthermore, as Complaint Counsel acknowledges, the ads are made in a cute, cartoonish "comic book-themed animation" style (CCFF 443) that portrays the POM bottle as a superhero, and the ad taglines appear in comic style font and in dialogue bubbles. (Compl. Ex. E-2 at 00:15). These kinds of advertisements were intended to be hyperbolic, humorous cheeky puffery, and that is not actionable. *See, e.g., Sterling Drug, Inc. v. F.T.C.*, 741 F.2d 1146, 1150 (9th Cir. 1984); *In re Thompson Medical*, 104 F.T.C. 648, 788-89 n. 6). Rather, as Dr. Butters testified, these ads were intended to be "a work of fiction" in that they are personifying the pomegranate bottle by comparing the bottle to a superhero. (Butters, Tr. 2906).

444. The first page of the "**Health Benefits**" section of pomwonderful.com displayed a large graphic depicting the POM Juice bottle hanging upside down on a pole, with the juice running through a tube at the bottom of the bottle, in the manner of a hospital intravenous line. The introductory text stated, "POM Wonderful 100% Pomegranate Juice is the only pomegranate juice backed by $25 million in medical research. Actually, we are the only pomegranate juice backed by any medical research at all." It also urged the viewer to "keep in mind that all of the research has been done on POM Wonderful 100%

Pomegranate Juice" and stressed that "[n]o other pomegranate juice can claim these distinctions, and no other brand has been clinically tested." (CX0473 (Compl. Ex. E-2 at 00:17)).

Response to Finding No. 444:

It is undisputed that, in April 2009, the first page of the "Health Benefits" section of pomwonderful.com displayed a POM Juice bottle hanging upside down on a pole, with juice running through a tube at the bottom of the bottle. The copy also informs the viewer that POM's pomegranate juice is backed by $25 million in scientific research and the research has been performed on POM pomegranate juice alone. (CX0473 (Compl. Ex. E-2 at 00:17). These advertisements do not make establishment claims about any particular disease because do not say or imply that any of the scientific research says any tests or studies show a particular fact. Rather, as Complaint Counsel admit, this webpage says only that POM Wonderful 100% Pomegranate Juice is the only pomegranate juice backed by $25 million in medical research," or "backed by any medical research at all." (CCFF 444; CX04736 (Compl. Ex. E-2 at 00:17). These are qualified statements at best, not establishment or efficacy claims. To the extent any claim is made, the fact that POM advertised the amount of money Respondents spent on scientific research does not convey the net impression that the Challenged Products are "clinically proven to prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction." (RFF 2507-19; Respondents' Post-Trial Br. at 76-77.) What this "backed by" ad actually conveys is that Respondents are committed to the science and leaerning the truth about pomegranates. (L. Resnick, Tr. 251). Contrary to Complaint Counsel's implication, it is completely illogical to infer from the fact that a certain amount of money was invested in research to the conclusion that the Challenged Products are proven to prevent, treat or reduce the risk of disease. Again, this is another one of Complaint Counsel's ill-defined, "logical leaps" from "backed by $23 million of initial scientific research" to "backed by $23 million in research that proved the Challenged Products prevent, treat or reduce the

risk of heart disease, prostate cancer or erectile dysfunction." Indeed, Complaint Counsel presented no evidence that consumers took away the message presumed by Complaint Counsel because Respondents' spent a certain amount of money on science and research. (RFF 28-29, 2515). Moreover, the "backed by" ads accurately and truthfully represented the dollars spent by Respondents on the totality of the science on the Challenged Products. (RFF 2510). Moreover, these ads are immaterial because there is no evidence that anyone bought POM Juice because they thought Respondents spent a certain amount of money in a particular area of research. Indeed, Professor Reibstein's survey showed the opposite: that no one bought POM Juice because of the amount of money spent on science. (PX0223-0006).

445. To illustrate these statements, the first page of "Health Benefits" also presented "medical results on POM Wonderful 100% Pomegranate Juice" under the bolded headings, "**Cardiovascular**," "**Prostate Health**," "**Erectile Function**," and "**Antioxidant Superpower**." (CX0473 (Compl. Ex. E-2 at 00:17-00:24)).

Response to Finding No. 445:

It is undisputed that, in April 2009, the first page of the "Health Benefits" section of pomwonderful.com included links to other pages titled, "Cardiovascular," "Prostate Health," Erectile Function," and "Antioxidant Superpower." This page of the Health Benefits section of pomwonderful.com and the links included are do not make establishment or efficacy claims about any particular disease because general health references to "cardiovascular," "prostate health," or "erectile function" do not say or imply that any of the research shows or proves a particular fact. (Compl. Ex. E-2 at 00:24.)

446. The "**Prostate Health**" section presented a "medical result" from the Pantuck Phase II Prostate Cancer Study (2006):

A preliminary UCLA medical study, published by The American Association for Cancer Research, found hopeful results for prostate health. The study followed 46 men previously treated for prostate cancer either with surgery or radiation. After drinking 8 oz POM Wonderful 100% Pomegranate Juice daily for two years, these men experienced

significantly slower PSA doubling times – from 15 months at the beginning of the study to 54 months at the end. PSA is a biomarker for prostate cancer, and slower PSA doubling time may indicate slower disease progression.

(CX0473 (Compl. Ex. E-2 at 00:24)).

Response to Finding No. 446:

It is undisputed that, in April 2009, the "Prostate Health" section on the first page of the "Health Benefits" section of pomwonderful.com summarized the Pantuck Phase II Prostate Cancer Study (2006). This page of the Health Benefits section of pomwonderful.com does not make establishment or efficacy claims about any particular disease because it does not say or imply that any of the research shows or proves a particular fact or that pomegranate juice prevents, treats, or reduces the risk of prostate cancer. Rather, the summary of the Pantuck Phase II Prostate Cancer Study presented is clearly qualified: The study is called "preliminary," and it states that "hopeful" results were found. (CX0473 (Compl. Ex. E-2 at 00:24)). The results summarized included "slower PSA doubling times," and the conclusion was summarized too: The study indicated that consumption of pomegranate juice "may indicate slower disease progression." (CX0473 (Compl. Ex. E-2 at 00:24.) The summary also made it clear the study followed 46 men. (*Id.*) Accurately summarizing and quoting the highly qualified results of a published scientific study about preliminary and potential benefits cannot logically convey, as Complaint Counsel argue, the net impression that the Challenged Products treat, prevent or reduce the risk of disease, or that they are clinically proven to do so without qualification.

447. The "**Erectile Function**" section presented a "medical result" from the Forest Erectile Dysfunction Study (2007):

A pilot study released in the International Journal of Impotence Research in 2007 examined 61 male subjects with mild to moderate erectile dysfunction. Compared to participants taking a placebo, **those men drinking 8oz. of POM Wonderful 100% Pomegranate Juice daily for four weeks were 50% more likely to experience improved erections**.

(CX0473 (Compl. Ex. E-2 at 00:24)).

Response to Finding No. 447:

It is undisputed that, in April 2009, the "Erectile Function" section on the first page of the "Health Benefits" section of pomwonderful.com summarized the Forest Erectile Dysfunction Study (2007). However, this page of the Health Benefits section of pomwonderful.com does not make establishment or efficacy claims about any particular disease because it does not say or imply that any of the research shows or proves a particular fact or that pomegranate juice prevents, treats or reduces the risk of erectile dysfunction. Rather, the summary of the Forest Erectile Dysfunction Study presented is clearly qualified: The study is called "a pilot study," and it states that men who drank POM's pomegranate juice were "more likely" than those who did not drink it to experience "improved erections." (CX0473 (Compl. Ex. E-2 at 00:24.) The summary also made it clear the study followed 61 men. (*Id.*) Accurately summarizing and quoting the highly qualified results of a published scientific study about preliminary and potential benefits cannot logically convey, as Complaint Counsel argue, the net impression that the Challenged Products treat, prevent or reduce the risk of disease, or that they are clinically proven to do so without qualification.

448. The "**Antioxidant Superpower**" section "medical results" were that "[n]umerous independent laboratory tests have shown that POM Wonderful 100% Pomegranate Juice has superior antioxidant content, ounce-for-ounce, compared to other juices and beverages . . . ." (CX0473 (Compl. Ex. E-2 at 00:24)).

Response to Finding No. 448:

It is undisputed that, in April 2009, the "Antioxidant Superpower" section of on the first page of the "Health Benefits" section of pomwonderful.com stated, "Numerous independent laboratory tests have shown that POM Wonderful 100% Pomegranate Juice has superior antioxidant content, ounce-for-ounce, compared to other juices and beverages…" However, this page of the Health Benefits section of pomwonderful.com

does not make establishment or efficacy claims about any particular disease because it does not say or imply that any of the research shows or proves a particular fact or that pomegranate juice reduces the risk, treats or prevents any disease or medical condition. (CX0473 (Compl. Ex. E-2 at 00:24)). Rather, all this section says is that POM's Juice has more antioxidants than other juices. This is a true statement. (RFF 2530, 2536, 2544).

449. The "**Cardiovascular**" section presented "medical results" from the Ornish MP Study (2005) and the Aviram CIMT/BP Study (2004):

- A 2005 study published in the American Journal of Cardiology showed improved blood flow to the heart in patients drinking 8oz. daily of POM Wonderful 100% Pomegranate Juice for 3 months. Researchers studied a total of 45 patients with coronary heart disease who had reduced blood flow to the heart. Patients drinking POM Wonderful 100% Pomegranate Juice experienced a 17% improvement in blood flow, compared to a 18% worsening in patients drinking a placebo . . . Read more
- One pilot study on 19 patients with atherosclerosis (clogged arteries) at the Technion Institute in Israel demonstrated a reduction in arterial plaque growth. After one year, arterial plaque decreased 30% for those patients who consumed 8oz of POM Wonderful 100% Pomegranate Juice daily, compared to a 9% worsening for patients who drank a placebo . . . Read more.

(CX0473 (Compl. Ex. E-2 at 00:24)).

Response to Finding No. 449:

It is undisputed that, in April 2009, the "Cardiovascular" section of the first page of the "Health Benefits" section of pomwonderful.com summarized two studies – the Ornish MP Study (2005) and the Aviram CIMT/BP Study (2004). This page of the Health Benefits section of pomwonderful.com does not make establishment or efficacy claims about any particular disease because it does not say or imply that any of the research shows or proves a particular fact or that pomegranate juice cures or treats or prevents any disease or medical condition. Rather, all this section says is that there is (a) a (45-patient) study that shows certain patients who drank POM's Juice experienced a 17% improvement in blood flow to the heart and (b) there is a pilot study of 19 patients that

showed patients who drank POM's Juice had decreased arterial plaque. (CX0473 (Compl. Ex. E-2 at 00:24)). The results of these studies are clearly qualified on the next link, the page titled "Heart Health – Emerging Science", which expressly states that the research is "preliminary" and "examines pomegranate juice consumption and cardiovascular health." (CX0473 (Compl. Ex. E-2 at 00:30)). Accurately summarizing and quoting the highly qualified results of a published scientific study about preliminary and potential benefits cannot logically convey, as Complaint Counsel argue, the net impression that the Challenged Products treat, prevent or reduce the risk of disease, or that they are clinically proven to do so without qualification. Finally, the actual studies themselves are two to three mouse-clicks away (if they appear at all) from the first page of the "Health Benefits" section of pomwonderful.com. (*Id.*)

450. The "Read more" link after the discussion of the Ornish MP Study (2005) directed the consumer to a page titled "**Heart Health – Emerging Science**." Despite an initial reference to "heart health," the introductory text immediately shifted the discussion to "heart disease," specifically:

> What does the current research say about heart health? Let's start with some facts – heart disease is one of the leading killers in America for women as well as men. Atherosclerosis, or too much plaque in the arteries, is a leading factor in heart attacks.
>
> Where does this plaque come from? The problem starts in your arteries. Emerging science suggests that free radicals may be the culprits that can oxidize LDL . . . "bad" cholesterol . . . turning it into the plaque that clogs up arteries. Initial Laboratory research suggests that antioxidants may help minimize the oxidation of LDL cholesterol.

(CX0473 (Compl. Ex. E-2 at 00:30) (underlined hyperlinks in original) (footnote links omitted)).

Response to Finding No. 450:

It is undisputed that, in April 2009, the "Read more" link after the discussion of the Ornish MP Study directed the consumer to a page titled, "Heart Health – Emerging Science." Contrary to what Complaint Counsel suggest, the references to "heart disease" simply summarize known medical facts about heart disease, plaque and cholesterol that are reasonably available to the average person. (CX0473 (Compl. Ex. E-2 at 00:30)). To

the extent POM's research is mentioned on this page, the references clearly describe the research as "preliminary" and makes it clear that the research only examines "pomegranate juice consumption and cardiovascular health." Moreover, full copies of the scientific studies are available by clicking on the links. (CX0473 (Compl. Ex. E-2 at 00:30)). Thus the page does not make any establishment or efficacy claims, but merely provides links to full copies of the studies. (*Id.*)

451. This description of heart disease was followed by links to information on the Ornish MP Study (2005), the Aviram CIMT/BP Study (2004), and the Aviram ACE/BP Study (2001). (CX0473 (Compl. Ex. E-2 at 00:30)).

Response to Finding No. 451:

The generic description of well-known "heart disease" on the "Heart Health – Emerging Science" page is not directly followed by links to information on the Ornish MP Study (2005), the Aviram CIMT/BP Study (2004) and the Aviram ACE/BP Study (2001). Rather, there is a paragraph between the references to "heart disease" and the links to information on these studies that makes it clear that the research is "preliminary" and that the research "examines" "pomegranate juice consumption and cardiovascular health." (CX0473 (Compl. Ex. E-2 at 00:30)). Therefore the page does not make any establishment or efficacy claims.

452. The link to the first study, the Ornish MP Study (2005), took the consumer to the published study results. (CX0473 (Compl. Ex. E-2 at 00:45)).

Response to Finding No. 452:

It is undisputed that the link takes the viewer (not necessarily a consumer-there is no evidence of consumer viewing of this link) to the published study results. (Mazis Tr. 2752; CX0473 (Compl. Ex. E-2 at 00:45). Furthermore, the study itself does not make an establishment claim because it does not say or imply that any of the research shows or proves a particular fact or that pomegranate juice reduces the risk, treats or prevents heart

disease. Rather, it concludes in a qualified manner that "daily consumption of pomegranate juice may improve stress-induced myocardial ischemia in patients who have" ischemic coronary heart disease. (CX0473 (Compl. Ex. E-2 at 00:49). Accurately summarizing and quoting the highly qualified results of a published scientific study about preliminary and potential benefits cannot logically convey, as Complaint Counsel argue, the net impression that the Challenged Products treat, prevent or reduce the risk of disease, or that they are clinically proven to do so without qualification.

453. The link to the second study, the Aviram CIMT/BP Study (2004), took the consumer to a page with text and graphs. (CX0473 (Compl. Ex. E-2 at 01:00)). At the top of this page was a quote attributed to Dr. Aviram that "[t]he present study clearly demonstrates for the first time that pomegranate juice consumption by patients with carotid artery stenosis possesses anti-atherosclerotic properties." (CX0473 (Compl. Ex. E-2 at 01:00)). Study results were presented as follows:

> This randomized controlled pilot study of 19 patients (ages 65-75) is the first to show that pomegranate juice may reduce the amount of plaque in the arteries of patients with heavy plaque buildup (severe carotid artery stenosis) as well as substantially benefiting several important blood parameters. Ten patients consumed 8 oz. a day of POM Wonderful pomegranate juice for 1 year. Nine patients who did not consume pomegranate juice served as controls. The intima-media thickness (IMT) of the carotid artery wall was measured and blood samples were taken at the beginning of the study and at 3, 6, 9 and 12 months. After 1 year, those patients who did not consume pomegranate juice showed a 9% increase in IMT, while those consuming juice showed a decrease in IMT of up to 30%. Furthermore, for those drinking pomegranate juice, systolic (but not diastolic) blood pressure was reduced by 21%, total antioxidant status of the blood increased by 130%, LDL oxidation decreased by 90%, antibodies to oxidized LDL decreased by 19% and serum paraoxonase 1 (PON1) increased by 83%. Major blood biochemical markers were not affected, including levels of LDL and HDL cholesterol. Benefits were maintained in five patients who continued drinking pomegranate juice for 2 additional years, with further improvements in serum lipid peroxidation.
>
> (CX0473 (Compl. Ex. E-2 at 01:00)).

Response to Finding No. 453:

It is undisputed that the link to the Aviram CIMT/BP Study (2004) takes viewers (not necessarily consumers-there is no evidence that any consumer viewed the link) to a page with text and a graph summarizing the results of the Study. (Mazis Tr. 2752; CX0473

(Compl. Ex. E-2 at 01:00). It is also undisputed that Dr. Aviram is quoted on this page. This page fails to make any establishment or efficacy claims. Dr. Aviram's quote does not make an establishment claim – it is not a statement by POM but a statement by Dr. Aviram about his own study that touts the properties of pomegranate juice. (CX0473 (Compl. Ex. E-2 at 1:00)). Similarly, the summary of the study itself is clearly qualified: It is identified as a 19 patient "randomized controlled pilot study" that shows "pomegranate juice may reduce the amount of plaque in the arteries of patients with heavy plaque buildup … as well as substantially benefiting several important blood parameters." (CX0473 (Compl. Ex. E-2 at 00:58 and 01:00). Accurately summarizing and quoting the highly qualified results of a published scientific study about preliminary and potential benefits cannot logically convey, as Complaint Counsel argue, the net impression that the Challenged Products treat, prevent or reduce the risk of disease, or that they are clinically proven to do so without qualification.

454. To emphasize the Aviram CIMT/BP Study (2004) results, a large bar graph titled **"Reduced Plaque"** appeared below the study summary. The "Reduced Plaque" bar graph measured the "% Reduction in Plaque Thickness," with a bar in red highlighting "-30%" for POM Wonderful Pomegranate Juice and a bar in gray showing "9%" for "No Pomegranate Juice." (CX0473 (Comp. Ex. E-2 at 01:00)). When "view full-size" was clicked, a larger version of the chart appeared. The red and gray bars were animated, strikingly depicting the "decrease in IMT of up to 30%" reported in the summary paragraph, with the red bar for POM Juice moving downward, and the gray bar for "No Pomegranate Juice" moving upward. (CX0473 (Complaint Ex. E-2 at 01:06)).

Response to Finding No. 454:

It is undisputed that a graph or chart summarizing the Aviram CIMT/BP Study (2004) appears below the summary of the study on pomwonderful.com's April 2009 website, and that an animated graph or chart also appears on the page. POM objects to Complaint Counsel's description of the graph and the animated graph in the webpage as vague, ambiguous and argumentative. The graph and study of the summary state that a "pilot study" is the first to show that pomegranate juice may reduce the buildup of plaque in the arteries…" (CX0473 (Compl. Ex. E-2 at 1:12). This is a qualified statement and the

graph, which accurately illustrates the results, must be viewed in the context of this qualified statement. Accurately summarizing and quoting the highly qualified results of a published scientific study about preliminary and potential benefits cannot logically convey, as Complaint Counsel argue, the net impression that the Challenged Products treat, prevent or reduce the risk of disease, or that they are clinically proven to do so without qualification

455. The link to the third study, the Aviram ACE/BP Study (2001), also took the consumer to another page with text and graphs. (CX0473 (Complaint Ex. E-2 at 01:25)). At the top of this page appeared a quote attributed to Dr. Aviram that:

> the significant inhibitory effect of pomegranate juice on serum ACE activity and the minor attenuation in blood pressure . . . in addition to its potent inhibitory effect on lipid peroxidation, suggests that pomegranate juice consumption may offer wide protection against cardiovascular diseases.

(CX0473 (Compl. Ex. E-2 at 01:25)). Study results were presented as follows:

> This pilot study demonstrates that pomegranate juice lowers blood pressure in patients with hypertension. Ten patients, ranging in age from 62 to 77, with an average blood pressure of over 155±7/83±7 drank 8 oz. (1.5 mmol total polyphenols equivalent) of POM Wonderful pomegranate juice each day for 2 weeks. This resulted in a 5% decrease in systolic blood pressure. ACE (angiotensin converting enzyme), which helps lower blood pressure, prevent heart disease and reduce the risk of stroke, was also decreased by 36%. Patients were already on ACE inhibitors or calcium channel blockers.

(CX0473 (Compl. Ex. E-2 at 01:25)).

Response to Finding No. 455:

It is undisputed that the link on the April 2009 website to the Aviram ACE/BP Study (2001) takes a viewer to another page with text and graphs. However, there is no evidence that any consumer viewed the link or the study or the page. (Mazis Tr. 2752; CX0473 (Compl. Ex. E-2 at 01:00). Furthermore, Dr. Aviram's quote does not make an establishment claim – it is not a statement by POM but a statement by Dr. Aviram about his own study that touts the properties of pomegranate juice in a qualified manner: The study "suggests that pomegranate juice consumption may offer wide protection against cardiovascular diseases." (CX0473 (Compl. Ex. E-2 at 01:25). This summary makes no

establishment claims with respect to heart disease, prostate cancer or erectile dysfunction. It merely describes the study in a qualified manner. (CX0473 (Compl. Ex. E-2 at 01:25)). Accurately summarizing and quoting the highly qualified results of a published scientific study about preliminary and potential benefits cannot logically convey, as Complaint Counsel argue, the net impression that the Challenged Products treat, prevent or reduce the risk of disease, or that they are clinically proven to do so without qualification.

456. To emphasize the Aviram ACE/BP Study (2001) results, a large bar graph titled "**Decreased ACE Activity**" appeared below the study summary. The graph measured "Average Serum ACE Activity," with a shorter red bar for average ACE activity after two weeks of POM Juice consumption (8oz./day) displayed next to a taller gray bar representing average ACE activity before POM Juice consumption. (CX0473 (Compl. Ex. E-2 at 01:25)). When "view full-size" was clicked, a larger version of the chart appeared, in which the bars were animated to depict the reported reduction in ACE activity after two weeks of POM Juice consumption. (CX0473 (Compl. Ex. E-2 at 01:28)).

Response to Finding No. 456:

It is undisputed that a graph or chart regarding the Aviram ACE/BP Study (2001) appears below the study summary on pomwonderful.com's April 2009 website. POM objects to the characterization of the bar graph as "large" and as being used to "emphasize" (versus illustrate) the study results as vague, ambiguous and argumentative. Furthermore, there is no evidence that any consumer viewed the link or the study or the page. (Mazis Tr. 2752; CX0473 (Compl. Ex. E-2 at 01:00) Finally, the summary and graph summary make no establishment claims with respect to heart disease, prostate cancer or erectile dysfunction, but merely illustrated the results of the study. Accurately summarizing and illustrating the highly qualified results of a published scientific study about preliminary and potential benefits cannot logically convey, as Complaint Counsel argue, the net impression that the Challenged Products treat, prevent or reduce the risk of disease, or that they are clinically proven to do so without qualification.

457. The "Health Benefits" section pomwonderful.com also featured pages on "**Antioxidants**," "**Cancer**," "**Aging**," and "**Glossary**." (CX0473 (Compl. Ex. E-2 at 01:44)).

Response to Finding No. 457:

Complaint Counsel's proposed finding is devoid of a proper record citation in contravention of 16 C.F.R. § 3.46(a). Thus it should be disregarded as a proposed finding of fact. However, it is undisputed that the website pomwonderful.com has a section titled, "Health Benefits" and it has links to "Antioxidants," "Cancer," "Aging," and "Glossary" pages.

458. The "**Antioxidants**" page, depicting the POM Juice bottle with a superhero's cape, described the role of antioxidant-rich POM Juice in combating disease-causing free radicals: "Emerging science suggests that unstable little molecules called free radicals may be linked to disease. . . . Antioxidants like those found in POM Wonderful Pomegranate Juice fight hard to help prevent free radicals from doing their damage." (CX0473 (Compl. Ex. E-2 at 02:49) (underlined hyperlinks in original)).

Response to Finding No. 458:

It is undisputed that there was an "Antioxidant" page on pomwonderful.com in April 2009. However, there is no evidence that any consumer viewed the link or the study or the page. (Mazis Tr. 2752; CX0473 (Compl. Ex. E-2 at 01:00). The copy on the "Antioxidant" page does not make an establishment or efficacy claim because it does not say or imply that POM's juice reduces the risk, treats or prevents any disease or medical condition or that any of the science mentioned is absolute or definite in nature. Rather, all this section says is that "emerging" or preliminary science "suggests" that free radicals "may be linked to disease" and that "[a]ntioxidants like those found in POM['s]" Juice "help prevent" free radical damage. (CX0473 (Compl. Ex. E-2 at 02:43). This is tantamount to saying pomegranate juice may help you stay healthy and contains abundant antioxidants, like a superfood. Furthermore, as Complaint Counsel admits, the POM 100% Pomegranate Juice bottle on this page of the website is wearing a "superhero's cape," and as such was intended to be hyperbolic, humorous cheeky puffery, and that is

not actionable. *See, e.g., Sterling Drug,* 741 F.2d at 1150; *In re Thompson Medical,* 104 F.T.C. 648, 788-89 n.6). Rather, as Dr. Butters testified, this depiction of the bottle is intended to be "a work of fiction" in that it is personifying the pomegranate bottle by comparing the bottle to a superhero. (Butters, Tr. 2906).

459. The "**Antioxidants**" page also linked to "**The Importance of Antioxidants**" page, which elaborated on the mechanism of action involving free radicals, disease, and the "Antioxidant Superpower" POM Juice's ability to neutralize free radicals:

> Emerging science suggests that antioxidants are scavengers that can neutralize free radicals, which may help to prevent the cell and tissue damage that may be linked to disease. . . . Emerging science further suggests that when we eat fruits and vegetables, they may help protect us just as they help protect plants. With incredibly high levels of naturally occurring polyphenol antioxidants, POM Wonderful Pomegranate Juice is truly the Antioxidant Superpower™.

(CX0473 (Compl. Ex. E-2 at 03:10) (underlined hyperlinks in original)).

Response to Finding No. 459:

It is undisputed that the "Antioxidant" page on pomwonderful.com in April 2009 linked to a page titled, "The Importance of Antioxidants." However, there is no evidence that any consumer viewed the link or the study or the page. (Mazis Tr. 2752; CX0473 (Compl. Ex. E-2 at 01:00). Contrary to what Complaint Counsel state, "The Importance of Antioxidants" page does not "elaborate" on POM's Juice's "ability to neutralize free radicals." Instead, the page states in a qualified manner that "[e]merging science suggests that antioxidants are scavengers that can neutralize free radicals, which may help to prevent the cell and tissue damage that may be linked to disease…" (CX0473 (Compl. Ex. E-2 at 3:03) (emphasis added). This page makes it clear that any benefits from POM's juice are qualified, and that POM's Juice should be viewed through the lens of a fruit, not a drug: "Emerging science further suggests that when we eat fruits and vegetables, they may protect us just as they help protect plants. With incredibly high levels of naturally occurring polyphenol antioxidants, POM Wonderful Pomegranate

Juice is truly the Antioxidant Superpower." (CX0473 (Compl. Ex. E-2 at 3:03) (emphasis added).

460. The "**Cancer**" page stated: "Emerging science has shown that diets rich in fruits and vegetables that contain antioxidants, along with regular exercise, might slow or help prevent the development of cancer. Two great sources of antioxidants are POM Wonderful Pomegranate Juice and POM Tea." The page featured a link to the Pantuck Phase II Prostate Cancer Study (2006). (CX0473 (Compl. Ex. E-2 at 03:45)).

Response to Finding No. 460:

There is no "Cancer" page on the pomwonderful.com April 2009 website. Thus, Complaint Counsel's proposed finding of fact is vague, ambiguous, and contravenes 16 C.F.R. § 3.46(a). However, there is a "Cancer" link on the left side of the page that takes the viewer to a page titled, "Cancer – Emerging Science." (CX0473 (Compl. Ex. E-2 at 03:45)). All of the information on this page is couched in conditional language and does not constitute an establishment claim regarding heart disease, prostate cancer, erectile dysfunction, or any other disease or condition, particularly since the statements make it clear that POM's Juice should be viewed through the lens of a fruit, not a drug. For example, the page says that "[e]merging science has shown that diets rich in fruits and vegetables that contain antioxidants, along with regular exercise, might slow or help prevent the development of cancer." (CX0473 (Compl. Ex. E-2 at 3:59) (emphasis added). It then identifies POM's Juice as a great source of antioxidants, something that has been shown over and over again by reliable, credible science. (*Id.*)

461. The "**POM Glossary**" page defined terms used throughout pomwonderful.com, such as "ACE," "Atherosclerosis," "Free Radicals," and "Plaque." (CX0473 (Compl. Ex. E-2 at 04:15-07:08)).

Response to Finding No. 461:

It is undisputed that the "POM Glossary" page of the pomwonderful.com website defined terms such as "ACE," "Atherosclerosis," "Free Radicals," and "Plaque" as well as many other terms such as "Antioxidants," "Anthocyanins," "Ellagic Acid," "Nitric Oxide,"

"Phytochemicals," "Polyphenols," "Punicalagin," and "Tannins." (CX0473 (Compl. Ex. E-2 at 4:15, 7:08)). However, this page of the Health Benefits section of pomwonderful.com and the links included are irrelevant to any determination about POM's ads, because they were pulled from the website before August 2009. (PX0296 at 0010; Mazis, Tr. 2753-54).

462. The "POM Glossary" definitions advertised the benefits of POM Juice. For example, the definition of "ACE" (*i.e.*, angiotensin-converting enzyme) included the statement, "[r]esearch shows POM Wonderful reduced ACE by 36% in ten elderly patients with high blood pressure after drinking an 8 oz. glass a day for only 2 weeks and also lowered their systolic blood pressure by 5%." (CX0473 (Compl. Ex. E-2 at 04:15)).

Response to Finding No. 462:

Contrary to what Complaint Counsel state, the "POM Glossary" definitions do not "advertise[]" POM Juice. Rather, as Complaint Counsel's own example makes clear, the definition of the term "ACE" is followed by a summary of research POM sponsored that is relevant to ACE. This research summary is not an advertisement, nor does it constitute an establishment claim regarding heart disease, prostate cancer, or erectile dysfunction. Accurately summarizing and quoting the highly qualified results of a published scientific study about preliminary and potential benefits cannot logically convey, as Complaint Counsel argue, the net impression that the Challenged Products treat, prevent or reduce the risk of disease, or that they are clinically proven to do so without qualification.

463. The "POM Glossary" definition of "Atherosclerosis" concluded with "Naturally, the less plaque, the better. And that's where POM Wonderful comes in. A pilot study of 19 elderly patients with atherosclerosis showed that an 8 oz. glass a day can reduce plaque build-up in the arteries by up to 30%." (CX0473 (Compl. Ex. E-2 at 5:04)).

Response to Finding No. 463:

Contrary to what Complaint Counsel state, the "POM Glossary" definitions do not "advertise[]" POM Juice. Rather, as Complaint Counsel's own example makes clear, the definition of the term "Atherosclerosis" is followed by a summary of research POM

sponsored that is relevant to Atherosclerosis. (CX0473 (Compl. Ex. E-2 at 04:15)). This research summary is not an advertisement, nor does it constitute an establishment claim regarding heart disease, prostate cancer, or erectile dysfunction. Accurately summarizing and quoting the highly qualified results of a published scientific study about preliminary and potential benefits cannot logically convey, as Complaint Counsel argue, the net impression that the Challenged Products treat, prevent or reduce the risk of disease, or that they are clinically proven to do so without qualification.

464. Similarly, the "POM Glossary" definition of "Plaque" stated: "What we're talking about is a common cause for heart attack and stroke. Naturally, the less plaque, the better. And that's where POM Wonderful comes in. A pilot study of 19 elderly patients with atherosclerosis showed that an 8 oz. glass a day can reduce plaque build-up in the arteries by up to 30%." (CX0473 (Compl. Ex. E-2 at 06:36) (hyperlink omitted)).

Response to Finding No. 464:

Contrary to what Complaint Counsel state, the "POM Glossary" definitions do not "advertise[]" POM Juice. Rather, as Complaint Counsel's own example makes clear, the definition of the term "Plaque" is followed by a summary of research POM sponsored that is relevant to plaque and atherosclerosis. (CX0473 (Compl. Ex. E-2 at 04:15)). This research summary is not an advertisement, nor does it constitute an establishment claim regarding heart disease, prostate cancer, or erectile dysfunction. Accurately summarizing and quoting the highly qualified results of a published scientific study about preliminary and potential benefits cannot logically convey, as Complaint Counsel argue, the net impression that the Challenged Products treat, prevent or reduce the risk of disease, or that they are clinically proven to do so without qualification.

465. At the bottom of the "POM Glossary" page was a link button labeled "**Healthcare Professionals**," and the medical caduceus symbol. (CX0473 (Compl. Ex. E-2 at 07:03)). This "Healthcare Professionals" link button appeared at the bottom of nearly all of the pages in the "Health Benefits" section of pomwonderful.com. (*See*, *e.g.*, CX0473 (Compl. Ex. E-2 at 00:23, 00:44, 01:25, 02:45, 07:18)).

Response to Finding No. 465:

It is undisputed that, on the pomwonderful.com website in April 2009, there is a "Healthcare Professionals" link. However, this link in pomwonderful.com is irrelevant to any determination about POM's ads, because this link is not intended for consumers' use, but rather, for healthcare professionals' use. (PX0296 at 0010; Mazis, Tr. 2753-54). In fact, the page link "Healthcare Professionals" links to a page titled, "Healthcare Practitioners," which states "We created his section just for healthcare professionals. It's filled with information that we hope you can utilize and perhaps share with your patients." (CX0473 (Compl. Ex. E-2 at 07:23) (emphasis added). Thus it is not advertising.

466. The main page of the **"Healthcare Professionals"** section depicted the POM Juice bottle wearing a stethoscope. (CX0473 (Compl. Ex. E-2 at 07:22)). The POM logo at the top of the page also contained the silhouette of the caduceus symbol within the red heart-shaped "O" in "POM." Other related pages in this section depicted POM Juice being poured into a teaspoon with the headline "**Powerful Antioxidant Prescription**." (CX0473 (Compl. Ex. E-2 at 07:28)).

Response to Finding No. 466:

It is undisputed that there was a page on pomwonderful.com in April 2009 that included a depiction of a POM Juice bottle wearing a stethoscope, and of POM Juice being poured into a teaspoon. These depictions and the accompanying statements are not advertisements as set forth in Response to Finding of Fact No. 465, nor do they make establishment claims about any particular disease. Specifically, nothing on this page says or implies that any of the scientific research says any tests or studies show a particular fact about POM's Juice. Similarly, nothing on either of these pages implies that the POM bottle with the stethoscope or the depiction of POM Juice being poured into a teaspoon are designed to sell the product. Rather, they are illustrating a section of the webpage for healthcare professionals in a cheeky manner akin to puffery. (*See, e.g.,* RFF 2392-93). No one would reasonably believe that a POM bottle could listen through a stethoscope to

someone's chest, and no one believes that POM, a 100% juice product, is to be administered out of its bottle in a teaspoon like a medicine. Indeed, the depiction of a POM Juice bottle wearing the stethoscope appears on the page titled, "Healthcare Practitioners," which states "We created this section just for healthcare professionals. It's filled with information that we hope you can utilize and perhaps share with your patients." (CX0473 (Compl. Ex. E-2 at 07:23) (emphasis added). The picture of the POM Juice bottle pouring into a teaspoon is on the next page, accessible via a direct link from the Healthcare Practitioner page, and the text on the page addresses how a doctor might want to talk to his or her patients about a "diet rich in fruit and vegetables." (CX0473 (Compl. Ex. E-2 at 07:27) (emphasis added). As the website implies, the words and pictures on these pages must be seen through the lens of a fruit and as part of a healthy diet. Thus it is not advertising targeting consumers.

467. Another "Healthcare Professionals" page titled "Getting Your Patients Started," displayed the POM Juice bottle on a medicine cabinet shelf, and referenced "[y]ears of research" and ongoing clinical studies "based on consumption of 8 oz. of 100% POM Wonderful Pomegranate Juice daily." (CX0473 (Compl. Ex. E-2 at 07:40)). The page also displayed the following warnings for "Special Patient Populations":

- According to the American Dietetic Association, 3.5 oz of POM Wonderful 100% Pomegranate Juice equals one fruit serving for diabetics.
- Because the juice contains high levels of potassium, patients who must avoid potassium should not drink pomegranate juice.

(CX0473 (Compl. Ex. E-2 at 08:02)).

Response to Finding No. 467:

It is undisputed that there was a page on pomwonderful.com in April 2009 that included a depiction of a POM Juice bottle on a shelf in a bathroom. It is undisputed too that the text on the page where this bottle appears is titled, "Getting Your Patients Started" and that the page has references to patients with diabetes and to patients who must avoid potassium. As set forth in Response to Finding No. 465 and 466,tThese depictions and

the accompanying statements are not advertisements, nor do they make establishment claims about any particular disease. Specifically, nothing on this page says or implies that any of the scientific research says any tests or studies show a particular fact about POM's Juice. To the contrary, the page states, in qualified language, that "POM Wonderful Pomegranate Juice may help guard the body against free radicals… that emerging science shows may be linked to disease…" and "promising preliminary research examines potential links between pomegranate juice consumption and health." (CX0473 (Compl. Ex. E-2 at 07:41). This is not an establishment claim concerning heart disease, prostate cancer or erectile dysfunction. Furthermore, the page is not directed towards consumers. Both the title of this page ("Getting Your Patients Started") and the text "years of research offer compelling reasons to encourage your patients to drink pomegranate juice…" make it clear that this page is directed towards medical practitioners. (CX0473 (Compl. Ex. E-2 at 07:41). Thus it is not an advertisement. Finally, Complaint Counsel ignores the cheeky, fun aspect of the illustration on this page – a POM bottle next to toothpaste and Q-Tips is not meant to sell pomegranate juice as a drug to consumers.

468. Pomwonderful.com also included a page titled, "**The Science of POM Wonderful**." (CX0473 (Compl. Ex. E-2 at 08:58)). The page depicted the POM bottle alongside a microscope with the text,

> A number of top scientists in their fields, including a Nobel Laureate, are researching areas covering antioxidant activity, cardiovascular disease, circulation, cancer and others. To date, multiple pilot, peer-reviewed studies have been completed and published, while a number of others are still in progress.

(CX0473 (Compl. Ex. E-2 at 08:58) (underlined hyperlink in original)).

The "peer-reviewed studies" link took the consumer to another page titled, "**Real Studies. Real Results**," which summarized and provided explanatory text and graphs on the Aviram CIMT/BP Study (2004) and the Aviram ACE/BP Study (2001). (CX0473 (Compl. Ex. E-2 at 09:01); *see* CCFF ¶¶ B.4.g.435-456)).

Response to Finding No. 468:

It is undisputed that there was a page on pomwonderful.com in April 2009 that included a depiction of a POM Juice bottle next to a microscope. It is also undisputed that the text of the page states that top scientists are "researching areas covering antioxidant activity, cardiovascular disease, circulation, cancer and others." (CX0473 (Compl. Ex. E-2 at 07:52). This page says nothing about what the studies say, nor does it imply what the research into pomegranate juice in these areas (antioxidant activity, cancer, etc.) proves or does not prove. Though there are links to summaries of studies and, in some cases, studies themselves on this page, none of the studies state definitively that the tests or studies prove a certain fact. (CX0473 (Compl. Ex. E-2 at 08:58)). Therefore the page does not make any establishment claims. Furthermore, the page is not directed towards consumers. This page is part of the section on the website titled, "POM Wonderful – Practitioners, the Science." This is directed towards health care practitioners. Thus the page is not an advertisement. *See* Response to Finding Nos. 465-66. Finally, the page itself does not include the studies themselves; those are at least one click away (on a different page) or simply summarized.

469. "The Science of POM Wonderful" page also listed studies in bibliography format under the headings, "Cardiovascular Studies," "Cancer Studies," "Erectile Function," "Antioxidant Composition Studies," "Diabetes Studies," and "Bioavailability Studies." The study listings included links to the study papers. (CX0473 (Compl. Ex. E-2 at 10:15-12:09)).

Response to Finding No. 469:

It is undisputed that POM listed links to studies on "The Science of POM Wonderful" page in April 2009. These pages say nothing about what the studies say, nor do they imply what the research into pomegranate juice in these areas (antioxidant activity, cancer, etc.) proves or does not prove. Though there are links to summaries of studies and, in some cases, studies themselves on this page, none of the studies state definitively

that the tests or studies prove a certain fact. (CX0473 (Compl. Ex. E-2 at 10:15-12:09)). Therefore the pages do not make any establishment claims. Furthermore, the pages are not directed towards consumers. This page is part of the section on the website titled, "POM Wonderful – Practitioners, the Science." This is directed towards health care practitioners. Thus the page is not an advertisement. (CX0473 (Compl. Ex. E-2 at 08:58; 09:01). *See* Response to Finding Nos. 465-66.

470. In addition, pomwonderful.com has featured a gallery of previous and current advertisements that have appeared in other media. (Rushton, Tr. 1364). The "**POM Ads**" section of pomwonderful.com contained a selection of video ads, including one that opened with the image of three adults wearing white lab coats, seated at a table. In the video, the scientist seated in the center holds a pomegranate as a voice-over narrates,

Pomegranate contains powerful antioxidants needed to prevent cancer and diseases.

As the scientist seated on the left struggles to open the pomegranate, the scientist seated on the far right places a straw into a bottle of POM Juice and effortlessly drinks. The voiceover adds,

POM Juice makes it a little easier.

(CX0473 (Compl. Ex. E-3 at 00:20)).

Response to Finding No. 470:

It is undisputed that, in April 2009, pomwonderful.com's video gallery included a series of video ads. The ad with the image of three adults wearing lab coats is clearly a humorous depiction of how to open and get a pomegranate's nutrients, including antioxidants. (CX0473 (Compl. Ex. E-3 at 00:20)). During the ad, the focus is on the actor on the left, who is trying to bite into a pomegranate, drill into it, karate chop it, and otherwise open it. At the end of the ad, there is a reference to a website called "HowToOpenAPomegranate.com" and that ad is followed by other, similar ads. (*Id*.) Each ad features the female actress on the right calmly and intelligently drinking a bottle of POM Juice, while the male actor on the left keeps trying to "open" a pomegranate in various silly ways. (*Id.*) Even though there is a voice over that says, "Pomegranate contains powerful antioxidants needed to prevent cancer and disease, the net impression

of this ad is not that POM's pomegranate juice prevents disease, it is that POM's pomegranate juice is "easier" to drink and easier to get nutrients, like antioxidants, from it than it is to open and eat a raw pomegranate. (CX0473 (Compl. Ex. E-3 at 00:24-01:01). Indeed, the final voice over says, "POM Juice makes it a little easier," clearly referring to the fact that a pomegranate is not an easy fruit to open and eat. (*Id.*) Therefore, the net impression of this ad is not that pomegranate juice treats, prevents or reduces the risk of any disease, but rather, that drinking POM Juice is an easier way to get antioxidant benefits associated with pomegranates. Finally, it is well established that antioxidants protect cells against the effects of free radicals, which play an important role in cardiovascular disease, cancer and other disease caused by oxidative stress. (*See, e.g.,* RFF 745-810). And, it is well-established that pomegranate juice has more antioxidants than other beverages. (RFF 2526-30). Thus, any statements made herein are substantiated.

471. The pomwonderful.com website, through textual references, graphs, and medical imagery, touts POM Juice's "health benefits," "real studies [and] real results," and POM's research on heart disease, prostate cancer, erectile dysfunction, and other health conditions. . The pomwonderful.com website conveys the net impression that drinking eight ounces of POM Juice daily treats, prevents, or reduces the risk of heart disease, prostate cancer, and erectile dysfunction, and that these health benefits are clinically proven. *(See* CCFF ¶¶ 443-470).

3. The "Community" Version of Pomwonderful.com Made Establishment Claims Regarding Heart Disease, Prostate Cancer, and Erectile Dysfunction

Response to Finding No. 471:

The pomwonderful.com website memorialized in CX0473 (Compl. Ex. E-2 and E-3) was pulled from POM's website in April 2009. Th net impression of this website is not that drinking 8 oz of POM Juice a day treats, prevents, or reduces the risk of heart disease, prostate cancer, and/or erectile dysfunction. As set forth above, most of these ads, videos, or other taglines, copy and text do not mention heart disease, prostate cancer, and/or erectile dysfunction. Moreover, many of these ads, videos, text and other copy do

not mention a "dose" or the measurement "8oz" at all; instead, they are cheeky, puffery, over-the-top images of personified juice bottles pretending to be superheroes, or simply cheeky illustrations used in conjunction with text. (*See, e.g.,* CX0473 (Compl. Ex. E-2 at 00:11) The net impression of the ads, videos, website, copy, taglines or other messages on POM's website is not that taking "8oz" of POM's Juice daily treats, prevents, or reduces the risk of heart disease, prostate cancer, and erectile dysfunction. To the contrary, the language of all the ads, videos, taglines, copy and text itself generally uses such qualifiers as "emerging science suggests," "help protect," "promising results," "initial study," and "preliminary study." *See* Response to Finding Nos. 458-59, 467. Instead, the net impression of the language used by POM in videos, ads and on its website is that drinking Pomegranate Juice "reduces the risk," or helps maintain health like a healthy diet of fruits and vegetables and exercise "reduces the risk" of disease and/or maintains health. Finally, the net impression is not that POM's Juice is a drug. Rather, POM's Juice is a food product, wholly derived from the pomegranate fruit. The fact that the Challenged Products are wholly- derived from the pomegranate fruit is heavily emphasized in the body copy and the visual imagery of the Challenged Ads as well as on the products themselves. (CX0473 (Compl. Ex.-2 and E-3)). For example, in all of the ads and images on the website, there is a dominant image of deep, ruby red pomegranate juice in bottle shaped like two pomegranates stacked on top of one another. (*See, e.g.,* CX0473 (Compl. Ex. E-2 at 00:11.) The words "100% Pomegranate Juice" displayed on face of the POM Juice bottle depicted in the Challenged Ads; and there is repeated textual reference to "POM Wonderful 100% Pomegranate Juice. (*See, e.g., id.*) Accordingly, the net impression of the ads is that POM's Juice is healthy and good for you, as well as that it is a food product derived wholly from the pomegranate.

472. The pomwonderful.com site was frequently updated and reworked to satisfy Mrs. Resnick. (Rushton, Tr. 1372; *see also* CCFF ¶ B.5.242 (regarding the launch of the "Community" version of pomwonderful.com)).

Response to Finding No. 472:

It is undisputed that the pomwonderful.com home page was frequently updated and that Mrs. Resnick, among others, would request changes to it. (Rushton Tr. at 1371-72).

473. On the October 2009 homepage of pomwonderful.com, the rotating frames displayed the text:

Backed by Science.

POM Wonderful products are backed

by $32 million in medical research.

READ OUR PUBLISHED STUDIES ►

(CX0473 (Oct. 2009, pomwonderful.com at 00:23)).

The "$32 million" in medical research statistic was also noted in other parts of the website, including under "**Our Health Story**," in the "**Health**" section, and on the "**Our Company**" and "**POM Truth**" pages in the "**About**" section. (CX0473 (Oct. 2009, pomwonderful.com at 01:00, 05:17, 05:50, 06:30); *see also* CX0473 (Jan. 2010, pomwonderful.com at 01:38, 01:47, 1:58)).

Response to Finding No. 473:

POM objects to this proposed finding of fact. There is no website capture from pomwonderful.com dated in or about October 2009 on CX0473, and therefore there is no way to verify what Complaint Counsel says about any website captures from that date. There is, however, a website capture from January 27, 2010 on CX0473. However, both the October 2009 and January 2010 web pages and the links included are irrelevant to any determination about POM's ads, because they were captures from the website after August 2009, and are therefore not at issue as conceded by Professor Mazis. (PX0296 at 0010; Mazis, Tr. 2753-54). With respect to the pomwonderful.com website capture from January 27, 2010, it is true that POM's website's "Our Company" page states that it is the "only company that grows, harvests, processes and ships our own pomegranates. Plus, we're the only pomegranate company whose products are backed by over $32 million in

scientific research." That statement is included together with several bullet points concerning POM's sustainable business practices and a statement about POM's commitment to "wellness," and right below a sentence stating that POM "grow[s] and market[s] pomegrantates and pomegranate-based products that are healthy, honest and essential to the well-being of humankind." CX0473 (Compl. Ex. E-5, at 0:138-40). The statement "backed by over $32 million in scientific research" does not make any sort of establishment claim, nor does it reference any claim concerning heart disease, prostate cancer or erectile dysfunction. Rather, the statement, when viewed in the context of the entire "Our Company" page, states only that POM is committed to wellness, that it has conducted millions in research and that its products are food products derived from the whole pomegranate fruit. (*Id.*) Finally, the statement "backed by over $32 million in scientific research" is in no way false or misleading. They accurately represent the dollars spent on research. (*See* RFF, Section XVII(G)(2) and 2510). The studies concerning one disease or condition, such as the effect of antioxidants or of nitric oxide, are sufficiently interrelated to other diseases and conditions that it is not misleading to treat all of Respondents' scientific expenditures – now approximately $34 million – as "backing" Respondents' health claims. (RFF 2511).

474. In December 2009, one of the rotating frames on the pomwonderful.com homepage displayed the headline "Let's Talk about Prostate Cancer with David Heber, MD. Center for Human Nutrition, UCLA. What is the relationship between nutrition and cancer? See what the doctor says ►" (CX0473 (Dec. 2009, pomwonderful.com at 00:15)).

Response to Finding No. 474:

POM objects to this proposed finding of fact. There is no website capture from pomwonderful.com dated in or about December 2009 on CX0473, and therefore there is no way to verify what Complaint Counsel says about any website captures from that date. The ALJ should therefore disregard this proposed finding of fact. The December 2009 web pages and the links included are irrelevant to any determination about POM's ads,

because they were capture form the website after August 2009, and are therefore not at issue as conceded by Professor Mazis. (PX0296 at 0010; Mazis, Tr. 2753-54).

475. The "See what the doctor says" link took the consumer to a page in the "Community" section of pomwonderful.com titled "The relationship between cancer and nutrition," where the video, "Let's Talk about Prostate Cancer with David Heber, MD," could be viewed. The introductory text on this page noted that "David Heber, MD is the Director of the Center for Human Nutrition at UCLA. You can find POM Wonderful studies by Dr. Heber in the POM Health section of our site." (CX0473 (Dec. 2009, pomwonderful.com at 00:15-07:15) (hyperlinks omitted)).

Response to Finding No. 475:

POM objects to this proposed finding of fact. There is no website capture from pomwonderful.com dated in or about December 2009 on CX0473, and therefore there is no way to verify what Complaint Counsel says about any website captures from that date. The ALJ should therefore disregard this proposed finding of fact. The December 2009 web pages and the links included are irrelevant to any determination about POM's ads, because they were capture form the website after August 2009, and are therefore not at issue as conceded by Professor Mazis. (PX0296 at 0010; Mazis, Tr. 2753-54).

476. In the "Let's Talk about Prostate Cancer" video, Dr. Heber answered questions about prostate cancer, including:

THE QUESTION

Is there anything new you're working on now that is particularly exciting?

[DR. HEBER:] We're working a lot on pomegranate juice and pomegranate extracts right now . . . . We've found that the pomegranate inhibits inflammation in the prostate gland, that it also inhibits prostate cancer growth in animals, both in early prostate cancer and advanced prostate cancer. And in humans, we were able to reduce the rate of rise of PSA in men with prostate cancer. There are some large trials now confirming that early trial, which hopefully will be completed within the next year. So I think that's a very interesting area. . . .

(CX0473 (Oct. 2009, pomwonderful.com at 05:53-07:15)).

Response to Finding No. 476:

POM objects to this proposed finding of fact. There is no website capture from pomwonderful.com dated in or about October 2009 on CX0473, and therefore there is no way to verify what Complaint Counsel says about any website captures from that date. The ALJ should therefore disregard this proposed finding of fact. The December 2009 web pages and the links included are irrelevant to any determination about POM's ads, because they were capture form the website after August 2009, and are therefore not at issue as conceded by Professor Mazis. (PX0296 at 0010; Mazis, Tr. 2753-54). To the extent that the ALJ considers what is written above. Dr. Heber is merely describing research he is currently working on (and the results of such research) in response to a particular question from an interviewer asking him about what he is working on. And he does not say that POM's products do anything in particular. He merely describes the results of some preliminary research on prostate cancer.

477. In October 2009, pomwonderful.com's "**Health**" section included pages titled "**POM Health**," "**Research Study Synopses**," "**Glossary**," "**Healthcare Professionals**," and "**Expert Articles**." (CX0473 (Oct. 2009, pomwonderful.com at 00:50)).

Response to Finding No. 477:

POM objects to this proposed finding of fact. There is no website capture from pomwonderful.com dated in or about October 2009 on CX0473, and therefore there is no way to verify what Complaint Counsel says about any website captures from that date. The ALJ should therefore disregard this proposed finding of fact. Additionally, October 2009 web pages and the links included are irrelevant to any determination about POM's ads, because they were capture form the website after August 2009, and are therefore not at issue as conceded by Professor Mazis. (PX0296 at 0010; Mazis, Tr. 2753-54).

478. The "**Health**" section included a page on "**Other Protective Effects**," stating, "[i]n addition to being the superior free radical scavenger, POM Wonderful's unique antioxidants have been shown to have other protective effects against oxidative stress."

(CX0473 (Oct. 2009, pomwonderful.com at 01:50)). Under the bold heading "**Inhibition of LDL Oxidation**," the page stated:

Pomegranate juice has a superior ability to prevent LDL cholesterol from being oxidized by free radicals. Emerging science suggests that LDL oxidation may be a precursor to atherosclerosis or arterial plaque.

This point was further emphasized with a graph showing POM Juice beating other antioxidant containing beverages in "Inhibition of LDL Oxidation" and a citation to a paper by N. Seeram, et al., on *Comparison of Antioxidant Potency of Commonly Consumed Polyphenol-Rich Beverages in the United States*.

(CX0473 (Oct. 2009, pomwonderful.com at 01:55) (underlined hyperlinks in original)).

Response to Finding No. 478:

POM objects to this proposed finding of fact. There is no website capture from pomwonderful.com dated in or about October 2009 on CX0473, and therefore there is no way to verify what Complaint Counsel says about any website captures from that date. The ALJ should therefore disregard this proposed finding of fact. Additionally, October 2009 web pages and the links included are irrelevant to any determination about POM's ads, because they were capture form the website after August 2009, and are therefore not at issue as conceded by Professor Mazis. (PX0296 at 0010; Mazis, Tr. 2753-54). To the extent that the ALJ considers the above text, it states only that pomegranate juice "can prevent" LDL cholesterol from being oxidized, and then describes what LDL oxidation "may" be in qualified terms. The rest of the text merely cites studies' names.

479. The "**Other Protective Effects**" page also featured a section on "**Protecting Nitric Oxide**." The section cited a 2006 published study by Louis J. Ignarro, identified as the "recipient of the Nobel Prize in Medicine," that "documented that pomegranate juice is uniquely potent in inhibiting the destruction of nitric oxide." The discussion concluded with "POM Wonderful 100% Pomegranate Juice was shown [in Dr. Ignarro's study] to be over one hundred times more potent than blueberry juice, concord grape juice and red wine." (CX0473 (Oct. 2009, pomwonderful.com at 01:56)).

Response to Finding No. 479:

POM objects to this proposed finding of fact. There is no website capture from pomwonderful.com dated in or about October 2009 on CX0473, and therefore there is no

way to verify what Complaint Counsel says about any website captures from that date. The ALJ should therefore disregard this proposed finding of fact. Additionally, October 2009 web pages and the links included are irrelevant to any determination about POM's ads, because they were capture form the website after August 2009, and are therefore not at issue as conceded by Professor Mazis. (PX0296 at 0010; Mazis, Tr. 2753-54). To the extent that the ALJ considers the above text, it states only that pomegranate juice "is uniquely potent in inhibiting the destruction of nitric oxide." It also compares the antioxidant levels in pomegranate juice to other juices and says that it pomegranate juice is more potent. This is a known fact. (RFF 2526-30). Nowhere does it even mention heart disease, prostate cancer, or erectile dysfunction.

480. The "**Health**" section page on "**Other Resources**," cited a 2009 article by Dr. Heber titled, "Oxidant Stress and Antioxidants." Next to a photo of Dr. Heber was a short biography and a description of Dr. Heber's "primary areas of research," including "the role of nutrition, phytochemicals, and botanical dietary supplements in the prevention and treatment of common forms of cancer and cardiovascular disease." (CX0473 (Oct. 2009, pomwonderful.com at 02:20)).

Response to Finding No. 480:

POM objects to this proposed finding of fact. There is no website capture from pomwonderful.com dated in or about October 2009 on CX0473, and therefore there is no way to verify what Complaint Counsel says about any website captures from that date. The ALJ should therefore disregard this proposed finding of fact. Additionally, October 2009 web pages and the links included are irrelevant to any determination about POM's ads, because they were capture form the website after August 2009, and are therefore not at issue as conceded by Professor Mazis. (PX0296 at 0010; Mazis, Tr. 2753-54). To the extent that the ALJ considers the above text, it only states a brief summary of Dr. Heber's primary areas of research.

481. The "**Health**" section also included a page of "**Research Study Synopses**." The introductory text explained that the published studies were on POM Juice and POMx. (CX0473 (Oct. 2009, pomwonderful.com at 02:43)). The study synopses, which also contained links to the full study texts, were grouped under categories such as

"**Cardiovascular,**" with subgroups "Atherosclerosis" and "Blood Flow/Pressure"; "**Prostate Cancer**"; "**Diabetes – Type II**"; and "**Erectile Function.**" (CX0473 (Oct. 2009, pomwonderful.com at 02:45-02:52)). These synopses appeared on a page titled "**Featured Scientific Studies**" in December 2009 and January 2010. (CX0473 (Jan. 2010, pomwonderful.com at 00:21-00:50); CX0473 (Dec. 2009, pomwonderful.com at 07:40)).

Response to Finding No. 481:

POM objects to this proposed finding of fact. There is no website capture from pomwonderful.com dated in or about December 2009 or October 2009 on CX0473, and therefore there is no way to verify what Complaint Counsel says about any website captures from that date. The ALJ should therefore disregard this proposed finding of fact. Additionally, October 2009 web pages and the links included are irrelevant to any determination about POM's ads, because they were capture form the website after August 2009, and are therefore not at issue as conceded by Professor Mazis. (PX0296 at 0010; Mazis, Tr. 2753-54). To the extent that the ALJ considers the above text, it simply provides a list of studies under headings on a website.

482. In October 2009, the "**Atherosclerosis**" subsection cited the Davidson CIMT Study (2009) as "a randomized, placebo-controlled, double-blind clinical trial follow[ing] 289 subjects at moderate risk for coronary heart disease. These subjects consumed 8 ounces per day of either [POM Juice] or a placebo beverage." (CX0473 (Oct. 2009, pomwonderful.com at 02:45)).

Response to Finding No. 482:

POM objects to this proposed finding of fact. There is no website capture from pomwonderful.com dated in or about October 2009 on CX0473, and therefore there is no way to verify what Complaint Counsel says about any website captures from that date. The ALJ should therefore disregard this proposed finding of fact. Additionally, October 2009 web pages and the links included are irrelevant to any determination about POM's ads, because they were capture form the website after August 2009, and are therefore not at issue as conceded by Professor Mazis. (PX0296 at 0010; Mazis, Tr. 2753-54). Accurately summarizing and quoting the highly qualified results of a published scientific

study about preliminary and potential benefits cannot logically convey, as Complaint Counsel argue, the net impression that the Challenged Products treat, prevent or reduce the risk of disease, or that they are clinically proven to do so without qualification.

483. Although the description of the Davidson CIMT Study (2009) conceded that "[a]fter 18 months, there was no reduction in the progression of intima-media thickness of the carotid artery (CIMT) in the POM group as a whole," the paragraph continued with the caveat, "[h]owever, further analysis revealed that the rate of CIMT progression slowed in nearly one third of POM patients, those with elevated cardiovascular disease risk factors." (CX0473 (Dec. 2009, pomwonderful.com at 07:40-07:44)).

Response to Finding No. 483:

POM objects to this proposed finding of fact. There is no website capture from pomwonderful.com dated in or about December 2009 on CX0473, and therefore there is no way to verify what Complaint Counsel says about any website captures from that date. The ALJ should therefore disregard this proposed finding of fact. The December 2009 web pages and the links included are irrelevant to any determination about POM's ads, because they were capture from the website after August 2009, and are therefore not at issue as conceded by Professor Mazis. (PX0296 at 0010; Mazis, Tr. 2753-54). Accurately summarizing and quoting the highly qualified results of a published scientific study about preliminary and potential benefits cannot logically convey, as Complaint Counsel argue, the net impression that the Challenged Products treat, prevent or reduce the risk of disease, or that they are clinically proven to do so without qualification.

484. Further defusing the finding of no reduction at 18 months, the paragraph went on to describe the positive results of the Aviram studies, reporting, for example, a 30% reduction in intima-media thickness of the carotid artery and a 20% decrease in the amount of LDL cholesterol oxidation. Although there were links to "read the study," the paragraph did not disclose that these positive results came from studies published in 2001 and 2004 with less than 30 people total, well before the 289-person study. (CX0473 (Oct. 2009, pomwonderful.com at 02:45); CX0473 (Dec. 2009, pomwonderful.com at 07:40-07:44); *see also* CX0542; CX0611).

Response to Finding No. 484:

POM objects to this proposed finding of fact. There is no website capture from pomwonderful.com dated in or about December 2009 or October 2009 on CX0473, and therefore there is no way to verify what Complaint Counsel says about any website captures from that date. The ALJ should therefore disregard this proposed finding of fact. Any web pages capture in or about December 2009 or October 2009 are irrelevant to any determination about POM's ads, because they were capture from the website after August 2009, and are therefore not at issue as conceded by Professor Mazis. (PX0296 at 0010; Mazis, Tr. 2753-54).

485. The "**Prostate Cancer,**" subsection, in addition to describing the Pantuck Phase II Prostate Cancer Study (2006), noted "[a] longer term (6-year) continued evaluation of active sub-group patients showed a further increase in PSA doubling time to 88 months [from 54]." (CX0473 (Jan. 2010, pomwonderful.com at 00:38)). This information is not part of a published study. (PX0061; CX0815; CX0955).

Response to Finding No. 485:

Any web pages capture in January 2010 are irrelevant to any determination about POM's ads, because they were capture from the website after August 2009, and are therefore not at issue as conceded by Professor Mazis. (PX0296 at 0010; Mazis, Tr. 2753-54). It is undisputed that, in January 2010, there was a reference to a follow up study to the Pantuck Phase II Prostate Cancer Study (2006) on POM's pomwonderful.com website. However, it is disputed that this follow up study was or is "not part of a published study." In fact, an abstract of the follow up study has been published in 2009 in the Journal of Urology. (PX0061). Additionally, all studies POM funded, whether published or unpublished, are interrelated and add to POM's knowledge base about the healthiness of pomegranate juice. (*See, e.g.,* CX 1276).

486. In December 2009 and January 2010, pomwonderful.com featured blog posts by "POM Experts" like Dr. Aviram. (CX0473 (Dec. 2009, pomwonderful.com at 08:06); CX0473 (Jan. 2010, pomwonderful.com at 00:54-01:01)).

Response to Finding No. 486:

POM objects to this proposed finding of fact. There is no website capture from pomwonderful.com dated in or about December 2009 on CX0473, and therefore there is no way to verify what Complaint Counsel says about any website captures from that date. Similarly, even though there are two website captures from January 2010 on CX0473, neither of them contain any blog posts by any POM "experts," (or anyone else), let alone Dr. Aviram. Additionally, the reference to "the positive results of the Aviram studies" is vague, ambiguous and overbroad. Any web pages capture in December 2009 or January 2010 are irrelevant to any determination about POM's ads, because they were capture from the website after August 2009, and are therefore not at issue as conceded by Professor Mazis. (PX0296 at 0010; Mazis, Tr. 2753-54). The ALJ should therefore disregard this proposed finding of fact.

487. In his blog post on "The Unique Antioxidants of Pomegranates," Dr. Aviram stated:

> [P]omegranates are superior to other antioxidants in protecting LDL ("the bad cholesterol") from oxidation (Aviram, Am Clin Nutr, 2000), and as a result, it inhibits atherosclerosis development, even in humans (Aviram, Clin Nutr, 2004), as well as its consequent cardiovascular events better than any other nutritional antioxidant. . . .
>
> Furthermore, pomegranate antioxidants are unique in their ability to increase the activity of the HDL ("the good cholesterol") . . . which breaks down harmful oxidized lipids in the atherosclerotic plaque.
>
> Finally, the unique antioxidants in pomegranates beneficially affect two additional important atherosclerotic processes by decreasing blood pressure (Aviram, At *[sic]* Atherosclerosis, 2001).
>
> (CX0473 (Oct. 2009, pomwonderful.com at 07:00-07:25)).

Response to Finding No. 487:

POM objects to this proposed finding of fact. There is no website capture from pomwonderful.com dated in or about December 2009 on CX0473, and therefore there is no way to verify what Complaint Counsel says about any website captures from that date.

Similarly, even though there are two website captures from January 2010 on CX0473, neither of them contain any blog posts by any POM "experts," (or anyone else), let alone Dr. Aviram. Any web pages capture in December 2009 or January 2010 are irrelevant to any determination about POM's ads, because they were capture from the website after August 2009, and are therefore not at issue as conceded by Professor Mazis. (PX0296 at 0010; Mazis, Tr. 2753-54). The ALJ should therefore disregard this proposed finding of fact. The ALJ should therefore disregard this proposed finding of fact. To the extent that the ALJ considers this finding of fact, however, these statements by Dr. Aviram are simply statements accurately summarizing the results of studies he conducted himself. Moreover, the statements in this alleged "blog" state that antioxidants in pomegranates are unique and beneficial to the body, and describe what the antioxidants can do. Accurately summarizing and quoting the highly qualified results of a published scientific study about preliminary and potential benefits cannot logically convey, as Complaint Counsel argue, the net impression that the Challenged Products treat, prevent or reduce the risk of disease, or that they are clinically proven to do so without qualification.

488. In the "**Community**" section of pomwonderful.com from December 2009, a page titled "**POM's Health Benefits: Fact or Fiction**" quoted Respondent Tupper as stating:

> "Based on the research that's been published on POM Juice, it's clear that Mother Nature gave this unique fruit some very special properties. As our scientists like to say, POM Juice is truly 'health in a bottle.' When you look at the medical research that has been conducted on POM and compare it to research that's been done on other foods and beverages, what's been done on POM is way, way more extensive. It's almost more akin to research being done on pharmaceutical drugs."
>
> (CX0336_0001)

Response to Finding No. 488:

The December 2009 web pages and the links included are irrelevant to any determination about POM's ads, because they were capture from the website after August 2009, and are therefore not at issue as conceded by Professor Mazis. (PX0296 at 0010; Mazis, Tr.

2753-54). It is undisputed that Exhibit CX0336_0001 quotes Mr. Tupper talking about POM's Juice. Mr. Tupper says only that the pomegranate is "unique" and has "special properties" and that it's "health in a bottle." These are simply statements about POM Juice's healthy properties and a statement about the quality of POM's research, and the stringent standards to which it is held.

489. The same "**POM's Health Benefits: Fact or Fiction**" page quoted Dr. Gillespie, identified as "Vice President of Clinical Development," as stating, "[s]ome of our research areas are beginning to accumulate quite impressive clinical data. For example, I think the human evidence in prostate health is one of the strongest areas, and we continue to fund more research here. Also, there could be some additional research done in cardiovascular health and erectile function, as well as several other areas." (CX0336_0001).

Response to Finding No. 489:

The December 2009 web pages and the links included are irrelevant to any determination about POM's ads, because they were capture from the website after August 2009, and are therefore not at issue as conceded by Professor Mazis. (PX0296 at 0010; Mazis, Tr. 2753-54). It is undisputed that Exhibit CX0336_0001 quotes Dr. Gillespie talking about POM's research. Dr. Gillespie's statements are qualified generalized statements about the strongest areas of data and results of the research: "some of our research areas are beginning to accumulate quite impressive clinical data….evidence in prostate health is one of the strongest areas…there could be some additional research done in cardiovascular health and erectile function…" These statements simply describe research data and possible future research in broad strokes.

490. In the "**Community**" section of pomwonderful.com from December 2009, a page titled "**POM: Sweet B And Safe for Diabetics**" quoted Mr. Tupper as stating,

> There have actually been several studies published about diabetic patients who consume 8 ounces of POM juice every day over an extended period. Over the course of the studies, various parameters of diabetics, blood sugar as well as other important blood markers did not worsen.
>
> On the flipside, the patients' state of oxidative stress, which is a measurement of how much free radical pressure exists in your body, actually decreased. Diabetes is a very

complicated disease, with many potential side effects. Diabetics are at risk for heart disease, kidney disease and other complications, many of which are fundamentally a result of oxidative stress. Since diabetics often experience higher levels of oxidative stress, the uniquely strong natural antioxidants that make POM so healthy are particularly beneficial.

(CX0336_0003 (hyperlinks omitted)). *But see* CCFF ¶ 1.467 (POM included warning to healthcare professionals elsewhere on its website that according to the American Dietetic Association, only 3.5 oz of POM Juice equals one fruit serving for diabetics).

Response to Finding No. 490:

The December 2009 web pages and the links included are irrelevant to any determination about POM's ads, because they were capture from the website after August 2009, and are therefore not at issue as conceded by Professor Mazis. (PX0296 at 0010; Mazis, Tr. 2753-54). It is undisputed that Exhibit CX0336_0003 quotes Mr. Tupper talking about POM's Juice. It is also undisputed that elsewhere on pomwondeful.com there is a warning from the American Diabetic Association about how much POM Juice a diabetic can consume. (CX0336 at _003 and CX0473 (Compl. Ex. E-2 at 07:40). However, and contrary to Complaint Counsel's suggestion, the quote at issue fails to mislead consumers. Nowhere does Mr. Tupper suggest his advice is the substitute or should substitute for the advice of a medical doctor or medical provider. And, pomegranate juice is no more unsafe for diabetics than any other fruit juice. (Heber, Tr. 2011). As Dr. Heber testified, fruit juice does not have a particular risk for type 2 diabetics as long as the individual's overall diet has the proper glycemic load. (*Id.*) A particular food is not unsafe simply because it has a high glycemic index; and the glycemic index of pomegranate juice is 50, which is a midlevel glycemic index. (*Id.*) Finally, Mr. Tupper's statements are qualified statements about antioxidants' abilities to reduce oxidative stress, antioxidants in POM's Juice, and statements about how pomegranates are healthy. (CX0336 at _003). These statements that a juice, wholly derived from a fruit, is healthy and that there are studies published about it with respect to diabetic patients who consume 8 ounces of POM over a period are not actionable statements. Accurately

summarizing and quoting the highly qualified results of a published scientific study about preliminary and potential benefits cannot logically convey, as Complaint Counsel argue, the net impression that the Challenged Products treat, prevent or reduce the risk of disease, or that they are clinically proven to do so without qualification.

491. In the "**Community**" section of pomwonderful.com from December 2009, a page titled "**What Exactly Are Antioxidants Anyway?**" quoted Mr. Tupper as stating,

> It's fine to say a product works as an antioxidant in a test tube, but that's just scratching the surface. What you really have to do is make sure that your product B and the antioxidants B end up being absorbed by your body, get transported through your blood stream, and make it to your vital organs, because that's really where the benefit occurs. Which is why we go beyond the test tube and do all this clinical research. It isn't until you see an effect in humans with measurements that are medically meaningful that you know you've got something going on.

(CX0336_0010 (emphasis added)).

Response to Finding No. 491:

The December 2009 web pages and the links included are irrelevant to any determination about POM's ads, because they were capture from the website after August 2009, and are therefore not at issue as conceded by Professor Mazis. (PX0296 at 0010; Mazis, Tr. 2753-54). It is undisputed that Exhibit CX0336_0010 quotes Mr. Tupper talking about antioxidants. The statements say nothing about heart disease, prostate cancer or erectile dysfunction, or any other disease. In fact, none of the Challenged Products are even mentioned in this excerpt.

492. The "**POM Community**" section of pomwonderful.com in December 2009 included consumer testimonials. (CX0336_0011-19). One message from a consumer stated, "I have been drinking POM for about a month, daily . . . I can tell you that I feel much better!! My cholesterol and Blood pressure are slightly lower . . . I do not know if these things are related but I Swear by POM! I call it 'Pomegranate Power!!'" (CX0336_0015).

Response to Finding No. 492:

The December 2009 web pages and the links included are irrelevant to any determination about POM's ads, because they were capture from the website after August 2009, and are therefore not at issue as conceded by Professor Mazis. (PX0296 at 0010; Mazis, Tr. 2753-54). CX0336_0011-19 contain unsolicited messages from consumers to POM. POM objects to the characterization of these messages as "testimonials." On page CX0336-15, it is true that one message states that the consumer has been drinking POM Juice for a month, feels better and his cholesterol and blood pressure have dropped. The consumer also states "I do not know if these things [the drop in his cholesterol and blood pressure and drinking POM] are related" but that he "swear[ed]" by POM. This unsolicited comment by a consumer does not make an "establishment claim" about prostate cancer, heart disease, erectile dysfunction or any other medical condition. To the contrary, the consumer did not know if the drinking of POM was related to his improved conditions or not, and expressly said so. (CX0336_0015)

493. Also in the "**POM Community**" section, another consumer stated, "I'm writing to tell you what POMwonderful *[sic]* has done for my mother suffering from a severe heart infection," continuing, "[w]e have stocked up on the juice and she swears that the pomegranate juice helped keep her immunity up through her vulnerable time and is also what has kept [the] infection from getting worse due to keeping her heart functions strong and the bloo[d] flowing more efficiently." (CX0336_0017).

Response to Finding No. 493:

Accurately summarizing and quoting the highly qualified results of a published scientific study about preliminary and potential benefits cannot logically convey, as Complaint Counsel argue, the net impression that the Challenged Products treat, prevent or reduce the risk of disease, or that they are clinically proven to do so without qualification. It is undisputed that, on CX0336_0017, a consumer has written to POM about what the consumer believes POM's Juice has done for her mother. This unsolicited comment by a consumer does not make an "establishment claim" about prostate cancer, heart disease,

erectile dysfunction or any other medical condition. It just states what the consumer believes. Furthermore, the consumer expressly states that "I know that your product is not on the market to act as [sic] cure or medical device, other than preventative care and healthy diet practice…" (CX0336_0017).

494. The October 2009, December 2009, and January 2010 versions of pomwonderful.com, through textual references, graphs, medical imagery, consumer testimonials, and "expert articles," tout POM Juice's "health benefits," "medical results," and POM's research on heart disease, prostate cancer, and erectile dysfunction, and other health conditions. Pomwonderful.com conveys the net impression that drinking eight ounces of POM Juice daily treats, prevents, or reduces the risk of heart disease, prostate cancer, and erectile dysfunction, and that these health benefits are clinically proven. (*See* CCFF ¶¶ 473-493).

Response to Finding No. 494:

The October 2009, December 2009 and January 2020 web pages are irrelevant to any determination about POM's ads because they were capture from the website after August 2009, and are therefore not at issue as conceded by Professor Mazis. (PX0296 at 0010; Mazis, Tr. 2753-54). POM objects to this proposed finding of fact. There is no website capture from pomwonderful.com dated in or about December 2009 or October 2009 on CX0473, and therefore there is no way to verify what Complaint Counsel says about any website captures from that date, or to conclude what Complaint Counsel is suggesting. The ALJ should therefore disregard this proposed finding of fact. However, if the ALJ considers this finding of fact, CX0336 (which captures some of the website from pomwonderful.com in December 2009) and other evidence in this case makes it clear that the net impression conveyed by POM's website is not that POM's Juice treats, prevents, or reduces the risk of heart disease, prostate cancer, and erectile dysfunction. As set forth above (RRFF 473-493), the majority of the statements at issue are statements about POM's Juice's healthy properties. Other statements were written by consumers, not POM, about POM's Juice and how they believed it was helping them. But even in those testimonials, it is clear that the consumers do not think POM is a drug with a single target of action, or that it treats, reduces the risk or prevents anything. (*See, e.g.,*

CX0336_0017). What statements like these show is that consumers take away from an advertisement of a healthy whole food product – like a pomegranate, pomegranate juice or pomegranate extract – is markedly different than the lens consumers would use when viewing advertising for an over-the-counter medication or drug, like Prilosec or Lipitor. *See Removatron Int'l Corp. v. F.T.C.,* 884 F.2d 1489, 1497 (1st Cir. 1989) (looking to "common-sense" net impression of an allegedly false and deceptive advertisement). Complaint Counsel, however, completely disregard this very significant, common-sense and critical distinction, among other things, in their facial analysis. Taken to its logical end, Complaint Counsel would contend that the universal proverb "An apple a day keeps the doctor away" is actionable if apple growers were to use this tagline in their advertising. This is certainly not the right result.

495. More recently, pomwonderful.com has made marketing claims for POM's sports recovery drink that were similar in tone to the challenged claims in this case. For example, the website's description of the drink included statements like, "How did POM perform in published clinical research?"; "**Speeds muscle recovery** – POM reduced post-exercise strength loss by more than 30% compared to a placebo."; "**Reduces muscle soreness**" – POM reduced post-exercise soreness by 28% compared to a placebo." The page also displayed under the heading "Super effective," a graph illustrating "Faster Strength Recovery," comparing the drink to the placebo. Explanatory bullet points accompanying the graph state: "Preliminary clinical studies have shown promising post-exercise benefits, including faster strength recovery and reduced pain following weight lifting" and "Results based on daily 2oz dosage." (CX0473 (May 2010, pomwonderful.com at 00:40-01:38)).

Response to Finding No. 495:

The May 2020 web pages are irrelevant to any determination about POM's ads because they were capture from the website after August 2009, and are therefore not at issue as conceded by Professor Mazis. (PX0296 at 0010; Mazis, Tr. 2753-54). POM objects to this proposed finding of fact. There is no website capture from pomwonderful.com dated May 2010 on CX0473, and therefore there is no way to verify what Complaint Counsel says about any website captures from that date. POM objects to this proposed finding of fact, too, as speculative and irrelevant. POM's alleged marketing claims for a sports

recovery drink are not at issue in this case, and the sports recovery drink is not one of the Challenged Products. In fact, POM no longer makes the sports recovery drink that Complaint Counsel references in this proposed finding of fact. To the extent that the ALJ considers this proposed finding of fact, however, any claims that were made were supported by adequate, reliable and credible scientific results. (PX0146). Furthermore, the alleged "marketing claims" are not similar in tone to the challenged claims in this case and prove nothing.

4. Pomegranatetruth.com Made Establishment Claims Regarding Heart Disease, Prostate Cancer, and Erectile Dysfunction

496. The pomegranatetruth.com homepage was titled "**The truth about our pomegranates**" and stated at the center of the page in a bold subheading, "**Backed by science.** Directly following this heading, flanked by a large image of the medical caduceus symbol, was the explanatory text:

> POM is the only pomegranate juice backed by $25 million in medical research. To date, numerous published clinical studies have documented the benefits of drinking pomegranate juice, benefits that include improved heart and prostate health and better erectile function. **All of these studies featured patients who drank POM Wonderful 100% Pomegranate Juice, not any other brands.** Read more.

(CX0473 (Compl. Ex. E-1 at 00:10)).

Response to Finding No. 496:

POM objects to this proposed finding of fact because the website capture referenced herein and on CX0473 at 00:10 does not state exactly what Complaint Counsel says it does. The words "All of these studies featured patients who drank POM Wonderful 100% Pomegranate Juice, not any other brands," are not followed by the words or link, "Read More," but instead by "Since POM is totally different from other pomegranate juices (see below), that means ours is the only one you can trust to deliver genuine pomegranate health benefits." This implies that the pomegrantetruth.com website captures in this section are not the same as those referenced in this section. Furthermore, it is undisputed that, in April 2009, pomegranatetruth.com's homepage informed the

viewer that POM's pomegranate juice is backed by $25 million in scientific research and the research has been performed on POM pomegranate juice alone. This webpage says only that POM Wonderful 100% Pomegranate Juice is the only pomegranate juice backed by $25 million in medical research," or "backed by any medical research at all." (CCFF 496). These are qualified statements at best. To the extent any claim is made, it is that POM juice is supported by $25 million dollars in medical research. This was true at the time. (RFF 2507-17). Moreover, these statements are immaterial because there is no evidence that anyone bought POM Juice because they thought Respondents spent a certain amount of money in a particular area of research. Indeed, Professor Reibstein's survey showed the opposite: that no one bought POM Juice because of the amount of money spent on science. (PX0223-0006).

497. The "Read more" link directed the consumer to a page titled, in large, bold, red letters, "**Backed by Science**." (CX0473 (Compl. Ex. E-1 at 01:15)). The "**Backed by Science**" page reiterated that "POM is the only pomegranate juice backed by $25 million in medical research," continuing, "Actually, we are the only pomegranate juice backed by any medical research at all." Reinforcing the scientific theme was a large image of the POM Juice bottle depicted with projecting arms of a molecular model chemistry set. (CX0473 (Compl. Ex. E-1 at 01:15)).

Response to Finding No. 497:

It is undisputed that CX0473 at 01:15 displays a page from the pomegranatetruth.com website in April 2009 titled, "Backed by science" with an illustration of a POM Juice bottle surrounded by a molecular model. (CX0473 (Compl. Ex. E-1 at 01:15). The fact that POM advertised the amount of money Respondents spent on scientific research does not convey the net impression that the Challenged Products are "clinically proven to prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction." (RFF 2507-19; RPTB at 76-77.) What this "backed by" ad actually states is that Respondents were committed to the science and learning the truth about pomegranates. (L. Resnick, Tr. 251). Contrary to Complaint Counsel's implication, it is completely illogical to infer from the fact that a certain amount of money was invested in research to

the conclusion that the Challenged Products are proven to prevent, treat or reduce the risk of disease. Again, this is another one of Complaint Counsel's ill-defined, "logical leaps" from "backed by $25 million of initial scientific research" to "backed by $25 million in research that proved the Challenged Products prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction." Indeed, Complaint Counsel presented no evidence that consumers took away the message presumed by Complaint Counsel because Respondents' spent a certain amount of money on science and research. (RFF 28-29, 2515). Moreover, the "backed by" ads accurately and truthfully represented the dollars spent by Respondents on the totality of the science on the Challenged Products. (RFF 2510). Moreover, these ads are immaterial because there is no evidence that anyone bought POM Juice because they thought Respondents spent a certain amount of money in a particular area of research. Indeed, Professor Reibstein's survey showed the opposite: that no one bought POM Juice because of the amount of money spent on science. (PX0223-0006). Finally, an establishment claim cannot be inferred from the illustration of a POM bottle surrounded by molecules or a molecular model. This is an illustration that is hyperbolic, humorous cheeky puffery, and that is not actionable. *See, e.g., Sterling Drug, Inc. v. F.T.C.,* 741 F.2d 1146, 1150 (9th Cir. 1984); *In re Thompson Medical,* 104 F.T.C. 648, 788-89 n. 6).

498. After urging the consumer to "keep in mind that all of the research has been done on POM Wonderful 100% Pomegranate Juice" and that "[n]o other pomegranate juice can claim these distinctions, and no other brand has been clinically tested," the "**Backed by Science**" page states, "So what are the medical results on POM Wonderful 100% Pomegranate Juice?" (CX0473 (Compl. Ex. E-1 at 01:17); *see also* CX0473 (Compl. Ex. E-1 at 03:58) (stating on the "Wonderfully superior" page of pomegranatetruth.com that "POM is the only pomegranate juice made exclusively from the Wonderful variety, which is the only variety featured in all of the promising medical research you have heard about," and "[p]atients drinking POM Wonderful 100% Pomegranate Juice in clinical trials have experienced promising results in hearth health, prostate health, and erectile function.")).

Response to Finding No. 498:

It is undisputed that CX0473 at 01:17 displays a page titled, "Backed by science" from the pomegranatetruth.com website in April 2009, and that on that page, there is a sentence that says, "…keep in mind that all of the research has been done on POM Wonderful 100% pomegranate juice." (CX0473 (Compl. Ex. E-1 at 01:17). Similarly, it is undisputed that there is another sentence on that same page that says, "So what are the medical results on POM Wonderful 100% Pomegranate Juice?" (*Id.*) And, the "Wonderfully superior" page of this website states in part what Complaint Counsel says, but also that the "medical research" done on this varietal is "promising" and that persons who participated in any "clinical trials" using the Wonderful variety of pomegranate juice "experienced promising results," among other things. (*Id.* at 03:58). The page titled, "Wonderfully superior," uses qualified language and makes it clear that "Patients drinking POM Wonderful 100% Pomegranate Juice in clinical trials have experienced promising results in heart health, prostate health, and erectile dysfunction." The studies described on the "Backed by science" page are similarly qualified, described as "preliminary," "hopeful," and "initial." (CX0473 (Compl. Ex. E-1 at 01:24). The results of the studies are described, but simply referring to the results of research does not convert advertising into an establishment claim. Accurately summarizing and quoting the highly qualified results of a published scientific study about preliminary and potential benefits cannot logically convey, as Complaint Counsel argue, the net impression that the Challenged Products treat, prevent or reduce the risk of disease, or that they are clinically proven to do so without qualification.

499. Selected "medical results" from the Ornish MP Study (2005), the Pantuck Phase II Prostate Cancer Study (2006), and the Forest Erectile Dysfunction Study (2007) were presented under the bold subheadings "**Heart Health**," "**Prostate Health**," "**Erectile Dysfunction**," respectively. (CX0473 (Compl. Ex. E-1 at 01:25)). The study descriptions were substantially similar to those on the pomwonderful.com website. (*See* CCFF ¶¶ 1.445-1.447, 1.449).

Response to Finding No. 499:

It is undisputed that certain results of certain studies (including Ornish MP Study (2005), the Pantuck Phase II Prostate Cancer Study (2006) and the Forest Study (2007)) were referred to and summarized on the page titled, "Backed by science" on the pomegranatetruth.com April 2009 website. (CX0473 (Compl. Ex. E-1 at 01:25). The descriptions use qualified language such as, "Patients drinking POM Wonderful 100% Pomegranate Juice in clinical trials have experienced promising results in heart health, prostate health, and erectile dysfunction." (CX0473 (Compl. Ex. E-1 at 01:24). Similarly, the Pantuck Phase II Study is described as "initial" and as finding "hopeful results for prostate health." (*Id.*) The Forest Study was described as showing that men who drank POM Wonderful "were 50% more likely" to experience "improved erections." (*Id.*) The results of the studies are described, but simply referring to the results of research does not convert advertising into an establishment claim. Accurately summarizing and quoting the highly qualified results of a published scientific study about preliminary and potential benefits cannot logically convey, as Complaint Counsel argue, the net impression that the Challenged Products treat, prevent or reduce the risk of disease, or that they are clinically proven to do so without qualification.

500. The pomegrantetruth.com website, through textual references and medical imagery, touts POM Juice's "health benefits," "medical results," and POM's research on heart disease, prostate cancer, and erectile dysfunction, and other health conditions. The pomegrantetruth.com website conveys the net impression that drinking eight ounces of POM Juice daily treats, prevents, or reduces the risk of heart disease, prostate cancer, and erectile dysfunction, and that these health benefits are clinically proven. (*See* CCFF ¶¶ 496-499).

Response to Finding No. 500:

POM objects to this finding of fact. However, if the ALJ considers this finding of fact, the whole of "pomegranatetruth.com" makes it clear that the net impression conveyed by this website is not that POM's Juice treats, prevents, or reduces the risk of heart disease,

prostate cancer, and erectile dysfunction. Rather, as the homepage itself makes clear, this website is about the health benefits of POM ("Backed by science"); the genuineness of the product (*e.g.*, there are no filler juices or added sugars, added "colorants or other low-grade fruit juices"); the Wonderful variety of pomegranates,"; the fact that POM "controls its pomegranate juice from tree to bottle"; and that it's grown in California. (CX0473 (Compl. Ex. E-1 at 00:16-1:23). Put differently, the net impression conveyed by pomegranatetruth.com is that POM's Juice (unlike many of its competitors' juices) is a healthy food product derived wholly from the pomegranate fruit, with no added fillers, which may have certain health benefits. The net impression is not that POM Wonderful 100% pomegranate juice is a drug or medicine, but something which if consumed may help consumers maintain health, just like eating a healthy diet may do. (RRFF 496-99

5. Pompills.com Made Establishment Claims Regarding Heart Disease, Prostate Cancer, and Erectile Dysfunction

501. The pompills.com website was an e-commerce site and had everything from learning about the product to ordering the product. (CX1347 (Glovsky, Dep. at 134)).

Response to Finding No. 501:

It is undisputed that Ms. Glovskey testified that the pompills.com website was an e-commerce site and had everything from learning about the product to ordering the product.

502. The pompills.com homepage displayed the large, bold heading "**Antioxidant Superpill**," accompanied by the image of a bottle of POMx Pills. The equivalence of POMx Pills to POM Juice was immediately communicated in the subheading "**The Power of POM. Now in a single pill**," and by the image in the center of the homepage of a bottle of POMx Pills connected by an equals sign to an eight-ounce bottle of POM Juice. The caption under this image stated, "[a]ll the antioxidant power of an 8oz. glass of POM Wonderful 100% Pomegranate Juice in the convenience of a calorie-free capsule." A red button to "**BUY NOW**" appeared prominently below this description. (CX0473 (Compl. Ex. E-8 at 00:10)).

Response to Finding No. 502:

It is undisputed that, in April 2009, the pompills.com homepage was titled, "Antioxidant Superpill," accompanied by the image of a bottle of POMx Pills; and that underneath the text "The power of POM. Now in a single pill," appeared, together with a picture of a pill and an equal sign, and a bottle of POM Juice. The POMx Pill bottle is shaped like a pomegranate (like the upper half of the POM Juice bottle), reinforcing the image of the pomegranate fruit. It is also undisputed that the text, "All the antioxidant power of an 8oz glass of POM …. Juice in the convenience of a calorie-free capsule" and the "buy now" button appeared on the homepage in April 2009. (CX0473 (Compl. Ex. E-8 at 00:10). The page says only that there is antioxidant power in the Pill and the Juice. And, the antioxidant content of pomegranate juice is well-known, and well-established. (RFF 2518-44).

503. In April 2009, the menu bar at the top of the pompills.com homepage included links to "**Health Benefits**," "**Potency**," "**POMx Pills**," "**POMx Liquid**," and "**Buy Now**." (CX0473 (Compl. Ex. E-8 at 00:10)). In January 2010, "**Health Benefits**," was replaced with "**Medical Research**" on the menu bar. (CX0473 (Compl. Ex. E-9 at 00:04)).

Response to Finding No. 503:

It is undisputed that, in April 2009, the menu bar at the top of the pompills.com homepage included links to "POMx Pills," "POMx Liquid," "Health Benefits," "Potency," "About Us," "Buy Now," "Contact Us," "Shopping Cart," and "My Account." (CX0473 (Compl. Ex. E-8 at 00:10). The page says only that there is antioxidant power in the Pill and the Juice. And, the antioxidant content of pomegranate juice is well-known, and well-established. (RFF 2518-44). With respect to the pompills.com January 2010 homepage, which is irrelevant as conceded by Professor Mazis (PX0296 at 0010; Mazis, Tr. 2753-54), it is undisputed that the same links appear on the homepage as appeared on the April 2009 homepage with one exception: Instead of "Health Benefits," a link titled "Medical Research" appears. (CX0473 (Compl. Ex. E-9 at 00:06). The page says only that there is antioxidant power in the Pill and the Juice. And, the antioxidant content of pomegranate juice is well-known, and well-established. (RFF 2518-44).

504. The "**POMx Pills**" page displayed the headline "**Take it daily. Feel it forever.**" The message that POMx Pills are equivalent to POM Juice was conveyed in the subheadings, "**One POMx Pill = the antioxidant power of an 8oz glass of POM Wonderful 100% Pomegranate Juice**," and "**POM in a Pill**"; in the text "All of the antioxidant power of POM Wonderful 100% Pomegranate Juice is now available in a supplement. So you can still get your daily antioxidants from an 8oz. glass of juice, or now the convenience of a calorie-free pill"; and in a caption to a diagram of a POMx Pill reading "fact 2. The antioxidant power of an 8oz. glass of juice, in a calorie-free pill." (CX0473 (Compl. Ex. E-8 at 00:15-00:25)).

Response to Finding No. 504:

It is undisputed that, in April 2009, the pompills.com website page titled, "POMx Pills" displayed the headline, "Take it daily. Feel it forever." It is also undisputed that, in April 2009, the pompills.com website page titled, "POMx Pills" contained copy equating POMx to the antioxidant power of an 8oz glass of POM Juice. (CX0473 (Compl. Ex. E-8 at 00:21). The page does not mention heart disease, prostate cancer or erectile

dysfunction. Instead, the page as a whole emphasizes that POMx is made from the whole fruit of the pomegranate alone, and is a natural food-derived product. (CX0473 (Compl. Ex. E-8 at 00:21). For example, the page also has a heading on it titled, "Ingredients: 100% California-Grown Wonderful Variety Pomegranates," and emphasizes that POMx is "made from the same California pomegranates in 100% POM Wonderful Pomegranate Juice." (*Id.*; *see also*, RFF 494).

505. The "**POMx Pills**" page also displayed a red "**BUY NOW**" button. (CX0473 (Compl. Ex. E-8 at 00:15-00:25)).

Response to Finding No. 505:

It is undisputed that in April 2009, the POMx Pills page displayed a "BUY NOW" button. Moreover, a "buy now" button does not make or convert the page into an "establishment claim." Instead, the page as a whole emphasizes that POMx is made from the whole fruit of the pomegranate alone, and is a natural food-derived product. (CX0473 (Compl. Ex. E-8 at 00:21). For example, the page also has a heading on it titled, "Ingredients: 100% California-Grown Wonderful Variety Pomegranates," and emphasizes that POMx is "made from the same California pomegranates in 100% POM Wonderful Pomegranate Juice." (*Id.*; *see also*, RFF 494).

506. The toll-free number for placing orders, 1-888-POM-PILL, appeared at the bottom of nearly all pages on the pompills.com website. (CX0473 (Compl. Ex. E-8 at 04:23)).

Response to Finding No. 506:

It is undisputed that the toll free number 1-888-POM-PILL appears at the bottom of some of the POMx webpages in April 2009. Moreover, a toll free number cannot, and does not make an establishment claim. Instead, the page as a whole emphasizes that POMx is made from the whole fruit of the pomegranate alone, and is a natural food-derived product. (CX0473 (Compl. Ex. E-8 at 00:21). For example, the page also has a heading on it titled, "Ingredients: 100% California-Grown Wonderful Variety Pomegranates,"

and emphasizes that POMx is "made from the same California pomegranates in 100% POM Wonderful Pomegranate Juice." (*Id.*; *see also*, RFF 494).

507. The "**POMx Pills**" page stated, "Research has shown that the naturally occurring polyphenol antioxidants in pomegranates have extraordinary health benefits." Continuing down the page, other bold subheadings touted POMx Pills as "**The Most Concentrated Source of Pomegranate Antioxidants Available**" and "**Ultra Potent**." (CX0473 (Compl. Ex. E-8 at 00:25)).

Response to Finding No. 507:

It is undisputed that, in April 2009, the POMx Pills page stated that "Research has shown that the naturally occurring polyphenol antioxidants in pomegranates have extraordinary health benefits," and that subheadings included, "The Most Concentrated Source of Pomegranate Antioxidants Available" and "Ultra Potent." To the extent the ALJ considers this page, it does not make a broad establishment claim concerning any particular disease, or heart disease, prostate cancer, or erectile dysfunction. To the contrary, the page does not mention heart disease, prostate cancer or erectile dysfunction. Instead, the page as a whole emphasizes that POMx is made from the whole fruit of the pomegranate alone, and is a natural food-derived product. (CX0473 (Compl. Ex. E-8 at 00:21). For example, the page also has a heading on it titled, "Ingredients: 100% California-Grown Wonderful Variety Pomegranates," and emphasizes that POMx is "made from the same California pomegranates in 100% POM Wonderful Pomegranate Juice." (*Id.*; *see also*, RFF 494).

508. Under the subheading "**Science, Not Fiction**," the "**POMx Pills**" page stated:

- Made from the only pomegranates backed by $25 million in medical research and the POM Wonderful brand
- Clinically tested
- Proven to be easily absorbed
- Guards your body against free radicals
- Promotes prostate and heart health

(CX0473 (Compl. Ex. E-8 at 00:35)).

Response to Finding No. 508:

It is undisputed that, in April 2009, the POMx Pills page had a subheading, "Science, Not Fiction," and that underneath that subheading bullet points appeared concerning the fact that POMx was made from pomegranates "backed by $25 million in medical research," that it was clinically tested and easily absorbed, that it "guards your body against free radicals" and "promotes prostate and heart health." To the extent the ALJ considers this page, it does not make any establishment claims about any particular disease because do not say or imply that any of the scientific research says any tests or studies show a particular fact. Rather, as Complaint Counsel admit, this webpage says only that POMx is "backed by $25 million in medical research," and that POMx "promotes prostate and heart health." These are qualified statements at best, not establishment claims. To the extent any claim is made, the fact that POM advertised the amount of money Respondents spent on scientific research does not convey the net impression that the Challenged Products are "clinically proven to prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction." (RFF 2507-19; Respondents' Post-Trial Br. at 76-77.) What this "backed by" ad actually states is that Respondents spent a particular sum of money on scientific studies on the Challenged Products. This is a reflection of the company's dedication to science and to health. (L. Resnick, Tr. 251; *see also* CCFF 309, 310, 311). Contrary to Complaint Counsel's implication, it is completely illogical to infer from the fact that a certain amount of money was invested in research to the conclusion that the Challenged Products are proven to prevent, treat or reduce the risk of disease. Again, this is another one of Complaint Counsel's ill-defined, "logical leaps" from "backed by $23 million of initial scientific research" to "backed by $23 million in research that proved the Challenged Products prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction." Indeed, Complaint Counsel

presented no evidence that consumers took away the message presumed by Complaint Counsel because Respondents spent a certain amount of money on science and research. (RFF 28-29, 2515). Moreover, the "backed by" ads accurately and truthfully represented the dollars spent by Respondents on the totality of the science on the Challenged Products at the time. (RFF 2510). Furthermore, these ads are immaterial because there is no evidence that anyone bought POM Juice because they thought Respondents spent a certain amount of money in a particular area of research. Indeed, Professor Reibstein's survey showed the opposite: that no one bought POM Juice because of the amount of money spent on science. (PX0223-0006). Finally, throughout its advertising, POM highlights that POM Juice is a 100% juice product wholly-derived from the pomegranate fruit, and that POMx is 100% derived from the exact same fruit. (*See* RFF 494).

509. The "**POMx Liquid**" page featured the headline "**Not for the Faint of Heart**." Directly below this headline, a subheading stated, "**POMx Liquid: The most concentrated source of pomegranate antioxidants available**," elaborating, "[t]ake your antioxidants into your own hands. The Antioxidant Superpower is now available in a single teaspoon. POMx Liquid is a highly concentrated, incredibly powerful blend of all-natural polyphenol antioxidants made from the very same pomegranates in POM Wonderful 100% Pomegranate Juice." (CX0473 (Compl. Ex. E-8 at 01:00)).

Response to Finding No. 509:

It is undisputed that, in April 2009, the POMx Liquid homepage had the headline "Not for the Faint of Heart," and that it stated, "POMx Liquid: The most concentrated source of pomegranate antioxidants available." (CX0473 (Compl. Ex. E-8 at 01:00). The page also stated that the "Antioxidant Superpower is now available in a single teaspoon," and that it POMx Liquid "is a highly concentrated, incredibly powerful blend of all-natural polyphenol antioxidants made from the very same pomegranates in POM Wonderful 100% Pomegranate Juice." (*Id.*) To the extent the ALJ considers this page, it does not make any establishment claims about any particular disease because it does not say or imply that any of the scientific research says any tests or studies show a particular fact. Rather, as Complaint Counsel admit, this webpage says that the extract is made from the

whole fruit. It is a food derived product, not a drug. It is an unsupported leap of logic to say that the references to antioxidants in this webpage somehow make an establishment claim about heart disease, prostate cancer, and erectile dysfunction.

510. The "**POMx Liquid**" page also depicted the POMx Liquid bottle and teaspoon with the caption, "One teaspoon = the antioxidant power of 8oz. of POM Wonderful 100% Pomegranate Juice" and a link to "BUY NOW." (CX0473 (Compl. Ex. E-8 at 01:00)).

Response to Finding No. 510:

It is undisputed that, in April 2009, the POMx Liquid homepage on pompills.com had a picture of the POMx Liquid bottle and a teaspoon. There is also copy that says "One teaspoon = the antioxidant power of 8oz of POM Wonderful 100% Pomegranate Juice." There is also a "buy now" link, as this is an e-commerce site. (CX0473 (Compl. Ex. E-8 at 01:00) To the extent the ALJ considers this page, it does not make any establishment claims about any particular disease because it does not say or imply that anything about prostate cancer, erectile dysfunction, and/or heart disease. (CX0473 (Compl. Ex. E-8 at 01:00)

511. The "**POMx Liquid**" page contained substantially similar language touting the research behind the product as the POMx Pills page. (*Compare* CX0473 (Compl. Ex. E-8 at 00:35) *with* (CX0473 (Compl. Ex. E-8 at 01:15)).

Response to Finding No. 511:

It is undisputed that the April 2009 POMx Liquid homepage on pompills.com had information concerning the antioxidant properties of pomegranates and POMx Liquid. To the extent the ALJ considers this page, POM objects to the characterization of the information on the page as "contain[ing] substantially similar language touting the research behind the product as the POMx Pills page," as argumentative, vague and ambiguous. In fact the POMx Liquid page does not have any references or links to any particular studies, nor does it mention anything about erectile dysfunction. The only references on the POMx Liquid page are to antioxidants and general health benefits

associated with them, and a reference to the product "promot[ing] prostate and heart health." (CX0473 (Compl. Ex. E-8 at 01:12). This is not an establishment claim; it does not imply that POMx Liquid 'cures, treats or prevents' prostate *cancer* or heart *disease.*

512. The "**Health Benefits**" section of pompills.com featured links to web pages titled "Research," "Antioxidant Benefits," "Heart Health," and "Prostate Health." (CX0473 (Compl. Ex. E-8 at 01:38)).

Response to Finding No. 512:

It is undisputed that, in April 2009, the POMx pompills.com's "Heatlh Benefits" page featured these links. To the extent the ALJ considers this page, none of the copy on this page makes an establishment claim. The copy is qualified and tentative, and none of it says that it reduces the risk, prevents or treats erectile dysfunction, prostate cancer or heart disease. For example, the copy under "Research" states only that the "antioxidants in POMx are supported by $25 million in initial scientific research … and we've uncovered encouraging results." The copy under "Antioxidant Benefits," states "Recent scientific research suggests that free radicals …. Destroy healthy cells… contributing to disease… Emerging science tells us that antioxidants help guard … against free radicals." And the copy under "Heart Health" says that "findings suggest that pomegranate juice may help counteract factors leading to arterial plaque…" (CX0473 (Compl. Ex. E-8 at 01:36). By way of illustrating Complaint Counsel's illogical leaps, "supported by $25 million of initial scientific research" is not the same as saying "supported by $25 million in research that proves the Challenged Products prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction." Indeed, Complaint Counsel presented no evidence that consumers took away the message presumed by Complaint Counsel because Respondents spent a certain amount of money on science and research. (RFF 28-29, 2515). Moreover, the "backed by" ads accurately and truthfully represented the dollars spent by Respondents on the totality of the science on the Challenged Products at the time. (RFF 2510). Furthermore, these ad pages are immaterial because there is no

evidence that anyone bought POM Juice because they thought Respondents spent a certain amount of money in a particular area of research. Indeed, Professor Reibstein's survey showed the opposite: that no one bought POM Juice because of the amount of money spent on science. (PX0223-0006).

513. A list of study citations followed this introduction under the headings "**Cardiovascular Studies**," "**Cancer Studies**," "**Chemical Composition Studies**," "**Diabetes Studies**," and "**Bioavailability Studies**." (CX0473 (Compl. Ex. E-8 at 01:43-04:23)).

Response to Finding No. 513:

In April 2009, POM's pompills.com website featured links to study citations under various headings. To the extent the ALJ considers this page, POM disputes that "a list of study citations followed" the "introductory" "Health Benefits" page of pompills.com. This is not true. Rather, if a viewer clicks on the link under "Research," it takes the viewer to another page titled "Research" and that page has links on it to particular studies funded by POM. To access the studies, yet another click is needed. Furthermore, the "Research" page does not make any establishment claims. Rather, the list of the studies follows copy that stresses the fact that, for "centuries, the pomegranate has been valued as a symbol of health," and makes it clear that research began by POM in 1998 to uncover the truth, and see if the legends were true. Then the copy makes it clear that the viewer can learn more about the "pilot, peer-reviewed studies" by clicking on the links. (CX0473 (Compl. Ex. E-8 at 0:142). No "claims" are made at all.

514. The "**Cardiovascular Studies**" listed on the "**Research**" page included those with titles like, "Pomegranate juice improves myocardial perfusion in coronary heart patients," "Pomegranate juice pilot research suggest anti-atherosclerosis benefits," and "Pomegranate juice helps promote normal systolic blood pressure." (CX0473 (Compl. Ex. E-8 at 01:41)). These titles were POM's paraphrases of the studies' actual titles. (CX0473 (Compl. Ex. E-8 at 01:43-02:31)). For example, the study POM listed as "Pomegranate juice improves myocardial perfusion in coronary heart patients," was published with the title "Effects of Pomegranate Juice Consumption on Myocardial Perfusion in Patients with Coronary Heart Disease." (CX0473 (Compl. Ex. E-8 at 02:05-02:10)).

Response to Finding No. 514:

In April 2009, POM's pompills.com website's "Research" page included several links to studies under the heading "Cardiovascular Studies." However, this webpage is irrelevant (according to Mazis) to any determination in this case because it was pulled from the website before August 2009. (PX0296 at 0010; Mazis, Tr. 2753-54). To the extent the ALJ considers this page, POM objects to Complaint Counsel's characterization of the studies as having titles that were "POM's paraphrases of the studies' actual titles" as being incorrect and argumentative. To the contrary, some of those links included the actual title of the study, such as the link to Dr. Ignarro's study, "Pomegranate juice protects nitric oxide against oxidative destruction and enhances the biological actions of nitric oxide." (CX0473 (Compl. Ex. E-8 at 01:54). The other "titles" simply described the studies at issue, and did so in a way that does not make establishment claims. For example, one of the examples that Complaint Counsel has brought out, makes a very qualified statement and description of the study: "Pomegranate juice helps promote normal systolic blood pressure." This description does not make a claim that pomegranate juice cures, treats or prevents heart disease, let alone erectile dysfunction or prostate cancer. The same is true of the other "titles" or descriptors used. This is yet another example of the illogical leaps that Complaint Counsel is asking the ALJ to make so that it can carry its burden of proof.

515. The "**Cancer Studies**" listed on the "**Research**" page included those with titles like, "Pomegranate juice delays PSA doubling time in humans," "Pomegranate polyphenols have anti-inflammatory effects on colon cancer cells," and "Pomegranate juice shows superior anti-cancer bioactivity when compared to its purified compounds." (CX0473 (Compl. Ex. E-8 at 02:56)). These titles were POM's paraphrases of the studies' actual titles. (CX0473 (Compl. Ex. E-8 at 02:34-03:10)). For example, the study POM listed as "Pomegranate juice delays PSA doubling time in humans," was published with the title "Phase II Study of Pomegranate Juice for Men with Rising Prostate-Specific Antigen Following Surgery or Radiation for Prostate Cancer." (CX0473 (Compl. Ex. E-8 at 02:34-02:45)).

Response to Finding No. 515:

In April 2009, POM's pompills.com website's "Research" page included several links to studies under the heading "Cancer Studies." However, this webpage is irrelevant (according to Mazis) to any determination in this case because it was pulled from the website before August 2009. (PX0296 at 0010; Mazis, Tr. 2753-54). To the extent the ALJ considers this page, POM objects to Complaint Counsel's characterization of the studies as having titles that were "POM's paraphrases of the studies' actual titles" as being argumentative. The links described or summarized the studies' topics. Further, none of the descriptive links make an establishment claim, such as POMx cures cancer. Instead, the links said things like, "Pomegranate juice delays PSA doubling time in humans" or "Pomegranate juice shows superior anti-cancer bioactivity when compared to its purified compounds." (CX0473 (Compl. Ex. E-8 at 02:56). They do not say things like "Pomegranate juice delays PSA doubling time in humans and therefore treats, cures, and/or prevents prostate cancer." This is yet another example of the illogical leaps that Complaint Counsel is asking the ALJ to make so that it can carry its burden of proof.

516. The "**Diabetes Studies**" listed on the "**Research**" page included those with titles like, "Pomegranate juice has antioxidant benefits for people with type 2 diabetes," and "Pomegranate juice stimulates unique antioxidant function relevant to diabetes." (CX0473 (Compl. Ex. E-8 at 02:56)).

Response to Finding No. 516:

In April 2009, POM's pompills.com website's "Research" page included several links to studies under the heading "Diabetes Studies." To the extent the ALJ considers this page, POM objects to Complaint Counsel's implication that somehow, the titles of the links either mis-characterize the studies or make an establishment claim. The website links say things like, "Pomegranate juice has antioxidant benefits for people with type 2 diabetes." (CX0473 (Compl. Ex. E-8 at 02:56). They do not say things like "Pomegranate juice prevents or cures diabetes." Furthermore, it is true that pomegranates have antioxidants

that can benefit all persons, including persons with diabetes; indeed, the antioxidant properties of pomegranates, and the benefits of antioxidants, are well-established. (PX0192). This is yet another example of the illogical leaps that Complaint Counsel is asking the ALJ to make so that it can carry its burden of proof.

517. Another page, titled "**Why take an antioxidant supplement?**" described free radicals as "unstable molecules [that] aggressively destroy healthy cells in our bodies and may be linked to everything from the wrinkles we get as we age to more serious health threats like cancer and heart disease. In fact, scientists have already linked free radicals to as many as 60 different types of diseases." (CX0473 (Compl. Ex. E-8 at 04:37)). Farther down the page, under the red, bold subheading "POMx: The Antioxidant Superpill," was the text:

> It's enough to make other antioxidants feel inferior: in the fight against free radicals, POMx is the Antioxidant Superpill. POMx fights free radicals with more concentrated pomegranate antioxidants than any other 100% pomegranate supplement. . . . POMx is made from the only pomegranates with $25 million in medical research behind them, and backed by the POM Wonderful brand. A single capsule or teaspoon of POMx gives you all the antioxidant power of an 8oz. glass of POM Wonderful 100% Pomegranate Juice – the very same juice that in a preliminary UCLA medical study showed hopeful results for men with prostate cancer.
>
> (CX0473 (Compl. Ex. E-8 at 04:50)).

Response to Finding No. 517:

It is undisputed that, in April 2009, pompills.com had a page titled, "Why take an antioxidant supplement?" To the extent the ALJ considers this page, it does not make any establishment claims that the product treats, prevents or reduces the risk of disease. The webpage is describing the known health benefits of antioxidants, and stressing that POMx comes from pomegranates, a fruit with known antioxidant properties. Similarly, the page points out another known fact: That pomegranates have more antioxidants than other fruits and points out that the POMx pills are "made from … pomegranates," a known "superfruit." (CX0473 (Compl. Ex. E-8 at 4:40). It is thus clear that this is a fruit or food-derived product, not a drug, and certainly not a product designed to replace conventional medical care or medicine. To the extent that Complaint Counsel are concerned about the statement that "POMx is made from the only pomegranates with $25

million in medical research behind them," that statement, too, fails to make an establishment claim, particularly since it is followed by a qualifying example: the same pomegranates that are used to make POMx are used to make the Juice, "the very same juice that in a preliminary UCLA medical study showed hopeful results for men with prostate cancer." (CX0473 (Compl. Ex. E-8 at 4:40). By way of illustrating Complaint Counsel's illogical leaps, "supported by $25 million of medical research" is not the same as saying "supported by $25 million of medical research that proves the Challenged Products prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction." Indeed, Complaint Counsel presented no evidence that consumers took away the message presumed by Complaint Counsel because Respondents spent a certain amount of money on science and research. (RFF 28-29, 2515). Moreover, the "backed by" ads accurately and truthfully represented the dollars spent by Respondents on the totality of the science on the Challenged Products at the time. (RFF 2510). Furthermore, these ad pages are immaterial because there is no evidence that anyone bought POM Juice because they thought Respondents spent a certain amount of money in a particular area of research. Indeed, Professor Reibstein's survey showed the opposite: that no one bought POM Juice because of the amount of money spent on science. (PX0223-0006).

518. A section on "**Heart Health**" stated:

> We have researched the effects of pomegranate juice on cardiovascular health for almost 10 years, and findings suggest that pomegranate juice may help counteract factors leading to arterial plaque build-up, as well as inhibit a number of factors associated with heart disease. Initial pre-clinical tests have shown that POMx has equivalent cardiovascular benefits to POM Wonderful Juice, and additional studies are now going on. Learn more.

The "Learn more" link took the consumer to a page titled "**The Heart of The Matter**." (CX0473 (Compl. Ex. E-8 at 05:05) (underlined hyperlink in original)).

Response to Finding No. 518:

It is undisputed that, in April 2009, the pompills.com website had a page titled, "Health Benefits," and a section or link on it titled, "Heart Health." To the extent the ALJ considers this page, it does not make any establishment claims. The text under "Heart Health" is qualified and does not say that POMx reduces the risk, treats, or prevents heart disease. Rather, it says that POM has "researched the effects of pomegranate juice on cardiovascular health … and findings suggest that pomegranate juice may help counteract factors leading to arterial plaque buildup, as well as inhibit a number of factors associated with heart disease." (CX0473 (Compl. Ex. E-8 at 5:06)). It stresses that the research is "initial" and "pre-clinical" and informs the viewer that additional studies are going on. (*Id.*) This is again an example of Complaint Counsel's overreaching.

519. "**The Heart of The Matter**" page displayed a large image of the medical caduceus symbol. Directly under this image was a link to "Order POM Pills Now!" Next to the medical caduceus symbol was the subheading in red, "Amaze your cardiologist. Take POMx." The explanatory text under "Amaze your cardiologist" stated:

> POMx is made from the only pomegranates supported by $25 million of initial scientific research from leading universities . . . . The very same pomegranates in POM Wonderful 100% Pomegranate Juice that showed encouraging results in initial cardiovascular health studies.
>
> Let's start with some facts: atherosclerosis (or too much plaque in the arteries) is a leading cause of heart disease. Emerging science suggests that free radicals may be the culprits that can oxidize LDL (also known as "bad" cholesterol) – turning it into plaque that clogs up arteries. And science also tells us that pomegranate antioxidants neutralize free radicals.

(CX0473 (Compl. Ex. E-8 at 05:09)).

Response to Finding No. 519:

It is undisputed that, in April 2009, the pompills.com website had a page titled, "Health Benefits," a section or link on it titled, "Heart Health," and a "Learn more" link that took the viewer to a page titled, "The Heart of The Matter." (CX0473 (Compl. Ex. E-8 at 5:06-09.) To the extent the ALJ considers this page, it does not make any establishment

claims. The tagline "Amaze your cardiologist. Take POMx" is followed by text that states, in qualified terms, that POMx may have health benefits and is backed by preliminary or initial science: POMx is "made from the only pomegranates supported by $25 million of initial scientific research from leading universities…" (CX0473 (Compl. Ex. E-8 at 5:09). This is a far cry from saying that the $25 million in medical research proves that POMx reduces the risk, treats or prevents heart disease. Further, the copy makes it clear that POMx is not a drug, but a food-based supplement derived from pomegranates, a healthy, antioxidant rich fruit. (CX0473 (Compl. Ex. E-8 at 5:09)). For example, the copy states that POMx is made from "the very same pomegranates in POM Wonderful 100% Pomegranate Juice that showed encouraging results in initial cardiovascular health studies." This is another example of Complaint Counsel's overreaching.

520. "**The Heart of the Matter**" page also presented summaries of the Aviram CIMT/BP Study (2004) and the Ornish MP Study (2005) that were substantially similar to those on pomwonderful.com. (CX0473 (Compl. Ex. E-8 at 05:10); *see also* CCFF ¶ 449 (summaries of the Aviram and Ornish studies)).

Response to Finding No. 520:

It is undisputed that, in April 2009, the pompills.com website had a page titled, "The Heart of The Matter" with summaries of Dr. Aviram's CIMT/BP Study (2004) and Dr. Ornish's MP Study (2005) underneath the qualified titled, "Promising results from studies on POM Wonderful Juice." To the extent the ALJ considers this page, POM objects to the characterization of the summaries of the Aviram and Ornish studies as "substantially similar to those on pomwonderful.com" because it is vague and ambiguous. Further, the page (and these particular study descriptions) do not make any broad establishment claims about any particular disease because it does not say or imply that any of the research shows or proves a particular fact or that pomegranate juice reduces the risk, treats or prevents any disease or medical condition. Rather, these

summaries say is that there is (a) a small (45 patients) study that shows certain patients who drank POM's Juice experienced a 17% improvement in blood flow to the heart and (b) there is a pilot study (not a full-fledged study) on a small amount of patients (19) that showed patients who drank POM's Juice had decreased arterial plaque. Finally, the page does say that "pomegranate antioxidants neutralize free radicals." (CX0473 (Compl. Ex. E-8 at 5:09). But this is a well-established fact – pomegranates do have antioxidants, and antioxidants do neutralize free radicals (PX0192) – and POM does not say here that antioxidants cure, treat or prevent diseases of any sort. The statement therefore does not make an establishment claim, either; and it is true.

521. The "**Prostate Health**" section of the "**Health Benefits**" page stated "A preliminary UCLA medical study on POM Wonderful 100% Pomegranate Juice showed hopeful results for men with prostate cancer who drank an 8oz. glass of pomegranate juice daily. And every POMx capsule provides the antioxidant power of an 8oz. glass of POM Wonderful 100% Pomegranate Juice. Learn more." (CX0473 (Compl. Ex. E-8 at 05:50)). The "Learn more" link took the consumer to a page titled "**Pomegranates and Prostate Health**." (CX0473 (Compl. Ex. E-8 at 05:55) (underlined hyperlink in original)).

Response to Finding No. 521:

It is undisputed that, in April 2009, the pompills.com website had a page titled, "Health Benefits" with a "Prostate Health" section on it. To the extent the ALJ considers this page, the copy under the "Prostate Health" Section does not make any establishment claims. For example, it does not say that POMx or POM's Juice reduces the risk, treat or prevent prostate cancer. Rather, it describes the Pantuck Phase II Prostate Cancer Study (2006) as "preliminary" in nature and the results as "hopeful." (CX0473 (Compl. Ex. E-8 at 05:50). The link at the end of the summary is titled, "Learn More," and the link takes the viewer to a page titled "Pomegranates and Prostate Health." The copy on the "Pomegranates and Prostate Health" page does not make any broad establishment claims that the product treats, prevents or reduces the risk of disese, either. Instead, the page describes Dr. Pantuck's study as "reveal[ing] promising news" and makes it clear that the

men studied in the study had undergone traditional, medical treatment for prostate cancer, and that they did not substitute pomegranate juice or POMx for conventional medical care: They were "treated surgically or with radiation for prostate cancer" and were also given POM 100% Pomegranate Juice. (CX0473 (Compl. Ex. E-8 at 05:58).

522. Like "**The Heart of the Matter**" page, the "**Pomegranates and Prostate Health**" page also prominently displayed the medical caduceus symbol. Directly under the caduceus symbol was a quote from the July 4, 2006 issue of *The New York Times* that "Findings from a small study suggest that pomegranate juice may one day prove an effective weapon against prostate cancer." (CX0473 (Compl. Ex. E-8 at 05:55)).

Response to Finding No. 522:

In April 2009, the pompills.com website had both a "Heart of the Matter" and a "Pomegranates and Prostate Health" page. Additionally, POM objects to this proposed finding of fact as misleading because – contrary to Complaint Counsel's suggestion – only the "Pomegranates and Prostate" page, and not the "Heart of the Matter" page has the New York Times quote on it. However, to the extent the ALJ considers this page, the copy under the "Heart of the Matter" and a "Pomegranates and Prostate Health" pages does not make establishment claims for the reasons set forth above. (*See,* RRFF ¶¶ 521, 520). Further, the New York Times quote is not an advertisement or statement made by POM, but rather, a statement made by an independent third party about the Pantuck Phase II Prostate Cancer Study (2006). It is a qualified statement too that does not suggest pomegranate juice will prevent, treat or reduce the risk of disease. Rather, it says that "Findings from a small study suggest that pomegranate juice may one day prove an effective weapon against prostate cancer." This is not an establishment claim, either.

523. On the "**Pomegranates and Prostate Health**" page the explanatory text under the subheading "**Prostate Health**" focused on prostate cancer:

> Prostate cancer is the most commonly diagnosed cancer among men in the United States, and the second leading cause of cancer death in men, after lung cancer. However, emerging science suggests that diet, lifestyle and dietary supplements may improve prostate health.

(CX0473 (Compl. Ex. E-8 at 05:55)).

Response to Finding No. 523:

It is undisputed that, in April 2009, the "Pomegranates and Prostate Health" page on the pompills.com website had a subheading "Prostate Health" with copy that stated "Prostate cancer is the most commonly diagnosed cancer among men in the United States" and that "emerging science suggests that diet, lifestyle and dietary supplements may improve prostate health." (CX0473 (Compl. Ex. E-8 at 6:02, 5:55). To the extent the ALJ considers this page, the copy under the subheading "Prostate Health" (as is true with all the copy on this page) does not make an establishment claim. Instead, it recites well-known statistics about prostate cancer and it states in a qualified manner that "emerging science suggests" that diet, lifestyle and supplements "may improve prostate health." It does not say that "established science proves that supplements will improve prostate health."

524. Following this statement about prostate cancer, the "**Pomegranates and Prostate Health**" page referenced the Pantuck Phase II Prostate Cancer Study (2006), interpreting the reported result as indicating a "350% increase" in PSA doubling time:

> Men who had been treated surgically or with radiation for prostate cancer were given 8oz. of POM Wonderful 100% Pomegranate Juice. A majority of the 46 men participating in the study experienced a significantly extended PSA doubling time. . . . Before the study of pomegranate juice, the average PSA doubling time for the participants was 15 months. After drinking 8oz. of juice daily, the average PSA doubling time increased to 54 months. That's a 350% increase.
>
> (CX0473 (Compl. Ex. E-8 at 05:55)).

The page also explained that "PSA (prostate-specific antigen) is a marker that is thought to be associated with the progression of prostate cancer; a slower PSA doubling time may reflect slower progression of the disease." Placing the mouse over the hyperlinked word "doubling time" produced a pop-up text box that reiterated, "The amount of time it takes for the prostate-specific antigen[s] (also called PSA levels) to double in men with prostate cancer may reflect the progression of the disease. A longer doubling time may indicate a slower growing cancer." (CX0473 (Compl. Ex. E-8 at 05:55-05:59) (underlined hyperlink in original)).

Response to Finding No. 524:

In April 2009, the "Pomegranates and Prostate Health" page on the pompills.com website had a summary of the Pantuck Phase II Prostate Cancer Study (2006). (CX0473 (Compl. Ex. E-8 at 5:55). To the extent the ALJ considers this page, the copy under the subheading "Promising News" does not make any establishment claims. Rather, it truthfully describes and reports the results of the study, in qualified terms. For example, the description of the study is that it is a "[p]reliminary study" that "revealed promising news," and the results are reported as follows: The men in this study had received conventional prostate cancer treatment ("surgically or with radiation"); PSA doubling time "is a marker that is thought to be associated with the progression of prostate cancer; a slower PSA doubling time may reflect slower progression of the disease." (CX0473 (Compl. Ex. E-8 at 5:55). Furthermore, a quote from Dr. Heber follows the study description, making it clear that POMx and POM's 100% Juice have the same ingredients. (*Id.*) The quote, together with the study descriptor, make it clear both that POMx is not a substitute for conventional medical care and that POMx is a food or fruit based-supplement derived from the whole pomegranate.

525. Consistent with the statement on the "**Health Benefits**" page that "every POMx capsule provides the antioxidant power of an 8oz. glass of POM Wonderful 100% Pomegranate Juice," (*see* CCFF ¶ 524) the "**Pomegranates and Prostate Health**" page quoted Dr. Heber, identified as "Director of UCLA's Center for Human Nutrition," as stating:

The most abundant and most active ingredients in Pomegranate Juice are also found in POMx. Basic studies in our laboratory so far indicate that POMx and Pomegranate Juice have the same effect on prostate health.

(CX0473 (Compl. Ex. E-8 at 05:59)).

Response to Finding No. 525:

In April 2009, the "Pomegranates and Prostate Health" page on the pompills.com website had a quote from Dr. David Heber on it concerning the fact that some of the ingredients

in POM's Juice are the same as those in POMx. (CX0473 (Compl. Ex. E-8 at 5:55). Dr. Heber's quote does not make broad establishment claims. The quote does not suggest that POMx or pomegranate juice reduces the risk, prevents or treats prostate cancer; it just says that POMx and POM's 100% Juice have the same effect on prostate health. (*Id.*) The quote, together with the study descriptor at issue in CCFF ¶ 524, make it clear both that POMx is not a substitute for conventional medical care and that POMx is a food or fruit based-supplement derived from the whole pomegranate.

526. The pompills.com website also featured an "**FAQs**" page. (CX0473 (Compl. Ex. E-8 at 07:51)). The first set of FAQs, under the subheading "**Pomegranates and Health**," included questions like, "**Heart Disease: How does drinking pomegranate juice help the fight against cardiovascular disease?**"; "**Prostate Cancer: There has been promising news on the benefits of pomegranate juice in the fight against prostate cancer. Is this really true?**"; and "**Erectile Dysfunction: Can pomegranate juice benefit men with erectile dysfunction?**" (CX0473 (Compl. Ex. E-8 at 07:51)).

Response to Finding No. 526:

In April 2009, the pompills.comwebsite had a link to a page titled, "FAQs." None of the questions make or suggest establishment claims. In fact, they are simply questions, not statements or claims. Moreover, some of them are phrased in a qualified manner, even though they are questions. For example, a question on prostate cancer is phrased as, "Prostate Cancer: There has been promising news on the benefits of pomegranate juice in the fight against prostate cancer. Is this really true?" The FAQ is not phrased as such: "There is news that pomegranate juice has been found to prevent, treat or cure cancer." This again is an example of Complaint Counsel's illogical leaps and the extent to which it will go to try to carry its burden of proof in this case. Furthermore, the FAQs make it clear that POMx and POMx Liquid are derived from pomegranates, a fruit – for example, the first set of questions is titled, "Pomegranates and Health" and under that heading are included questions like, "Why are pomegranates and pomegranate juice so healthy?"

527. The response to the FAQ "**Heart Disease: How does drinking pomegranate juice help the fight against cardiovascular disease?**" discussed "Improved Cardiac Blood Flow" and "Decrease in Arterial Plaque," again summarizing the results from the Ornish MP

Study (2005) and the Aviram CIMT/BP Study (2004). (CX0473 (Compl. Ex. E-8 at 09:05)).

Response to Finding No. 527:

It is undisputed that, in April 2009, the pompills.comwebsite had a link to a page titled, "FAQs." To the extent the ALJ considers this, neither the question itself ("How does drinking pomegranate juice help the fight against cardiovascular disease?") or the summary afterwards of Dr. Aviram's CIMT/BP Study (2004) or Dr. Ornish's MP Study (2005) make establishment claims. The words "help the fight against" are qualified language; and the study summary afterwards does not say that pomegranate juice or POMx cures, treats, or prevents heart or cardiovascular disease. (CX0473 (Compl. Ex. E-2 at 09:05). To the contrary, Dr. Aviram is quoted as saying that "POMx is as potent an antioxidant as pomegranate juice, and just like pomegranate juice may promote cardiovascular health." (*Id.*) This is not an establishment claim that the product treats, prevents or reduces the risk of disease. Further, Dr. Aviram makes it clear that POMx is a 100% fruit-derived product, not a drug.

528. The response to the FAQ "**Heart Disease: How does drinking pomegranate juice help the fight against cardiovascular disease?**" also stated that "Initial pre-clinical tests have shown that POMx has equivalent cardiovascular benefits as POM Wonderful 100% Pomegranate Juice, and human studies are now ongoing" and quoted Dr. Aviram, identified as "one of the world's preeminent cardiovascular researchers," as commenting, "*The results of our pre-clinical studies showed that POMx is as potent an antioxidant as pomegranate juice, and just like pomegranate juice may promote cardiovascular health*." (CX0473 (Compl. Ex. E-8 at 09:05); *but see* CCFF ¶ B.4.395).

Response to Finding No. 528:

It is undisputed that, in April 2009, the pompills.comwebsite had a link to a page titled, "FAQs." To the extent the ALJ considers this, neither the question itself ("How does drinking pomegranate juice help the fight against cardiovascular disease?") or the summary afterwards of Dr. Aviram's CIMT/BP Study (2004) or Dr. Ornish's MP Study (2005) make establishment claims. The words "help the fight against" are qualified

language; and the study summary afterwards does not say that pomegranate juice or POMx cures, treats, or prevents heart or cardiovascular disease. (CX0473 (Compl. Ex. E-2 at 09:05). To the contrary, Dr. Aviram is quoted as saying that "POMx is as potent an antioxidant as pomegranate juice, and just like pomegranate juice may promote cardiovascular health." (*Id.*).This is not an establishment claim treats, prevents or reduces the risk of disease. Further, Dr. Aviram makes it clear that POMx is a fruit-derived product, not a drug.

529. The response to the FAQ "**Prostate Cancer:** There has been promising news on the benefits of pomegranate juice in the fight against prostate cancer. Is this really true?" once again summarized the Pantuck Phase II Prostate Cancer Study (2006). (CX0473 (Compl. Ex. E-8 at 09:05)). The answer went on to state that "[a] new study is underway to more fully investigate the potential of POMx to extend PSA doubling time" and quoted Dr. Heber, identified as "Director of UCLA's Center for Human Nutrition," as commenting, "*The most abundant and most active ingredients in pomegranate juice are also found in POMx. Basic studies in our laboratory so far indicate that POMx and pomegranate juice may have the same effects*." (CX0473 (Compl. Ex. E-8 at 09:05)).

Response to Finding No. 529:

It is undisputed that, in April 2009, the pompills.comwebsite had a link to a page titled, "FAQs." To the extent the ALJ considers this, neither the question itself ("Prostate Cancer: There has been promising news on the benefits of pomegranate juice in the fight against prostate cancer. Is this really true?") nor the summary afterwards make establishment claims. In fact, the FAQ is phrased in qualified terms, as is the answer, as Complaint Counsel themselves note: Q: "There has been promising news …" and A: "A preliminary study … revealed promising news… and a new study is underway to … investigate the potential of POMx to extend PSA doubling time." (CX0473 (Compl. Ex. E-2 at 09:05). Dr. Heber's quote does not convert the summaries or text into an establishment claim nor does it make an establishment claim that the product treats, prevents prostate cancer; it just says that does nothing more than its' clear that POMx and POM's 100% Juice are nutritional equivalents and that "basic studies" indicate that POMx and pomegranate juice "may have the same effects." (*Id.*) The quote, together

with the study descriptor at issue in CCFF ¶ 524, make it clear both that POMx is not a substitute for conventional medical care and that POMx is a food or fruit based-supplement derived from the whole pomegranate; and it makes it clear too that any statements about POMx are qualified.

530. The response to the FAQ "**Erectile Dysfunction: Can pomegranate juice benefit men with erectile dysfunction?**" cited the Forest Erectile Dysfunction Study (2007), stating: "Initial results linking POM Wonderful 100% Pomegranate Juice and erectile performance are promising. In a soon-to-be-published clinical study on men with erectile dysfunction, the group who consumed 8oz. of POM Juice daily experienced better erectile performance than the group who drank a placebo." (CX0473 (Compl. Ex. E-8 at 9:05)).

Response to Finding No. 530:

It is undisputed that, in April 2009, the pompills.comwebsite had a link to a page titled, "FAQs." To the extent the ALJ considers this, neither the question itself ("Erectile Dysfunction: Can pomegranate juice benefit men with erectile dysfunction?") or the summary afterwards make establishment claims. To the contrary, the question is just a question; and the summary is highly qualified: "Initial results linking POM Wonderful 100% Pomegranate Juice and erectile performance are promising. …" Further, this summary makes it clear that POMx is from a juice, a natural fruit product. Thus it is not being marketed as a drug.

531. The response to the FAQ "**Why are pomegranates and pomegranate juice so healthy?**" assured consumers that "Today, modern science confirms that the pomegranate is truly a medical marvel." (CX0473 (Compl. Ex. E-8 at 8:45) (emphasis added)).

Response to Finding No. 531:

It is undisputed that, in April 2009, the pompills.comwebsite had a link to a page titled, "FAQs." To the extent the ALJ considers this, neither the question itself ("Why are pomegranates and pomegranate juice so healthy?") nor the response make establishment claims. (CX0473 (Compl. Ex. E-8 at 8:45). The question certainly does not – it is just a

question, and it asks only, why are the fruit and the juice so healthy? The response, when considered in its entirety, makes it clear that POM is not claiming that pomegranates or pomegranate juice cure, treat or prevent disease. Rather, the response makes it clear that POM is talking generally about pomegranates' antioxidant content and the fact that "emerging science suggests" that antioxidants in pomegranates "help guard against free readicals which can aggressively destroy healthy cells." (*Id.*) Complaint Counsel has taken a sentence at the very end of the response and isolated it out of context. But when the whole context is revealed, it is clear that the sentence highlighted by Complaint Counsel is simply a way to emphasize that the history of pomegranates, which have been thought to have health benefits for thousands of years, may be borne out now by medical science: "As a matter of fact, the pomegranate has been celebrated in mythology, featured in fine art, and revered for its health benefits since the dawn of time. Today, modern science confirms that the pomegranate is truly a medical marvel." (*Id.*) Viewed in this context, it is clear no establishment claim is being made; and it is clear that the net impression of the FAQ and the answer is that pomegranates have antioxidants and health benefits like a very healthy fruit can.

532. Other FAQs repeatedly stressed the "extraordinary health benefits" of POMx and its polyphenol antioxidants. For example, in response to the FAQ, "**How long does it take for my system to get benefits of POMx?**" the response stated, "[b]ecause the polyphenol antioxidants in POMx are absorbed rapidly by the body, they can begin their healthy disease-fighting effects almost immediately. However, studies on POM Juice consumption have shown that it can take 1 to 2 years to see benefits." (CX0473 (Compl. Ex. E-8 at 10:34-10:53)).

Response to Finding No. 532:

It is undisputed that, in April 2009, the pompills.comwebsite had a link to a page titled, "FAQs." POM also objects to this proposed finding of fact as argumentative and misleading. To the extent that the ALJ considers this, the references to "extraordinary health benefits" of POMx, pomegranates, and antioxidants do not make establishment claims. (CX0473 (Compl. Ex. E-8 at 10:35). Rather, they tell the truth about

pomegranates and polyphenol antioxidants. For example, it is well-established that pomegranate juice has a unique form of antioxidants, and that these antioxidants have health benefits. (RFF 780-810). Furthermore, nothing on this page says that pomegranates or pomegranate juice cures, treats, or prevent diseases. Instead, the page says things like, "Research has shown that the naturally occurring polyphenol antioxidants in pomegranates have extraordinary health benefits like a very healthy fruit can." (CX0473 (Compl. Ex. E-8 at 10:35).

533. The response to the FAQ "**Dosage: How much POMx should I take?**," stated "Whether you choose pills or liquid, it is important to remember that to reap POMx's full health benefits, you must take it every day." (CX0473 (Compl. Ex. E-8 at 11:03)).

Response to Finding No. 533:

It is undisputed that, in April 2009, the pompills.comwebsite had a link to a page titled, "FAQs." To the extent that the ALJ considers this, the FAQ telling people to take POMx every day does not make a health claim. Instead, it reminds people that if they are to get health benefits POM is aware of, they have to take it every day. The FAX also that "there is no government Recommended Daily Intake or Daily Value established for pomegranate or polyphenol antioxidants. However, much of the preliminary medical research on the associated health benefits was done with a daily serving of 8oz of POM Wonderful 100% Pomegranate Juice. Since one POMx pill and one teaspoon of POMx liquid provide the antioxidant power of 8oz of POM Wonderful 100% Pomegranate Juice, our daily recommended serving is one pill or teaspoon." (CX0473 (Compl. Ex. E-8 at 11:01). The description of the research and "associated" health benefits is qualified; and the description makes it clear that POMx and POM Juice are both a healthy, fruit-based products. Thus, viewed in the context of the entire posting, the directive to take POMx every day does not convey the message that POMx Pills and POMx Liquid "prevent," "treat" or "reduce the risk" of certain disease; or that POMx Pills and POMx

Liquid are "clinically proven" to "treat," "prevent" or "reduce the risk" of certain diseases.

534. In January 2010, under the subheading "**Science Not Fiction**, the "**POMx Pills**" and "**POMx Liquid**" touted that the amount of money POM purportedly spent on medical research was $32 million." (CX0473 (Compl. Ex. E-9 at 00:16, 00:30)). This $32-million figure also appeared throughout the rest of pompills.com, including in the "**Medical Research**" section, the "**Research**," "**Antioxidant Benefits**," and "**Heart Health**" pages, and the "**About Us**" section of the website. (*See, e.g.,* CX0473 (Compl. Ex. E-9 at 00:36, 00:55, 01:01, 01:22, 02:12)).

Response to Finding No. 534:

It is undisputed that, in January 2010, there was a section on pompills.com titled, "POMx Pills," and a page in that section with the title line, "Take it daily. Feel it forever." (CX0473 (Compl. Ex. E-9 at 00:10-15). On that page, there was a heading titled, "Science, Not Fiction." It is also undisputed that throughout the website (and including under the heading "Science, Not Fiction") in January 2010, POM stated it spent $32million on medical research. (*See, e.g.,* CX0473 (Compl. Ex. E-9 at 00:15, 00:36). But these statements do not make "treat," "prevent," or "reduce the risk" claims about any particular disease because do not say or imply that any of the scientific research says any tests or studies show a particular fact. Rather, all the statements say is that "the antioxidants in POMx are supported by $32 million in initial scientific research …" and similar things. The fact that POM advertised the amount of money Respondents spent on scientific research does not convey the net impression that the Challenged Products are "clinically proven to prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction." (RFF 2507-19) What this "backed by" ad actually conveys is that Respondents are committed to the science and to learning the truth about pomegranates. Contrary to Complaint Counsel's implication, it is completely illogical to infer from the fact that a certain amount of money was invested in research, the conclusion that the Challenged Products are proven to prevent, treat or reduce the risk of disease. Again, this is another one of Complaint Counsel's ill-defined, "logical leaps" from "backed by $32

million of initial scientific research" to "backed by $32 million in research that proved the Challenged Products prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction." Indeed, Complaint Counsel presented no evidence that consumers took away the message presumed by Complaint Counsel because Respondents spent a certain amount of money on science and research. (RFF 28-29, 2515). Moreover, the "backed by" ads accurately and truthfully represented the dollars spent by Respondents on the totality of the science on the Challenged Products. (RFF 2510). Further, these ads are immaterial because there is no evidence that anyone bought the Challenged Products because they thought Respondents spent a certain amount of money in a particular area of research. Indeed, Professor Reibstein's survey showed the opposite: that no one bought POM Juice because of the amount of money spent on science. (RFF 2656).

535. The pompills.com website, through textual references, graphs, and medical imagery, touts the "medical benefits" of POMx Pills and POMx Liquid, and POM's research on heart disease, prostate cancer, and erectile dysfunction, and other health conditions. The pompills.com website conveys the net impression that taking one POMx Pill or one teaspoon of POMx Liquid, daily, treats, prevents, or reduces the risk of heart disease, prostate cancer, and erectile dysfunction, and that these health benefits are clinically proven. In addition, in representing that one POMx Pill or one teaspoon of POMx Liquid is equivalent to eight ounces of POM Juice, the pompills.com website also conveys the net impression that drinking eight ounces of POM Juice, daily, treats, prevents, or reduces the risk of heart disease, prostate cancer, and erectile dysfunction. (*See* CCFF ¶¶ 501-534).

Response to Finding No. 535:

Contrary to what Complaint Counsel contend, the net impression conveyed by pompills.com is not that taking one POMx Pill or one teaspoon of POMx Liquid or drinking one 8oz serving of POM treats," "prevents," or "reduces the risk" of heart disease, prostate cancer, erectile dysfunction, and other health conditions. Instead, the net impression of this site is that POMx is wholly derived from the pomegranate fruit; that POMx is nutritionally equivalent to the POM Juice; that POM invested up to $32 million in scientific research on the Challenged Products; that the Challenged Products

may have promising health benefits; that the Challenged Products have polyphenol antioxidants in them; and that the Challenged Products are healthy and may be beneficial for certain medical conditions, together with conventional medical care. To the extent a "reduce the risk" claim can be implied from the site, the overall net impression is not that taking one OMx Pill a day or one teaspoon of POMx Liquid a day "reduces the risk" of certain diseases, like a drug with a single target of action, but that it may help "reduce the risk," like many other whole foods, or like an especially healthy fruit or vegetable, or like a healthy diet of fruits and vegetables and exercise "reduce the risk" of disease. Finally, the net impression is not that POMx or POM Juice is a drug. Rather, POM Juice and POMx are food products, wholly derived from the pomegranate fruit. The fact that the Challenged Products are wholly- derived from the pomegranate fruit is heavily emphasized in the body copy and the visual imagery on the site as well as on the products themselves. Accordingly, the net impression of the ads is that POM Juice and POMx are healthy and good for you, as well as that they are food products derived wholly from the pomegranate.

6. Banner Ads Made Efficacy Claims Regarding Heart Disease and Prostate Cancer

a. "Heart Therapy" Banner Ad (CX0463)

536. In December 2008, POM disseminated an animated banner ad with the headline "Heart Therapy" depicting a bottle of POM Juice reclining on a couch, as in a therapist's office. The heart in the "POM" logo was animated to expand and contract, like a beating heart. The animation also included the sound effect of a beating heart. Under the image was the copy, "Backed by $25 million in medical research," with a link "Learn more" that directed the consumer to the pomwonderful.com website. (CX0463).

Response to Finding No. 536:

POM objects to the exhibit CX0463 because it is incomplete and impossible to verify whether what Complaint Counsel is saying about it is true. To the extent the ALJ considers this exhibit and this proposed finding of fact, from the incomplete copy of CX0463 it is possible to determine that there was an animated banner ad with the

headline "Heart Therapy" depicting a bottle of POM Juice lying on a couch, with a beating heart inside it. It is also possible to determine that the copy on this ad stated, "Heart Therapy" and "Backed by $25 million in medical research." However, there are no links on this ad. That said, this ad does not make an efficacy claim regarding heart disease; and none of the advertising is false or misleading. This ad makes no claim at all (let alone an efficacy claim); it merely says that $25 million in medical research has been spent on the product. This is not an establishment claim (*see, e.g.*, RRFF ¶ 444); and certainly, a claim that money was spent does not say anything about the efficacy of a product. The "Heart Therapy" tagline does not make any "efficacy" claim either. It is just a catchy phrase that, when viewed together with the bottle, personified as if it were a person on a therapist's couch, is non-actionable, cheeky, humorous puffery. *See, e.g., Sterling Drug,* 741 F.2d at 1150; *In re Thompson Medical,* 104 F.T.C. 648, 788-89 n. 6 (1984)). That said, and assuming *arguendo* that this banner ad did make an efficacy claim, the question would then be if it likely misled or deceived consumers. For example, in *Pantron I,* the court explained there was no question that the manufacturer claimed its hair loss product was effective; and so the only question was whether the representations about the product's effectiveness were likely to mislead or deceive consumers. *Pantron I, supra,* 33 F.3d at 1097. The inquiry then is whether there is a reasonable basis to support the claim. *F.T.C. v. QT, Inc.*, 448 F.Supp.2d 908, 959 (N.D. Ill. 2006); *Pantron I, supra,* 33 F.3d at 1097 ("[t]o prevail on its charge that defendant has misrepresented the efficacy of the 'Helsinki Formula,' the F.T.C. must prove that the product is wholly ineffective; *i.e.,* that it does not work at all."). Again, no such efficacy claim is made here; but it is true that in 2008 POM had spent over $25 million total in its medical research on pomegranates. (PX0367-69). And, it is true that the research to date – the "promising results" that Complaint Counsel refers to in CCFF ¶ 536 – were in fact promising and showed that pomegranate juice had health benefits. (PX0367-69). Finally, there is no evidence that consumers were deceived by this ad. Indeed, the only

evidence was to the contrary. Specifically, Dr. Reibstein's survey showed that very few consumers bought, would buy again, or recommend POM Juice because of a reason related to disease. (RFF 2623-2679).

537. In an internal document on "POM On-line Banner ads," from October 2008, copy points for a "Heart Therapy," banner ad included: "POM Wonderful 100% Pomegranate Juice is backed by $25 million in medical research with promising results for cardiovascular health," "Only our pomegranate juice has real, proven heart health benefits," and "Keep your heart healthy and drink a glass a day." The document also described the "close" of the ad as "Call to action to get consumer to click-through to learn more about POM Juice and heart health: http://www.pomwonderful.com/health_benefits." (CX0246_0002).

Response to Finding No. 537:

It is undisputed that CX0246 is an email with a "creative brief" for the on line banner ad "Heart Therapy," dated October 10, 2008. As Complaint Counsel admit, CX0246 is dated October 2008, but the online "Heart Therapy" banner ad in CX0463 is from a December 2008 web capture. (CCFF ¶ 537). The copy of CX0463 that Respondents have available to them does not contain any of the copy in CX0246 except the copy, "Backed by $25 million in medical research." (CX0463; CX0246). There was no evidence introduced during the case tying CX0246 to CX0463 and thus, with the exception of the phrase "Backed by $25 million in medical research," there is no evidence that any of the other copy points in CX0246 were intended to be communicated in CX0463, the text of CX0246 or was in fact used or seen by consumers in the banner ad at issue. In fact, Respondents introduced evidence that proves the only evidence of what the "Heart Therapy" ad claims or says is in the advertisements themselves, not the intent of the individuals involved in preliminary stages of development of this advertisement: There is only a tenuous relationship between creative briefs and final advertisement. The creative process was collaborative and fluid, with lots of people involved, which resulted in the final advertisement being vastly different than the rough idea initially discussed in the creative brief. (Perdigao, Tr. 609-14, 621-22, 2790-91; Leow, Tr. 458-59, 463-65; Tupper, Tr. 920, 929). Complaint Counsel's expert, Professor Stewart, even testified that

he did not know if any of the creative briefs had any effect on any advertisements and there was not any other evidence of any such effect. (Stewart, Tr. 3235).

538. The "Heart Therapy" banner ad, with the imagery and audio of the beating heart, "Heart Therapy" headline, and reference to "$25 million in medical research," conveys the net impression that POM Juice prevents or reduces the risk of heart disease. This net impression is even stronger if a consumer, as directed by the ad, were to click through to the pomwonderful.com website section on "Health Benefits." (*See* CCFF ¶¶ 536-37).

Response to Finding No. 538:

The "Heart Therapy" banner ad does not convey the net impression that POM Juice "prevents" or "reduces the risk" of heart disease, nor does it make an efficacy claim. As an initial matter, all the ad states is "Backed by $25 million in medical research." (CX0463). This copy does not say or imply that POM Juice "prevents" or "reduces the risk"of heart disease; at best, it says that POM Juice is supported by $25 million in medical research. (*Id.;* RFF 2507-19; Respondents' Post-Trial Br. at 76-77.) What this "backed by" ad actually conveys is that Respondents are committed to the science and to learning the truth about pomegranates. (RFF 271, 273, 275). Contrary to Complaint Counsel's implication, it is completely illogical to infer from the fact that a certain amount of money was invested in research the conclusion that the Challenged Products are proven to prevent or reduce the risk of disease. Again, this is another one of Complaint Counsel's ill-defined, "logical leaps." Indeed, Complaint Counsel presented no evidence that consumers took away the message presumed by Complaint Counsel because Respondents' spent a certain amount of money on science and research. (RFF 28-29, 2515). Moreover, the "backed by" ads were not misleading and accurately and truthfully represented the dollars spent by Respondents on the totality of the science on the Challenged Products. (RFF 2510).). This ad and the tagline "heart therapy" conveys something that is good for your heart in a humorous manner. (McLaws, Dep. at 139; D. Stewart, Tr. at 3205).

b. "I'm Off to Save Prostates" Banner Ad (CX0466)

539. In February 2009, POM disseminated an animated banner ad with the headline "HURRY! Prostates everywhere are in danger!" showing the POM Juice bottle flying like a super hero, then landing and announcing "I'm off to save PROSTATES!" The banner also displayed the copy "The Antioxidant Superpower," and a link to "Learn more." (CX0466).

Response to Finding No. 539:

POM objects to this proposed finding of fact because CX0466 does not contain the banner ad at issue. Assuming however that Complaint Counsel is referring to the banner ad contained in CX0468 (and not CX0466 as written in their proposed findings of fact, which is not a banner ad), it is undisputed that there was a banner ad with the headlines "HURRY! Prostates everywhere are in danger!" showing the POM Juice bottle flying like a superhero and announcing "I'm off to save PROSTATES!" It is also undisputed that the copy "The Antioxidant Superpower" and a link to "Learn more" appeared. However, this banner ad does not make an efficacy claim. Nowhere does it state or imply that POM Juice will "prevents" or "reduces the risk" of prostate disease. This ad was not intended to mean that POM Juice would treat prostate cancer. (L. Resnick, Tr. 217-18; CX 1426_0009). To the contrary, the ad was humorous and, as Dr. Butters testified, these "superpower" ads were intended to be a "work of fiction" in that they are personifying the pomegranate bottle by comparing the bottle to a superhero. (Butters, Tr. 2906). Similarly, Dr. Butters concluded that none of Respondents' advertisements stated explicitly or implied that any of the Challenged Products actually prevented, cured, or treated disease. (RFF 183-184). Finally, the ad here was truthful and adequately supported by competent and reliable scientific evidence. (RFF 2525).

540. This banner ad, with its animated copy of "HURRY! Prostates everywhere are in danger!" and "I'm off to save PROSTATES!" conveys the net impression that POM Juice prevents or reduces the risk of prostate cancer. This net impression is amplified if a consumer, as directed by the ad, were to click through to the pomwonderful.com website. (*See* CCFF ¶ 539).

Response to Finding No. 540:

The net impression of the banner ad at issue is not that POM Juice "prevents" or "reduces prostate cancer." Indeed, this ad does not state, expressly or impliedly, that POM pomegranate juice "prevents" or "reduces the risk" of prostate cancer. Rather, the ad conveys a general health message, that the Juice is good for your health generally and / or promotes a healthy prostate. Furthermore, as Complaint Counsel acknowledges, the ads are made in a cute, cartoonish "comic book-themed animation" style (CCFF 443) that portrays the POM bottle as a superhero, and the ad taglines appear in comic style font and in dialogue bubbles. These kinds of advertisements were intended to be hyperbolic, humorous cheeky puffery, and that is not actionable. *See, e.g., Sterling Drug, Inc. v. F.T.C.,* 741 F.2d 1146, 1150 (9th Cir. 1984); *In re Thompson Medical,* 104 F.T.C. 648, 788-89 n. 6 (1984)). Rather, as Dr. Butters testified, these ads were intended to be "a work of fiction" in that they are personifying the pomegranate bottle by comparing the bottle to a superhero. (Butters, Tr. 2906). Thus, the net impression is that of a good-humored ad that is cheeky and fun, and which grabs your attention, letting you know that POM Juice is good for your prostate health.

F. Health Claims in Public Relations Communications

1. POM's Press Releases Made Establishment Claims Regarding Heart Disease, Prostate Cancer, and Erectile Dysfunction

a. January 2003 Press Release (CX0013_0002-05)

541. POM issued a press release in January 2003 titled "Consumer Demand for POM Wonderful's Refrigerated All-Natural Pomegranate Juice Grows as the Health Benefits of Pomegranate Juice Become Recognized" with the subtitle "Scientific support indicates that drinking pomegranate juice provides the body with an active source of antioxidants and shows promise against cardiovascular disease." (CX0013_0002).

Response to Finding No. 541:

It is undisputed that in January 2003, POM issued a press release titled, "Consumer demand for POM Wonderful's refrigerated all-natural pomegranate juice grows as the

health benefits of pomegranate juice become recognized." This press release does not convey that drinking 8 ounces of OM Juice "treats, "prevents" or "reduces the risk" of certain diseases such as heart disease, prostate cancer, and/or erectile dysfunction. Rather, the press release emphasizes that POM Juice contains abundant naturally occurring antioxidants and describes "general antioxidant effects" that guard against free radicals, and emphasizes a truth: That pomegranates have more antioxidants that other juices due to the polyphenols it contains. (CX0013_002). Further, the press release repeatedly qualifies the potential health benefits of POM Juice. For example, the release says, "Antioxidants may be useful in counteracting premature aging, Alzheimer's, and cancer," and that "antioxidants found in pomegranate juice may also be more important than previously thought in promoting optimum cardiovascular health." (*Id.*)

542. The press release touted that "the antioxidant activity of POM Wonderful pomegranate juice exceeds that of other popular beverages known for their antioxidant properties" and "antioxidants may be useful in counteracting premature aging, Alzheimer's, and cancer." (CX0013_0002).

Response to Finding No. 542:

It is undisputed that in January 2003, POM issued a press release titled, "Consumer demand for POM Wonderful's refrigerated all-natural pomegranate juice grows as the health benefits of pomegranate juice become recognized." This press release does not convey that drinking 8 ounces of OM Juice "treats, "prevents" or "reduces the risk" of certain diseases such as heart disease, prostate cancer, and/or erectile dysfunction. Rather, the press release emphasizes that POM Juice contains abundant naturally occurring antioxidants and describes "general antioxidant effects" that guard against free radicals, and emphasizes a truth: That pomegranates have more antioxidants that other juices due to the polyphenols it contains. (CX0013_002). Further, the press release repeatedly qualifies the potential health benefits of POM Juice. Indeed, the particular statement at issue in this proposed finding of fact is qualified and does not make an

establishment claim: "Antioxidants may be useful in counteracting premature aging, Alzheimer's, and cancer." (*Id.*)

543. Noting that "cardiovascular diseases rank as America's No. 1 killer," the press release stated that "[m]edical research shows that daily consumption of just 1.5 mmol of polyphenols from pomegranate juice (the equivalent of an 8 fl oz serving of P♥M Wonderful pomegranate juice) confers heart health benefits by lessening factors that contribute to atherosclerosis (plaque in the arteries)." (CX0013_0002).

Response to Finding No. 543:

It is undisputed that in January 2003, POM issued a press release titled, "Consumer demand for POM Wonderful's refrigerated all-natural pomegranate juice grows as the health benefits of pomegranate juice become recognized." This press release does not convey that drinking 8 ounces of OM Juice "treats, "prevents" or "reduces the risk" of certain diseases such as heart disease, prostate cancer, and/or erectile dysfunction. Rather, the press release emphasizes in qualified language that drinking POM Juice may "confer" benefits because the "antioxidants found in pomegranate juice may also be more important … in promoting optimum cardiovascular health." To the extent a "reduce the risk" claim can be implied from this press release, the overall net impression is not that drinking eight ounces of POM Juice "reduces the risk" of certain diseases, such as heart disease like a drug with a single target of action, but that it may help "reduce the risk," like many other whole foods, or like an especially healthy fruit or vegetable, or like a healthy diet of fruits and vegetables and exercise "reduces the risk" of disease.

544. The press release presented, among other research, the results of the Aviram ACE/BP Study (2001), a "human study show[ing] that consuming pomegranate juice reduce[d] . . . ACE." Explaining that "[i]nhibition of ACE lessens the progression of atherosclerosis," the press release stated that "[p]omegranate juice inhibited ACE by 36% after two weeks of juice consumption." (CX0013_0003).

Response to Finding No. 544:

It is undisputed that in January 2003, POM issued a press release titled, "Consumer demand for POM Wonderful's refrigerated all-natural pomegranate juice grows as the

health benefits of pomegranate juice become recognized." This press release does not convey that drinking 8 ounces of OM Juice "treats, "prevents" or "reduces the risk" of certain diseases such as heart disease, prostate cancer, and/or erectile dysfunction. Rather, the portion of the press release at issue in this proposed finding of fact simply summarizes the results of a particular study. The study results must be viewed in the context of the entire press release, which makes it clear that the studies "indicate" with qualified language that "drinking pomegranate juice provides the body with … antioxidants," a known health benefits, and that "may be useful" in counteracting certain diseases and which "shows promise against cardiovascular disease." To the extent a "reduce the risk" claim can be implied from this press release, the overall net impression is not that drinking eight ounces of POM Juice "reduces the risk" of certain diseases, such as heart disease like a drug with a single target of action, but that it may help "reduce the risk," like many other whole foods, or like an especially healthy fruit or vegetable, or like a healthy diet of fruits and vegetables and exercise "reduces the risk" of disease.

545. The press release neither disclosed that Respondents sponsored the Aviram ACE/BP Study (2001) nor Respondents' relationship with Dr. Aviram. (CX0013).

Response to Finding No. 545:

It is undisputed that in January 2003, POM issued a press release titled, "Consumer demand for POM Wonderful's refrigerated all-natural pomegranate juice grows as the health benefits of pomegranate juice become recognized." Although the press release does not explicitly state that Respondents sponsored the study by Dr. Aviram summarized in the press release, it is clear from the "Editor's Note" that copies of the medical research were available from POM upon request, and citations to the articles were provided. The relationship between POM and the studies is not actively concealed. Further, POM has never interfered with the way that the studies were conducted or the

results of the studies; or whether the studies get published or not. (*See, e.g.*, RRF 381, 383, 441, 442).

546. The press release included a link to the pomwonderful.com website. (CX0013_0004).

Response to Finding No. 546:

It is undisputed that in January 2003, POM issued a press release titled, "Consumer demand for POM Wonderful's refrigerated all-natural pomegranate juice grows as the health benefits of pomegranate juice become recognized." Contrary to what Complaint Counsel contend, the press release does not include a link to the website but it invites readers to go to the website pomwonderful.com to learn more about the company POM Wonderful LLC and its products.

547. Ms. Posell noted that this 2003 press release was timed "to coincide and support [POM's] marketing efforts in Southern California" and that "[i]t communicates two critical consumer messages – that pomegranate juice contains more antioxidants than other beverages that are typically considered to be high in antioxidants and – that drinking pomegranate juice daily confers heart health benefits by lessening factors that contribute to atherosclerosis (plaque in the arteries)." (CX0013_0001).

Response to Finding No. 547:

It is undisputed that in January 2003, Ms. Posell wrote an email in which she attached the press release referred to in CCFF ¶¶ 541-548. However, Ms. Posell did not circulate this email to anyone other than Respondents. The press release does not convey that drinking 8 ounces of OM Juice a day "prevents," "treats" or "reduces the risk" of certain diseases, such as heart disease, prostate cancer, and/or erectile dysfunction. In this email, Ms. Posell focused on the antioxidant properties of pomegranate juice (which are well-known); and she stated that the consumer benefit is that drinking pomegranate juice confers heart health benefits by lessening factors that contribute to atherosclerosis. To the extent that it might be implied from this email that it was POM's intent to somehow communicate a "reduce the risk" claim to consumers, the overall net impression is not

that drinking POM Juice "reduces the risk" of certain diseases, such as heart disease, prostate cancer or erectile dysfunction like a drug with a single target of action, but that it may help "reduce the risk," like many other whole foods, or like an especially healthy fruit or vegetable, or like a healthy diet of fruits and vegetables and exercise "reduces the risk" of disease. This is particularly clear from the press release itself, which is phrased in qualified language. (RRFF 541-546).

548. The net impression of this press release is that drinking 8 ounces of POM Juice daily treats, prevents, or reduces the risk of heart disease, including by reducing arterial plaque, and a clinical study proves this effect. (CCFF ¶¶ 541-47).

Response to Finding No. 548:

The net impression of this press release is not that drinking 8 ounces of POM Juice daily "treats," "prevents" or "reduces the risk" of disease. Rather, the net impression is that drinking POM Juice contributes to a healthy lifestyle and that POM Juice contains abundant naturally occurring antioxidants that may help guard your body against free radicals. Drinking it therefore it may help "reduce the risk," like many other whole foods, or like an especially healthy fruit or vegetable, or like a healthy diet of fruits and vegetables and exercise "reduces the risk" of disease.

b. September 2005 Press Release (CX0044)

549. POM issued a press release in September 2005 titled "Pomegranate Juice May Affect the Progression of Coronary Heart Disease," which highlighted the results of the Ornish MP Study (2005). The release further stated, "Men and women with coronary heart disease who drink one glass of pomegranate juice daily may improve blood flow to their heart, according to a new study." (CX0044_0001).

Response to Finding No. 549:

It is undisputed that, in September 2005, POM issued a press released titled, "Pomegranate Juice May Affect the Progression of Coronary Heart Disease." However, this press release does not convey that drinking 8 ounces of POM Juice daily "treats," "prevents" or "reduces the risk" of certain diseases, such as heart disease, prostate cancer,

and/or erectile dysfunction. This is clear even from the title, which is phrased in qualified terms: pomegranate juice "May Affect" coronary heart disease. (CX0044_0001; Posell, Tr. at 391). It is also apparent from the sentence Complaint Counsel quotes here to support their assertions: "Men and women who drink one glass of pomegranate juice daily may improve blood flow to their heart…" (CX0044_0001; Posell, Tr. at 391). This statement, which is qualified, also says nothing about heart disease, it only mentions blood flow. This is another example of one of Complaint Counsel's illogical leaps – possibly improving blood flow is not claim that POM Juice "treats," "prevents" or "reduces the risk" of heart disease. Furthermore, the language used in the press release accurately and truthfully summarized the study at issue; and Respondents had competent and reliable scientific evidence to support the statements made therein. (RRF 2496, 2497).

550. The press release presented the Ornish MP Study (2005) as "the first randomized, double-blind, placebo-controlled trial showing that pomegranate juice may affect the progression of coronary heart disease, which is the #1 cause of death in the U.S. and in most of the world" and that "results . . . [would] be published in . . . the American Journal of Cardiology, one of the leading peer-reviewed cardiology journals." (CX0044_0001).

Response to Finding No. 550:

It is undisputed that, in September 2005, POM issued a press released titled, "Pomegranate Juice May Affect the Progression of Coronary Heart Disease." It is also undisputed that the Ornish MP Study was in fact published in the American Journal of Cardiology, which is one of the leading peer-reviewed cardiology journals. However, this press release (and the fact of where it was published) does no convey that drinking 8 ounces of POM Juice daily "treats," "prevents" or "reduces the risk" of certain diseases, such as heart disease, prostate cancer, and/or erectile dysfunction. As set forth above, the results of the studies are couched in qualified terms. (RRFF 549). Furthermore, the language used in the press release accurately and truthfully summarized the study at

issue; and Respondents had competent and reliable scientific evidence to support the statements made therein. (RRF 2496, 2497).

551. The press release reported the results of the Ornish MP Study (2005) as a statistically-significant improvement of approximately 17% in the pomegranate juice group and a worsening of approximately 18% in the comparison group, the equivalent of a 35% "relative between-group difference." (CX0044_0001).

Response to Finding No. 551:

It is undisputed that, in September 2005, POM issued a press released titled, "Pomegranate Juice May Affect the Progression of Coronary Heart Disease." However, this press release does not make any establishment claims regarding heart disease, prostate cancer, and/or erectile dysfunction and the press release itself is not seen by consumers. Moreover, as set forth above the results are couched in qualified terms. (RRFF 549). Furthermore, the language used in the press release accurately and truthfully summarized the study at issue; and Respondents had competent and reliable scientific evidence to support the statements made therein. (RRF 2496, 2497). This included the statistical results that are described here in Complaint Counsel's proposed finding of fact 551.

552. Dr. Ornish, identified as senior author of the study, founder of the Preventive Medicine Research Institute, and clinical professor of medicine at UCSF, is quoted as stating, "pomegranate juice may have important clinical benefits in those with coronary heart disease" and that "[a]lso, it may help to prevent it." (CX0044_0002).

Response to Finding No. 552:

It is undisputed that, in September 2005, POM issued a press released titled, "Pomegranate Juice May Affect the Progression of Coronary Heart Disease." It is also undisputed that Dr. Ornish is quoted in the press release at issue. However, this press release – and Dr. Ornish's quote – does not make any establishment claims regarding heart disease. As set forth above the results are couched in qualified terms. (RRFF 549). In fact, even Dr. Ornish states the results in qualified terms, noting that the study was

"relatively small" and saying only that "pomegranate juice may have important clinical benefits for those with coronary heart disease," and it "may prevent it." (CX0044_0002). This is not a claim that the product prevents, treats or reduces the risk of disease like a drug..

553. The press release stated that "[p]omegranate juice from POM Wonderful was used in this study." (CX0044_0002). It also provided a link to the pomwonderful.com website. (CX0044_0002).

Response to Finding No. 553:

It is undisputed that, in September 2005, POM issued a press released titled, "Pomegranate Juice May Affect the Progression of Coronary Heart Disease." However, POM fully disclosed its participation in the study: POM's Juice was used in the study and it was made clear to readers; and it is clear from the "Editor's Note" that copies of the medical research were available from POM upon request, and citations to the articles were provided. Contrary to what Complaint Counsel contend, the press release does not include a link to the website but it invites readers to go to the website pomwonderful.com to learn more about the company POM Wonderful LLC and its products. (CX0044_0002).

554. The press release did not disclose that POM had funded the Ornish MP Study (2005), and Ms. Posell noted in an email concerning this release that "we never cite the source of funding nor do we link the Resnicks to POM in press releases." (CX0044_0001). Ms. Posell also stated that she did not know "why [POM] would have issued [the press release] at all if [it] hadn't stated that the researchers used POM Wonderful pomegranate juice. This would not have been in POMs best interests." (CX0044_0001).

Response to Finding No. 554:

It is undisputed that, in September 2005, POM issued a press released titled, "Pomegranate Juice May Affect the Progression of Coronary Heart Disease." However, POM fully disclosed its participation in the study: POM's Juice was used in the study and it was made clear to readers in the study that POM Wonderful juice was used in the

study; it is clear also from the "Editor's Note" that copies of the medical research were available from POM upon request, and citations to the articles were provided. The relationship between POM and the studies is not concealed. Further, POM has never interfered with the way that the studies were conducted or the results of the studies; or whether the studies get published or not. (See, e.g., RRF 381, 383, 441, 442). Contrary to what Complaint Counsel contend, the press release does not include a link to the website but it invites readers to go to the website pomwonderful.com to learn more about the company POM Wonderful LLC and its products. (CX0044_0002). Finally, it should be noted that Complaint Counsel complain when POM does not directly (but does so indirectly) disclose its participation in the studies at issue in the press releases (*see, e.g.,* CCFF 545), and it also complains when POM does disclose its participation. (*See, e.g.,* CCFF 553). This highlights Complaint Counsel's illogical attempts to find POM liable in this case.

555. The net impression of this press release is that drinking 8 ounces of POM Juice daily treats, prevents, or reduces the risk of heart disease, including by improving blood flow to the heart, and clinical studies, research, or trials prove these effects. (CCFF ¶¶ 549-54).

Response to Finding No. 555:

The net impression of this press release is not that drinking 8 ounces of POM Juice daily treats, prevents or reduces the risk of heart disease. Rather, the net impression is that drinking POM's Juice contributes to a healthy diet and that the Juice contains abundant naturally occurring antioxidants that may help guard your body against free radicals. Drinking it therefore, at most, may help improve your odds of "reducing the risk" against disease like many other whole foods, or like an especially healthy fruit or vegetable, or like a healthy diet of fruits and vegetables and exercise "reduces the risk" of disease.

c. July 2006 Press Release (CX0065)

556. A press release POM issued in July 2006, titled "POMx, a Highly Concentrated Form of Healthy Pomegranate Antioxidants, Becomes Available to Consumers for the First Time," discussed research published by the American Association for Cancer Research

"indicat[ing] that a daily pomegranate regimen has a positive effect for men with prostate cancer" and that

[s]pecifically, drinking 8 ounces of P♥M Wonderful pomegranate juice daily prolonged post-prostate surgery PSA doubling time from 15 to 54 months (*Clinical Cancer Research, July 1, 2006*). PSA is a protein marker for prostate cancer and the faster PSA levels increase in the blood of men after treatment, the greater their potential for dying of prostate cancer.

(CX0065_0002).

Response to Finding No. 556:

It is undisputed that in July 2006, POM issued a press released titled, "POMx, a highly concentrated form of healthy pomegranates antioxidants, becomes available to consumers for the first time." It is also undisputed that this press release discussed the Pantuck Phase II Prostate Cancer Study (2006), referred to in the press release as research published by the American Association for Cancer Research. And, it is undisputed that the press release accurately summarized the fact that PSA is a protein marker for prostate cancer, and that drinking 8 ounces of POM's Juice prolonged post-prostate surgery doubling time. However, this press release, which did not go directly to consumers, also announces the release of POMx, defined as "an important natural ingredient" and a "concentrated form of pomegranate antioxidants." These are true statements, as POMx is made from Wonderful pomegranates, it has antioxidants, and the health benefits and importance of antioxidants are well established. (*See, e.g.,* RFFs 745-810). The emphasis on the fruit, and naturally occurring antioxidants, counters any "drug" connotations. Furthermore, any health benefits from POMx or pomegranate juice generally are couched in qualified language. For example, Professor Aviram is quoted as saying that POMx is as potent an antioxidant as pomegranate juice…and may protect against cardiovascular as well as other diseases." This a broad establishment claim that the product will prevent, treat or reduce the risk of disease, or do so like a drug.

557. The press release also quoted Dr. Heber, identified as "Professor of Medicine and Director, UCLA Center for Human Nutrition," as stating, "[b]asic studies indicate that

the effects of POMx and POM Wonderful pomegranate juice on prostate cancer are the same. The most abundant and most active ingredients in pomegranate juice are also found in POMx." (CX0065_0002).

Response to Finding No. 557:

It is undisputed that in July 2006, POM issued a press released titled, "POMx, a highly concentrated form of healthy pomegranates antioxidants, becomes available to consumers for the first time." It is also undisputed that this press release quotes Dr. David Heber. However, this press release – and Dr. Heber's quote – do not make any establishment claims regarding heart disease, prostate cancer, and/or erectile dysfunction. To the contrary, Dr. Heber's quote says only that POMx's effects are the same as the effects of pomegranate juice on prostate cancer. The paragraph above describes the results of the Pantuck Phase II Study as indicating that "a daily pomegranate regimen has a positive effect for men with prostate cancer" and that PSA doubling time increased. This is not an establishment claim, but rather, a qualified statement accurately describing the results of an RCT study. Finally, the press release makes it clear that the men studied in the study had undergone traditional, medical treatment for prostate cancer, and that they did not substitute pomegranate juice or POMx for conventional medical care. Rather, it states clearly that drinking POM's Juice together with getting surgery "prolonged post-prostate surgery PSA doubling time." (CX0065_002). No broad claim is made that the product will treat, prevent or reduce the risk of disease.

558. Ms. Glovsky testified that Dr. Heber "ha[d] been around the supplement market for a long time," and that "sometimes you'll have a product and you want to use a physician, a professor's name, that . . . helps give it credibility." (CX1347 (Glovsky, Dep. at 93)).

Response to Finding No. 558:

Undisputed that Ms. Glovsky testified as quoted. However, Dr. Heber believes in the health benefits of pomegranates and the antioxidants in them. (RFF 783-87). Dr. Heber believes that POMx, like pomegranate juice, may help "reduce the risk," like many other

whole foods, or like an especially healthy fruit or vegetable, or like a healthy diet of fruits and vegetables and exercise "reduces the risk" of disease. (RFF 783-87).

559. In an email pertaining to this press release, Ms. Posell wrote, "[t]his press release supports our overall strategy to explain the power of the Wonderful variety of pomegranate and to announce that we have developed POMx which is a new and healthy alternative to [POM Juice]. We need news, and this press release has it!! I use the prostate cancer study to substantiate our statements about POMx." (CX0062_0001).

Response to Finding No. 559:

POM objects to this proposed finding of fact as lacking foundation, misleading and improper, and mischaracterizing the evidence. Complaint Counsel has characterized the email in CX0062 as "an email pertaining to this press release." (CCFF 559). But the email in CX0062 is dated 7 days before the actual press release in CX0065; and the email in CX0062 refers to a "draft of the proposed press release about POMx," and purportedly attaches it – yet there is no attachment. Thus the email may or may not pertain to the press release in CX0065 – but it could pertain to an earlier draft that does not say what CX0065 says. To the extent that the ALJ considers this proposed finding, however, the email at CX0062 simply states that POM has developed POMx, a new and healthy alternative to pomegranate juice, and it states that the statements about POMx are substantiated by the Pantuck Phase II study. (CX0062). This is true; and the statements in CX0065 accurately summarized the Pantuck Phase II study. (RFF 2486, 2487). The press release supports an overall strategy to explain the antioxidant power of the Wonderful variety of pomegranates, a "great fruit". (Posell, Tr. 373).

560. Referring to a 2006 study on POMx, the press release also quoted Dr. Aviram as stating, "[t]he results showed that P♥Mx is as potent an antioxidant as pomegranate juice and just like pomegranate juice may protect against cardiovascular as well as other diseases." (CX0065_0001). The press release did not disclose that this 2006 study was on mice. (CX0062; CX0787_0002).

Response to Finding No. 560:

It is undisputed that the press release referred to herein quotes Dr. Aviram. However, there is no evidence that this press release – and Dr. Aviram's quote – went to consumers and did not make any braod claims regarding heart disease, prostate cancer, and/or erectile dysfunction. To the contrary, Dr. Aviram's quote is phrased in qualified language, and calls out the known antioxidant benefits of pomegranates: "The results showed that POMx is as potent an antioxidant as pomegranate juice, and just like pomegranate juice may protect against cardiovascular as well as other diseases." (CX0065_0001). To the extent that Complaint Counsel is complaining about the 2006 study being done on mice, that fact is undisputed. However, simply because the study is done on mice does not mean it is not relevant or that it does not have implications for human health. Finally, the language quoted in the press release accurately and truthfully summarized the 2006 Aviram Study and at the time the representations were made, Respondents had competent and reliable scientific evidence to support the statements made. (RFF 2500, 2501).

561. Ms. Glovsky testified that she believed the July 2006 press release was "premature" because no POMx product was available for purchase yet. (CX1347 (Glovsky, Dep. at 91)).

Response to Finding No. 561:

Undisputed that Ms. Glosky testified as cited. However, the statements in the press release, particularly those quotes from Dr. Aviram and Dr. Heber, are accurate.

562. The net impression of this press release is that drinking 8 ounces of POM Juice or taking one POMx Pill daily, treats prostate cancer by prolonging PSADT, and prevents or reduces the risk of heart disease, and clinical studies, research, or trials prove this effect. (CCFF ¶¶ 556-60).

Response to Finding No. 562:

Disputed. The net impression of this press release is not that drinking 8 ounces of POM Juice or taking on ePOMx Pill daily treats prostate cancer or prevents or reduces the risk of heart disease, or that clinical studies, research or trials prove this effect. To the contrary, the net impression is that drinking POM's Juice or taking POMx may be beneficial in the fight against prostate cancer like especially healthy fruits and vegetables may help fight the disease or improve your odds against disease. The press release is clear that these products contain abundant naturally occurring antioxidants that may help "reduce the risk," like many other whole foods, or like an especially healthy fruit or vegetable, or like a healthy diet of fruits and vegetables and exercise "reduces the risk" of disease. The press release also makes it clear that POMx is for consumers who are "not seeking calories and sugars" associated with pomegranate juice.

d. June 2007 Press Release (CX0128)

563. POM issued a press release in June 2007 titled "POM Wonderful 100% Pomegranate Juice May Improve Mild to Moderate Cases of Erectile Dysfunction, Study Finds." (CX0128_0002). Presenting the Forest Erectile Dysfunction Study (2007), the press release stated, "[r]esearch shows 8 ounces a day of POM Wonderful 100% Pomegranate Juice may help the management of erectile dysfunction" and "[a]ccording to a pilot study released in the *International Journal of Impotence Research* (http://www.nature.com/ijir), POM Wonderful 100% Pomegranate Juice was found to have beneficial effects on erectile dysfunction (ED), a disorder that affects 1 in 10 men worldwide and 10 to 30 million men in the United States alone." (CX0128_0002).

Response to Finding No. 563:

It is undisputed that, in June 2007, POM issued a press release titled, "POM Wonderful 100% Pomegranate Juice may improve mild to moderate cases of erectile dysfunction, study finds." However, this press release does not make any broad establishment claims regarding erectile function or dysfunction. To the contrary, the press release describes the results of the Forest Erectile Dysfunction Study (2007) using qualified language that made it clear the study was inconclusive and a pilot study: "Although the study did not

achieve overall statistical significance… the strong results of this pilot study are encouraging…" (CX0128_0003). Likewise, it is clear from the press release that pomegranate juice is not a treatment or cure (or even a stand alone preventative) for erectile dysfunction. Rather, the press release makes it clear that it is important for men with erectile problems to "maintain a healthy diet and exercise. Drinking pomegranate juice daily could be an important addition to the diete in the management of this condition." (CX0128_0004). Thus, like a healthy diet of fruits and vegetables and exercise, the press release makes it clear that drinking pomegranate juice could help manage this condition. (CX0128_0004). This is not an establishment claim that the product is clinically proven to treat, prevent or reduce the risk of disease.

564. The press release did not disclose that one of the study measures cited, the GAQ, was not validated to measure erectile dysfunction. (CX0128_0003).

Response to Finding No. 564:

It is undisputed that the global assessment questionnaire ("GAQ") is mentioned in the press release. Although the press release does not say that the GAQ is not recognized by the FDA, the GAQ is a single yes/no question that is informative, widely used, valuable to use in clinical studies, and commonly accepted as a standardized instrument among those conducting erectile dysfunction research. (RFF 1992-2002). In fact, the GAQ is used on all sexual medicine trials. (RFF 1999).

565. The press release quoted study co-author Dr. Harin Padma-Nathan, identified as Clinical Professor of Urology at the Keck School of Medicine, University of Southern California," as stating, "[t]hese findings are very encouraging as they suggest there is a non-invasive, non-drug way to potentially alleviate [ED] . . . . Drinking pomegranate juice daily could be an important addition to the diet in the management of this condition." (CX0128_0003-04).

Response to Finding No. 565:

It is undisputed that the June 2007 press release referred to in this proposed finding of fact quotes Dr. Harin Padma-Nathan as saying, "these findings are very encouraging as

they suggest there is a non-invasive, non-drug way to potentially alleviate this quality of life issue that affects so many men. For men with ED, it is important to maintain a healthy diet and exercise. Drinking pomegranate juice daily could be an important addition to the diet in the management of this condition." (CX0128_0004). This quote makes it especially clear that no broad establishment claims are being made in this press release – the language is preliminary, and qualified, and it stresses the potential role of pomegranate juice as part of a healthy diet. Thus, like a healthy diet of fruits and vegetables and exercise, the press release makes it clear that drinking pomegranate juice could help manage this condition. (CX0128_0004). This is not an establishment claim that the product is clinically proven to treat, prevent o reduce the risk of disease.

566. The press release included links to the pomwonderful.com and pompills.com websites. (CX0128_0004).

Response to Finding No. 566:

It is undisputed that, in the section of the June 2007 press release titled, "About POM Wonderful," there are links to pompills.com and pomwonderful.com.

567. The net impression of this press release is that drinking 8 ounces of POM Juice daily treats erectile dysfunction, and clinical studies, research, or trials prove this effect. (CCFF ¶¶ 563-65).

Response to Finding No. 567:

The net impression of this press release is not that drinking 8 ounces of POM Juice daily treats erectile dysfunction or that any clinical trials, studies or research prove this effect. Rather, the net impression is that a preliminary study indicates that drinking POM's Juice could be or may be an important addition to the diet in the management of this condition. Indeed, Dr. Padma-Nathan's quote makes this abundantly clear. (CX0128-0004).

2. In Media Appearances, Respondents Made Efficacy and Establishment Claims Regarding Heart Disease, Prostate Cancer, and Erectile Dysfunction

568. In her book *Rubies in the Orchard*, Mrs. Resnick wrote:

> In addition to being featured on all the great cooking shows, we have become a staple on the morning news, with pomegranate recipes and decorating tips, but above all with medical breakthroughs from POM Wonderful. You can't beat that kind of exposure for brand building, with credible, third-party endorsements – no matter how much money you spend.
>
> (CX0001_0026).

Response to Finding No. 568:

In addition to being featured on all the great cooking shows, we have become a staple on the morning news, with pomegranate recipes and decorating tips, but above all with medical breakthroughs from POM Wonderful. You can't beat that kind of exposure for brand building, with credible, third-party endorsements – no matter how much money you spend.

569. She also wrote that she had become acquainted with television host Martha Stewart and would send Ms. Stewart a case of pomegranates each year at the beginning of the harvest. Later, Ms. Stewart did a twelve-page spread on pomegranates in her magazine, *Martha Stewart Living*, and featured Mrs. Resnick on her television show touring the pomegranate orchards. (CX0001_0025; L. Resnick, Tr. 136-37).

b. November 2008 *The Martha Stewart Show* Interview with Lynda Resnick (CX0473 (Compl. Ex. E-6))

Response to Finding No. 569:

Respondents object to this finding of fact, as no such quote appears on page 0026 of exhibit CX0001. Similarly, although CX0001_0026 says it is page 128 of Mrs. Resnick's book, it is not page 128 of Mrs. Resnick's book, but rather, appears to be page 125 of her book. However, assuming that Complaint Counsel is referring to a similar quote on what appears to be page 125 of the actual book (and page CX0001_0025), Respondents respond as follows: it is undisputed that Mrs. Resnick wrote what is set forth in CCFF ¶

568. However, what Mrs. Resnick wrote does not make an establishment claim; indeed, it says nothing about heart disease, prostate cancer, or erectile dysfunction. Moreover, the above paragraph refers to brand building and credible third party endorsements. This has nothing to do with making establishment or efficacy claims. Additionally, what Mrs. Resnick wrote in her book is not actionable advertising. Indeed, Mrs. Resnick's book is meant for marketing professionals and not consumers per se.

570. In a television appearance on NBC's *The Martha Stewart Show* in November 2008, Lynda Resnick stated:

MRS. RESNICK: . . . But, the Wonderfuls are the [pomegranates] ones that we grow because they're the sweetest and they have the health benefits.

***

MRS. STEWART: But, the medical benefits even outweigh the mythical benefits?

MRS. RESNICK: Oh, they do, they do. I mean, it is the magic elixir of our age and of all ages, and we know that it helps circulation, it helps Alzheimer's, it helps all sorts of things in the body--

MRS. STEWART: Antioxidants.

MRS. RESNICK: Antioxidants. Polyphenol antioxidants off the chart.

MRS. STEWART: Right.

MRS. RESNICK: And if you know a man that you care about or you are a man, make him drink eight ounces of pomegranate juice a day because what it does for prostate cancer is amazing.

(CX0473 (Compl. Ex. E-6)).

Response to Finding No. 570:

POM objects to this proposed finding of fact because this is the first time it has been made aware that these are the statements at issue and under scrutiny by the FTC, and it has not had a full opportunity to defend itself. Respondents object to this finding of fact because Mrs. Resnick's appearance on the Martha Stewart Show is not actionable advertising as defined by the FTC in *In the Matter of R.J. Reynolds Tobacco Co., Inc.,* 111 F.T.C. 539 (1988). However, to the extent the ALJ considers it, the main purposes or

primary motivations for the interview given by Mrs. Resnick was not to sell POM products; and none of the statements "proposed a commercial transaction." Any statements by Mrs. Resnick on the Martha Stewart Show were her honest opinions in response to unsolicited questions posed by the interviewers and thus are protected by the First Amendment. (RFF ¶¶ 2548-2566). Further, Mrs. Resnick's reference to "medical benefits" of pomegranate juice during the course of her interview was strictly "reactive" and was directly in response to a question posed by Ms. Stewart. (CX 0473, (Compl. Ex. E-6); CX 1426, Ex. E-6). Finally, none of Mrs. Resnick's statements make establishment claims; nowhere does she say that pomegranate juice cures, treats or prevents heat disease, prostate cancer, or erectile dysfunction. At most, she says that drinking pomegranate juice "helps" "all sorts of things in the body" because it has "antioxidants." (CX0473 (Compl. Ex. E-6)). Pomegranates do in fact have antioxidants; and it is well-established that pomegranate juice has more antioxidants than other beverages. (RFF 785, 786-81). Mrs. Resnick's citation to the juice and antioxidants counters any "drug" connotations sought by Complaint Counsel.

571. The net impression of Mrs. Resnick's statements, including her response to Ms. Stewart's question about the "medical benefits" of POM, is that drinking 8 ounces of POM Juice a day treats, prevents, or reduces the risk of prostate cancer. (*See* CCFF ¶ 570).

c. June 2008 *Fox Business* Interview with Matthew Tupper (CX0473 (Compl. Ex. E-7))

Response to Finding No. 571:

The net impression of Mrs. Resnick's statements on Ms. Stewart's show and in her book concerning her appearance on Ms. Stewart's show is not that drinking 8 ounces of POM Juice a day treats, prevents or reduces the risk of prosate cancer or any other medical condition. Mrs. Resnick fully believes that the opinions she expressed in the interview were completely true. (L. Resnick, Tr. 156; CX 1375 (L. Resnick, Tropicana Dep. at 101); RFF ¶ 2560). Specifically, Mrs. Resnick stated that pomegranates have

antioxidants that can help all sorts of things in the body; and that 8 ounces of pomegranate juice "does" "amazing" things for prostate cancer. (CX0473 (Compl. Ex. E-6)). Thus the net impression is that Mrs. Resnick believes the fact that pomegranates have antioxidants in them that can help prostate cancer, not that pomegranates or POM's Juice can prevent or reduce the risk of prostate cancer. Further, the whole interview makes it clear that the net impression or focus is not even on the health benefits of pomegranates or POM's Juice, but on how to use and eat pomegranates and pomegranate juice (such as raw or in mixed drinks). (*Id.*) Even assuming *arguendo* that Mrs. Resnick's Martha Stewart interview constitutes "advertising" Complaint counsel has presented no evidence that showed any causal relationship between this interview and consumer purchasing decisions. If anything, the above quotes from Mrs. Resnick's book go to brand building; but even so, they do not prove that anyone purchased POM's Juice as a result of the Martha Stewart Show appearance. To the contrary, Dr. Reibstein's survey shows that no mention of disease in Mrs. Resnick's interview was material to consumers' purchase decisions because less than 1.5% of the hundreds of survey respondents even mentioned disease as a reson for buying POM's Juice. (Reibstein, Tr. at 2493; PX02223-0020).

572. In a television interview on *Fox Business* in June 2008, Mr. Tupper stated:

> **MR. TUPPER**: With pomegranate, the dose that's been shown to be effective is eight ounces a day . . . pomegranate is the one fruit that's actually been tested in human beings by dozens of researchers across the globe. There's actually been a study published recently on prostate cancer. Men suffering from advanced stages of prostate cancer drinking eight ounces a day saw the progression of the prostate cancer actually slow dramatically. In addition, there have been a number of studies published on cardiovascular disease in which sick patients again consuming eight ounces of pomegranate juice every day saw dramatic improvements in things like atherosclerosis, which is plaque in the arteries, the amount of blood flow delivered to the heart.
>
> ***
>
> **MR. SULLIVAN**: There's a lot of different pomegranate things. How many more products can you put out there, and how much of it is just hooey, . . . you know, pomegranate pills, et cetera?

***

MR. TUPPER: The products that we put into the market, though, all stem from the fundamental science of the pomegranate, and everything that we put into the market, whether it's juice, whether it's tea, whether it's the supplements that we sell, are all backed by an enormous investment in science. We've actually funded more than $25 million of scientific research worldwide since we started the business. And, therefore, every product that we sell is backed by that science. Every product that we sell contains those unique antioxidants. We don't do things for scents and flavors. We do them for the health benefits and for the science.

(CX0473 (Compl. Ex. E-7)).

Response to Finding No. 572:

POM objects to this proposed finding of fact because this is the first time it has been made aware that these are the statements at issue and under scrutiny by the FTC, and it has not had a full opportunity to defend itself. To the extent the ALJ considers this fact, Respondents object to this finding of fact because Mr. Tupper's appearance on *Fox Business* is not actionable advertising as defined by the FTC in *In the Matter of R.J. Reynolds Tobacco Co., Inc.,* 111 F.T.C. 539 (1988). However, to the extent the ALJ considers it, Mr. Tupper's statements do not constitute establishment or efficacy claims, nor should the statements be the basis for any action in this case. The substance of the *entire* interview itself (not just this small excerpt) makes it clear that the interview primarily focused on pomegranates – the newest superfood – POM, and pomegranate product applications. (RFF ¶¶ 2610-2621; CX0473 (Compl. Ex. E-7); Tupper, Ocean Spray Dep., at 24). Indeed, Mr. Tupper's references to the health benefits of pomegranate juice during the interview were very small, only about 100 seconds out of a 6 minute and 5 second interview. (CX0473 (Compl. Ex. E-7); RFF RFF ¶¶ 2610-2621). Similarly, Mr. Tupper's references to the health benefits of pomegranate juice during the course of his interview were strictly "reactive" as opposed to proactive. For example, Mr. Tupper's statement that the "dose that's been shown to be effective is 8 oz. a day" was in direct response to Brian Sullivan's question, "How much do you have to have?"

(Tuper, Tr. 1061-62; RRF ¶ 2616). Likewise, there is no evidence that Mr. Tupper's "main purpose" or "primary motivation for participating in an interview with FOX Business was to sell POM. (RRF ¶ 2614). To the contrary, Dr. Reibstein's survey shows that no mention of disease in Mr. Tupper's interview was material to consumers' purchase decisions because less than 1.5% of the hundreds of survey respondents even mentioned disease as a reson for buying POM's Juice. (Reibstein, Tr. at 2493; PX02223-0020). Additionally, Mr. Tupper's interview is constitutionally protected speech. These responses to the interviewers' questions were statements of his opinion and summaries of actual results of studies. None of the statements were untrue. Furthermore, to the extent that the statements made "backed by" claims (e.g., the reference to "we've funded more than $25 million in scientific research" and "therefore, every product we sell is backed by that science"), that claim was true at the time it was made. (RFF 2510). Indeed, Mr. Tupper's references to the health benefits of pomegranate juice during the interview were very small, only about 100 seconds out of a 6 minute and 5 second interview. (CX0473 (Compl. Ex. E-7); RFF RFF ¶¶ 2610-2621).

573. The net impression of Mr. Tupper's statements, including his references to published studies on prostate cancer and cardiovascular disease, his statement that "the dose [of pomegranate] that's been shown to be effective is eight ounces a day," and his statement that "everything that we put into the market … [is] backed by an enormous investment in science" is that drinking 8 ounces of POM Juice a day (1) treats heart disease including by decreasing arterial plaque and improving blood flow to the heart and (2) treats prostate cancer, and that these health benefits are clinically proven. (CCFF ¶¶ 572).

Response to Finding No. 573:

The net impression of Mr. Tupper's statements on *Fox Business* are not that drinking 8 ounces of POM Juice a day (1) treats heart disease including by decreasing arterial plaque and improving blood flow to the heart and (2) treats prostate cancer, and that these health benefits are clinically proven. Rather, the substance of the *entire* interview itself (not just this small excerpt) makes it clear that the interview primarily focused on pomegranates – the newest superfood – POM, and pomegranate product applications. (RFF ¶¶ 2610-

2621; CX0473 (Compl. Ex. E-7); Tupper, Ocean Spray Dep., at 24). Finally, the net impression of the statements Mr. Tupper made concerning POM's studies and research that it funded is that POM funds research and that POM's studies show particular results. He never says that POM Juice cures or treats prostate cancer or heart disease, so he never makes efficacy or establishment claims. No liability can attach to or be based on Mr. Tupper's appearance on *Fox Business* because (a) it was not advertising; (b) it is constitutionally protected speech; and (c) his opinions were not material to consumer purchasing decisions. (RFF ¶¶ 2610-2621; CX0473 (Compl. Ex. E-7)).

d. February 2009 *Early Show* Interview with Lynda Resnick (CX0472)

574. In a February 2009 interview on CBS's *Early Show* on the topic "Making it Happen: Turning Ideas into Ca$h," Mrs. Resnick described how POM started marketing POM Juice:

> [E]veryone knew in mythology that the pomegranate was the secret of everlasting life. And we decided to see if that was true, and we started doing scientific, peer-reviewed research. And we found out that, indeed, the pomegranate has all these health-giving properties. There isn't a man in America that shouldn't drink 8oz. a day [of pomegranate juice] because it keeps you from getting prostate cancer or from your PSA from rising. It's really an amazing, amazing thing. And good for circulation, too.
>
> (CX0472 at 01:40-2:07). She also stated:
>
> . . . [POM] is the antioxidant superpower. And once we realized the health-giving benefits, that was our marketing direction. And, people didn't know what a pomegranate was, but once they found out, they sure wanted it.
>
> (CX0472 at 02:36)

Response to Finding No. 574:

POM objects to this proposed finding of fact because this is the first time it has been made aware that these are the statements at issue and under scrutiny by the FTC, and it has not had a full opportunity to defend itself. To the extent the ALJ considers this fact, it is undisputed that Mrs. Resnick appeared on CBS's *Early Show* in February 2009 in a segment titled, "Cashing in on Ideas." However it is disputed that any statements made

during the interview are establishment or efficacy claims, or that they are actionable at all in this case. As an initial matter this appearance was not an advertisement. Rather, the primary purpose of this appearance was not to advertise any of Mrs. Resnick's companies' products, but rather to promote Mrs. Resnick's book and to talk about how to be a good marketer. Indeed, the interview focused on the history and the story behind the company, POM, and Mrs. Resnick's marketing secrets. (RRF ¶ 2567, 2575, 2576; CX0472_0003). With respect to the the segment quoted here, it lasted approximately 20 seconds- a small part of the whole interview- which lasted almost 4 minutes (approximately 3:50). Any statements as to prostate cancer and circulation are Mrs. Resnick's personal opinions and she staunchly belives that the opinions expressed in her interview are completely true. (CX 1375 (L. Resnick, Tropicana Dep. at 1010)). As such, these statements are protected under the First Amendment. Similarly, the substance of the interview itself shows that neither Mrs. Resnick's statements on the *Early Show* nor even her specific opinions on the benefits of pomegranate juice proposed a commercial transaction and are thus not actionable. (RRF ¶ 2576; CX0472_0003; 2579-2580). Assuming *arguendo* that the statements were made to make sales, Dr. Reibstein's survey shows that any mention of disease in Mrs. Resnick interview was not material to consumers' purchase decisions because less than 1.5% of the hundreds of survey respondents even mentioned disease as a reson for buying POM's Juice. (Reibstein, Tr. at 2493; PX02223-0020). Likewise, there is no evidence that Mrs. Resnick's "main purpose" or "primary motivation for participating in an interview with FOX Business was to sell POM. (RRF ¶ 2614). To the contrary, Mrs. Resnick talked openly about other of her companies' products, including Fiji Water. (CX0472_0003). In any event, no liability can be based on Mrs. Resnick's appearance on the *Early Show*.

575. Mrs. Resnick's statements expressly convey the net impression that drinking 8 ounces of pomegranate juice a day treats, prevents, or reduces the risk of prostate cancer, and clinical studies, research, or trials prove these effects. (CCFF ¶ 574).

e. March 2009 *Newsweek.com* Interview with Lynda Resnick (CX1426_00032-35)

Response to Finding No. 575:

The net impression of Mrs. Resnick's statements on the *Early Show* do not convey the net impression that drinking 8 ounces of pomegranate juice a day treats, prevents, or reduces the risk of prostate cancer, and clinical studies, research, or trials prove these effects. This is particularly apparent when the whole interview is viewed at the same time. The upshot of the interview is that Mrs. Resnick is sharing her marketing secrets with others and sharing the history of POM and other products her companies are involved with and/or created or marketed, like Fiji Water. This is belied by the title of the interview itself, "Cashing in on Ideas" and by the fact that the excerpts above upon which Complaint Counsel try to rest liability are only 20 seconds of an interview that lasted almost 4 minutes. To the extent that Mrs. Resnick's statements about the health benefits of pomegranate juice are considered alone, the net impression of those statements is that she believes that pomegranate juice has "health-giving properties" and that she believes it keeps men from getting prostate cancer. (CX00472_0003). This is her own personal belief and therefore is non actionable opinion. Her statements are also non actionable because they are not advertising, and they were not material to consumer purchasing decisions.

576. In a March 20, 2009 interview with *Newsweek.com*, posted on the pomwonderful.com "Blog" page, Mrs. Resnick stated:

[Interviewer:] Should I take vitamins?

[Lynda Resnick:] I don't know your family history. How's your father?

[Interviewer:] He's in good health. Had a bout of prostate cancer, but that's—

[Lynda Resnick:] You have to be on pomegranate juice. You have a 50 percent chance of getting it. Listen to me. It is the one thing that will keep your PSA normal. You have to drink pomegranate juice. There is nothing else we know of that will keep your PSA in check. Ask any urologist—your father should be on it. Your father should be on it. I'm sorry to do this to you, but I have to tell you. We just did a study at UCLA, on 43 men … It arrested their PSA. How old are you, 28?

[Interviewer:] Twenty-six.

[Lynda Resnick:] Get a base line now. [*Pause, wink*] It's also 40 percent as effective as Viagra. Not that you need it. But—couldn't hoit [sic]!

(CX1426_00032-35).

Response to Finding No. 576:

POM objects to this proposed finding of fact because this is the first time it has been made aware that these are the statements at issue and under scrutiny by the FTC, and it has not had a full opportunity to defend itself. To the extent the ALJ considers this fact, it is undisputed that in March 2009 *Newsweek* published on its website two pages of excerpts from an interview with Mrs. Resnick titled, "Striking Out on Your Own. Is now a good time to start a business?" However, this interview, and the statements in CCFF ¶ 576, are not actionable nor do they make establishment or efficacy claims. As an initial matter, the purpose of the interview was not to advertise. As the content of the *Newsweek* publication itself evidences, the primary focus of the article was Mrs. Resnick's business acumen and marketing strategies, as embodied in her book *Rubies in the Orchard*, as well as commentary on the economy and Bush administration. (CX1426, Exh. F; RRF ¶ 2582). Similarly, Mrs. Resnick's statements in response to a particular line of questioning started by the interviewer concerning vitamins are not actionable statements because they are statements of her opinion, which are protected under the First Amendment. (CX1375 (L. Resnick, Tropicana Dep. at 101)). Likewise, the content of the *Newsweek* article, itself, further evidence that neither Ms. Resnick's statements during the interview nor even her specific opinions on the benefits of pomegranate juice "proposed a commercial transaction." (CX1426, Exh. F). Indeed, Complaint Counsel has presented no evidence that the *Newsweek* interview was solely related to the economic interests of Mrs. Resnick and her audience. Further, there is no evidence of materiality or that consumers bought POM's products as a result of this article. To the contrary, Dr. Reibstein's Survey shows that no mention of disease in Mrs. Resnick's

interview was material to consumers' purchase decisions because less than 1.5% of the hundreds of survey respondents even mentioned disease as a reason for buying POM Juice. (Reibstein, Tr. at 2493; PX02223-0020). Thus no liability can be based on Mrs. Resnick's *Newsweek* interview because (a) it was not advertising; (b) it is constitutionally protected speech; and (c) her opinions were not material to the consumer purchasing decisions.

577. The net impression of Mrs. Resnick's statements recommending that a healthy, but at-risk person has to be on pomegranate juice, and referring to a study at UCLA, is that drinking POM Juice prevents or reduces the risk of prostate cancer, and that this effect is clinically proven. By comparing POM to Viagra, with a specific percentage measure of effectiveness, her statements also convey the net impression that drinking POM Juice treats, prevents, or reduces the risk of erectile dysfunction, and that this effect is clinically proven. (CCFF ¶ 576).

Response to Finding No. 577:

Incorrect. The net impression of Mrs. Resnick's statements recommending that a healthy, but at-risk person has to be on pomegranate juice, and referring to a study at UCLA, is not that drinking POM Juice prevents or reduces the risk of prostate cancer, and that this effect is clinically proven. Similarly, her statements comparing POM to Viagara do not convey the net impression that drinking POM Juice treats, prevents, or reduces the risk of erectile dysfunction, and that this effect is clinically proven. Rather, Mrs. Resnick's statements are an expression of her personal belief that POM will help keep a person healthy and help maintain prostate health. As noted above she fully believes in the "power of POM Juice" and thus her statements are protected under the First Amendment. Additionally, Mrs. Resnick's statements are inactionable because (as noted above) they are not advertising.

578. Respondents admitted in their Answer that *The Martha Stewart Show* interview with Mrs. Resnick, the *Fox Business* interview with Mr. Tupper, and the *Newsweek.com* interview with Mrs. Resnick (Complaint Exhibits E-6, E-7, and F (CX0473)) were "advertisements and promotional materials" that they disseminated or caused to be disseminated. (Answer ¶¶ 9-10).

Response to Finding No. 578:

Incorrect. This proposed finding of fact is disputed because the *The Martha Stewart Show* interview with Mrs. Resnick, the *Fox Business* interview with Mr. Tupper, and the *Newsweek.com* interview with Mrs. Resnick (Complaint Exhibits E-6, E-7, and F (CX0473)) are not actionable advertisements or promotional materials as defined by the FTC in *In the Matter of R.J. Reynolds Tobacco Co., Inc.,* 111 F.T.C. 539 (1988).

G. Further Evidence of Challenged Claims

1. The Bovitz Survey

579. In March 2009, at the request of Mrs. Resnick, POM asked the Bovitz Research Group ("Bovitz") to design a consumer survey to evaluate the effectiveness of the then-running "Super Hero" advertising campaign compared to POM's earlier "Dressed Bottle" campaign. (CX0286_0001; CX1378 (Kuyoomjian, OS Dep. at 191-92); CX1357 (Kuyoomjian, Dep. at 236-38); CX1370 (Perdigao, Welch Dep. at 95-96)).

Response to Finding No. 579:

Complaint Counsel misstate Diane Kuyoomjian's deposition testimony. In Ms. Kuyoomjian's deposition in *POM Wonderful LLC v. Ocean SprayCranberries, Inc.*, she testified that POM had made a decision to switch from the Dressed Bottle campaign to the Super Hero campaign and that Mrs. Resnick asked that some comparative research be done on two campaigns to validate that decision. (CX1378 (Kuyoomjian, OS Dep. at 191-92). However, in her deposition in this matter, Ms. Kuymoojian testified that she did not know remember who at POM decided that consumer reach on the two campaigns was needed, although she recalled that it was discussed in a meeting with Mrs. Resnick and that the decision to do the market research was made during that meeting. (CX1357, Kuyoomjian, Dep. at 238).

According to a March 8, 2009 email from Claire Nelson at POM to Bovitz, one of the many objectives of the Bovitz Survey was to evaluate the relative effectiveness of the two campaigns, given the current marketplace and business objectives. (CX0286_0002). Mr.

Perdigao further testified in *POM Wonderful LLC v. Welch Foods, Inc.* that Bovitz was asked to do some online consumer research "to see which campaign was more provocative, more interesting, more liked by consumers." (CX1370 (Perdigao, Welch Dep. at 96).

The Bovitz Survey is irrelevant to this case because it exposed participants only to POM's billboard advertising, which Complaint Counsel is not challenging. (RFF 2772). The Bovitz Survey also does not address materiality because, among other reasons, participants were not asked why they purchase POM Juice. (RFF 2754-55).

Moreover, the Bovitz Survey is methodologically flawed and unreliable because Question E imposed a stringent screening criteria, which created an overall bias in the survey towards extremely health-focused people, which is not representative of the overall population. (RFF 2759; PX0356 (Reibstein, Dep. at 173)). The sample size of only 100 POM users and 150 target consumers also was too small to reach statistical significance at the 95% confidence level. (RFF 2760-61; PX0356 (Reibstein, Dep. at 172-73); *see also* RFF 2766-68). The Bovitz Survey is also methodologically flawed and unreliable because participants were shown specific advertisements in a tightly controlled environment, which is not how consumers normally view ads. (RFF 2756, 2762; PX0356 (Reibstein, Dep. at 173-74)). Thus, the Bovitz Survey cannot be used to determine whether what was observed in the survey applies to a normal advertising viewing context. (RFF 2756, 2763). The Bovitz Survey also had no control and, thus participants might have had preconceived perceptions about pomegranate juice before being exposed to POM's billboard ads which could skew their perception of POM's billboard ads. (RFF 2757).

580. Mrs. Resnick was involved in the design and approval of the questionnaire for this campaign research. (CX1378 (Kuyoomjian, OS Dep. at 200-01); CX1359 (L. Resnick, Dep. at 75-78, 234-36)).

Response to Finding No. 580:

Complaint Counsel mischaracterizes Mrs. Resnick's testimony. Mrs. Resnick never testified that she designed the questionnaire; rather she testified that she "didn't write it or anything, but I'm sure that they passed it by me." (CX1359 (L. Resnick, Dep. at 235)).

581. The Bovitz Survey used a forced exposure methodology (*i.e.,* showing the advertisement for which you want to ascertain the consumer takeaway to the survey respondents) which is the proper method for advertising communication surveys. (CX0369_0004-07; PX0356 (Reibstein, Dep. at 174-75); Mazis, Tr. 2693-95).

Response to Finding No. 581:

The Bovitz Survey is methodologically flawed because, among other reasons, participants were shown specific advertisements in a tightly controlled environment, which forces a consumer to zero in on an ad in a way he or she would never do in the real world. (RFF 2756, 2762; PX0356 (Reibstein, Dep. at 173-74; Reibstein, Tr. 2509-10)). Thus, the Bovitz Survey cannot be used to determine whether what was observed in the survey applies to a normal advertising viewing context. (RFF 2756, 2763; Reibstein, Tr. 2509-10, 2513-14). Moreover, Professor Reibstein never testified that forced exposure methodology is the proper method for advertising communication surveys. (PX0356 (Reibstein, Dep. at 174-75)).

582. The Bovitz Survey participants were individuals who "engage in health conscious lifestyle[s] and/or hold attitudes toward improving their overall health" (PX0295a15-0005) and were the appropriate universe for the survey given that such individuals were the target audience for POM Juice advertising. (Stewart, Tr. 3207; Mazis, Tr. 2693-95; CX0286_0002-03).

Response to Finding No. 582:

Respondents deny that the Bovitz Survey participants were the appropriate universe for the survey and further deny that such individuals were the target audience for POM Juice advertising. (RFF 2759; PX0356 (Reibstein, Dep. at 173); (Tupper, Tr. 3017-18).

The Bovitz Survey imposed strict qualification requirements, including requiring participants to engage in a health-conscious lifestyle and/or hold attitudes toward improving their overall health. (RFF 2758; PX0225-0003; PX0223-0393). Question E, which is set forth fully below, asked respondents to answer ten questions, five of which were health-related statements.

Question E. Listed below are some statements that may or may not describe you. Using the scale provided, please indicate the extent to which each of the following statements describes you.

(RANDOMIZE ROWS)	**Describes me perfectly**	**Describes me well**	**Describes me somewhat**	**Describes me a little**	**Does not describe me at all**
I use my diet to manage my health	5	4	3	2	1
High fiber foods are a regular part of my diet	5	4	3	2	1
I regularly work out to stay fit	5	4	3	2	1
I try to include plenty of fruits and vegetables in my diet	5	4	3	2	1
I believe that what I eat can directly affect my health	5	4	3	2	1
I am the first of my friends to try new gadgets and technology	5	4	3	2	1
I prefer to watch movies at home instead of a theater	5	4	3	2	1
I am adjusting my lifestyle to be conscious of the environment	5	4	3	2	1
I enjoy cooking and trying new	5	4	3	2	1

(RANDOMIZE ROWS)	Describes me perfectly	Describes me well	Describes me somewhat	Describes me a little	Does not describe me at all
recipes that I find online					
I like to stay up on current events	5	4	3	2	1

(PX0223-0393). To qualify for participation in the survey, respondents had to respond with a "5" or a "4" on the rating scale with respect to at least three of the five health-related statements (*i.e.*, Questions 1 through 5). (PX0223-0393). Based on the screening criteria in Question E, the average healthy person would not qualify. Because the participants in the Bovitz Survey were not just "health-conscious" but health nuts, they were not a good representation of the overall consumer population. (RFF 2759; PX0356 (Reibstein, Dep. at 173)). This stringent screening criteria therefore created an overall bias in the survey towards extremely health-focused participants that were much more likely to be focused on health issues, which is not representative of the overall population. (RFF 2759; PX0356 (Reibstein, Dep. at 173)).

583. Bovitz conducted the survey by using five "Dressed Bottle" billboards and five "Super Hero" billboards to draw conclusions from survey respondents about ad meaning for both campaigns. (PX0295a15-0004-06, 0010-11).

Response to Finding No. 583:

The Bovitz Survey compared consumers' perceptions of the following ten billboard advertisements from POM's Super Hero and Dressed Bottle advertising campaigns (hereinafter, "Bovitz Stimuli"), (PX0223-0411-12; RF 2752):

Super Hero campaign ads:

- Holy Health! $25 million in medical research!
- I'm off to save PROSTATES!
- 100% PURE pomegranate juice to the rescue!
- BACK OFF …impostor juices!
- Risk your health in this economy? NEVER!

Dressed Bottle campaign ads:

- Cheat Death.
- The Antioxidant Superpower.

- Decompress.
- Heart therapy.
- Forever young.

Each of the Bovitz Stimuli also included a tagline, such as "The Antioxidant Superpower" or the "The antioxidant power of pomegranate juice" or something to that effect. (PX0223-0411-12). The Bovitz Stimuli contained no body copy, however – that is, they consist entirely of headlines. (PX0223-0411-12).

As testified to by Professor Reibstein, the Bovitz Survey was methodologically flawed and therefore no reliable conclusions could be drawn from it, including consumers' perception of POM's billboard advertising because of, among other things, the tightly controlled environment in which respondents were exposed to the Bovitz Stimuli. (RFF 2754-68; Reibstein, Tr. 2509-14; PX0356 (Reibstein, Dep. at 171-75).

584. A test of the communications of headlines and images in the context of a billboard ad sheds light on what the same headlines and images would convey in lengthier print ads. (Stewart, Tr. 3205-06, 3221).

Response to Finding No. 584:

Complaint Counsel notably omit Professor Stewart's response to the next question in which he admitted that adding text (*i.e.*, body copy) to the headlines and images "might modify" the message conveyed by the billboard ads. (Stewart, Tr. 3206). Professor Stewart further clarified that a copy test of the headlines and images "would help gain some insight into what messages were communicated by the image and the headline from a test of just those things." (Stewart, Tr. 3205-06). Any comparisons between billboard ads and lengthier print ads with the same headline is completely irrelevant because the print ads with the same headlines all have body copy, and the body copy of an ad drastically changes the meaning of an ad or what a reasonable person would take away from it. Indeed, a simple facial comparison of the "I'm off to save PROSTATES!"

billboard ad to the "I'm off to save PROSTATES!" print ad aptly illustrates this obvious point. (*Compare* PX0223-0411 *with CX0274).*

585. Four of the billboards tested by Bovitz included headlines and imagery featured in challenged ads. (*Compare* PX0295a15-0010-11 *with* CX0109_0001 and CX0463 ("Heart therapy."), CX0103_0001 ("Decompress."), CX0036_0001 and CX0188_0001 ("Cheat death."), CX0274_0001 and CX0466 ("I'm off to save PROSTATES!")). The headline of one test billboard included a reference to "$25 million in medical research," which was similar to references used in numerous challenged ads. (*See* PX0295a15-0010; *see*, *e.g.*, CX0274_0001).

Response to Finding No. 585:

Respondents acknowledge that four of the billboard ads (*i.e.*, "Heart therapy," "Decompress," "Cheat death" and "I'm off to save prostates") that were used as stimuli in the Bovitz Survey included headlines and imagery that Complaint Counsel challenge in certain of the Challenged Ads, but dispute that the billboard stimuli and any of the Challenged Ads with the same headlines are similar because the Challenged Ads contain body copy. (*See* CCFF 585; PX0223-0411-12). As indicated above, Complaint Counsel specifically assert that the following Challenged Ads are comparable to the Bovitz Stimuli simply because they have the same headlines:

Bovitz Stimuli	**Body Copy in Bovitz Stimuli?**	**Challenged Ad**	**Body Copy in Challenged Ad?**
"Heart therapy" billboard ad (PX0223-0412/PX0295a15-0011)	No (PX0223-0412/PX0295a15-0011)	"Heart therapy" banner ad (CX0463)_	Yes (CX0463)_
		"Heart therapy" print ad (CX0109)	Yes (CX0109)
"Decompress" billboard ad (PX0223-0412/PX0295a15-0011)	No (PX0223-0412/PX0295a15-0011)	"Decompress" print ad (CX0103)	Yes (CX0103)
"Cheat death" billboard ad (PX0223-	No (PX0223-0412/PX0295a15-	"Cheat death" print ads (CX0036/CX0188)	Yes (CX0036/CX0188)

Bovitz Stimuli	Body Copy in Bovitz Stimuli?	Challenged Ad	Body Copy in Challenged Ad?
0412/PX0295a15-0011)	0011)		
"I'm off to save PROSTATES!" billboard ad (PX0223-0411/PX0295a15-0010)	No (PX0223-0411/PX0295a15-0010)	"I'm off to save PROSTATES!" banner ad (CX0466)	Yes (CX0466)
		"I'm off to SAVE PROSTATES!" print ad (CX0274)	Yes (CX0274)

Complaint Counsel, however, cannot rely on the Bovitz Survey as relevant extrinsic evidence on the meaning of the Challenged Ads or what a reasonable person would take away from them because Complaint Counsel is not challenging billboard advertisements (*i.e.,* ads without body copy) in this case. (RFF 2234, 2770; Reibstein, Tr. 2540, 2574). As evidenced in the chart above, any comparisons between the Bovitz Stimuli and the Challenged Ad with the same headline is completely irrelevant because the Challenged Ads with the same headlines all have body copy, and the body copy of an ad can modify the meaning of the headlines and imagery. (D. Stewart, Tr. 3206).

The fact that the headline of one billboard stimuli (*i.e.*, Holy Health! $25 million in medical research") included a reference to "$25 million in medical research" is irrelevant to the fact that similar references to investment in scientific research in the Challenged Products were used in other Challenged Ads, such as the "I'm off to save PROSTATES!" print ad (CX0274 and "backed by" ads (RFF 2507-10)), because different headlines and totally unique body copy were at issue. (*Compare* PX0295a15-0010 *with* CX0274). For example, there was no body copy in the "Holy Health" billboard stimuli whereas the "I'm off to save PROSTATES!" print ad not only contained a different headline, but also contained the following body copy: "Man by man, gland by gland, The Antioxidant Superpower is 100% committed to defending healthy prostates. Powered by pure

pomegranate juice… backed by $25 million in vigilant medical research* … there's no telling just how far it will go to improve prostate health in the future." (CX0274) (*footnote omitted).

586. Respondents were shown one of six test ads chosen from the ten campaign ads being tested and asked one open-ended question, "Other than trying to get you to buy the product, what do you think is the main idea" that the ad "is trying to get across to you?" (CX0369_0004-07; Stewart, Tr. 3207, 3213).

Response to Finding No. 586:

Respondents do not dispute that the above-quoted question was part of the Bovitz Survey. It was Question 6 out of 18 questions in the Main Questionnaire. (CX0369_0007).

587. Such a question is reliable and it is appropriate to draw conclusions about advertising communication from open-ended questions without the use of any controls. (Stewart, Tr. 3213, 42).

Response to Finding No. 587:

Complaint Counsel mischaracterizes Professor Stewart's testimony. Professor Stewart did not testify that the questions asked in the Bovitz Survey were "reliable;" he merely testified generally that he was comfortable drawing conclusions about ad communication from open-ended questions without controls. (Stewart, Tr. 3242). Moreover, Professor Reibstein's testimony contradicts Professor Stewart's because Professor Reibstein found that the Bovitz Survey was methodologically flawed and very unreliable. (*See* RRFF 579).

588. The main ideas for each of three relevant ads surveyed were as follows:

- Fourteen percent of the general target audience and seventeen percent of POM Juice users in the Bovitz Survey, when shown an advertisement picturing a POM Juice bottle inside a blood pressure cuff, with the headline "Decompress" and a sub-headline "POM Wonderful Pomegranate Juice. The Antioxidant Superpower," said the ad's main idea was "helps/lowers blood pressure." (PX0295a15-0011, 0018, 0046; Stewart, Tr. 3213-14). This significant consumer takeaway as surveyed is consistent with findings that the imagery and language of the challenged "Decompress" print advertisement (CX0103_0001; CCFF ¶ B.1.g.357) created a net impression to consumers that POM Juice treats, prevents, or reduces the risk of heart

disease, including by reducing blood pressure. (*See* CCFF ¶¶ B.1.g.361, C.5.b.540; *see also* Stewart, Tr. 3221).

- Forty-three percent of the general target audience and forty-eight percent of POM Juice users in the Bovitz Survey, when shown an advertisement picturing a POM Juice bottle saying, "I'm off to save PROSTATES!" and a sub-headline "The Antioxidant Superpower," said the ad's main idea was "good for prostates." (PX0295a15-0010, 17, 45). This significant consumer takeaway as surveyed is consistent with a finding that the challenged "I'm off to save PROSTATES!" print ad (CX0274_0001; CCFF ¶B.2.b.372) and banner ad (CX0466; CCFF ¶ C.4.534) communicated a message that drinking POM Juice treats, prevents, or reduces the risk of prostate cancer. (*See* CCFF ¶ B.2.b.376).

- Twenty-two percent of the general target audience and thirty-one percent of POM Juice users in the Bovitz Survey – who were shown an advertisement picturing a POM Juice bottle saying, "HOLY HEALTH! $25 million in medical research" and a sub-headline "The Antioxidant Superpower" – said the ad's main idea was "$25 million spent on research/research based." (PX0295a15-0010, 0017, 0045). This significant consumer takeaway as surveyed is consistent with findings that a number of the challenged ads communicated that the claimed benefits were research-based. (*See, e.g.*, CCFF ¶¶ B.2.b.372-88, B.4.a.398-B.4.e.429).

Response to Finding No. 588:

Complaint Counsel mischaracterize the results of the Bovitz Survey and its application to any of the Challenged Ads (*i.e.*, "Decompress" print ad (CX0103), "I'm off to save PROSTATES!" print (CX0274) and banner (CX0466) ads)).

Respondents dispute that the Bovitz Survey is probative extrinsic evidence of the meaning of the Challenged Ads or what a reasonable person would take away from them. First, the Bovitz Survey is not probative because any comparisons between the Bovitz Stimuli (which had no body copy) and the Challenged Ad with the same headline is completely irrelevant because the Challenged Ads with the same headlines all have body copy, and the body copy of an ad drastically changes the meaning of an ad or what a reasonable person would take away from it. (*See supra* RRFF 585; D. Stewart, Tr. 3206). Second, the Bovitz Survey itself was methodologically flawed and unreliable for the reasons stated in above in Response to Finding No. 579. (*See supra* RRFF 579).

Third, Complaint Counsel's attempt to apply any of the findings in Bovitz to the support any net impression analysis of the Challenged Ads is misplaced. For example, Complaint Counsel assert that 14% of the general population and 17% of the POM population in the Bovitz Survey said the "main idea" of the "Decompress" billboard ad was that it "helps/lowers blood pressure." (CCFF 588). From this finding Complaint Counsel erroneously contend that the "Decompress" print ad (CX0103) creates the net impression that "POM Juice treats, prevents, or reduces the risk of heart disease." (CCFF 588). This is not true because Complaint Counsel fail to mention that the Bovitz Survey also allegedly concluded that (1) 64% of the general population and 73% of the POM population stated the "main idea" of the "Decompress" billboard was ""healthy/health benefits/juice;" (2) 16% of the general population and 20% of the POM population responded that "antioxidants" were the "main idea" and (3) 6% of the general population and 13% of the POM population said the "main idea" of the billboard was "calming, relieves stress/relaxing." (PX0295a15-0018, 46). Complaint Counsel's assertion that the "Decompress" print ad conveys the net impression that "POM Juice treats, prevents, or reduces the risk of heart disease, including by reducing blood pressure" according makes no sense, in light of all those alleged findings.

Similarly, Complaint Counsel contend that 43% of the general population and 48% of the POM population in the Bovitz Survey stated that the "main idea" of the "I'm off to save PROSTATES" billboard ad was that it was "good for prostates." (CCFF 588). From this finding Complaint Counsel erroneously contend that the "I'm off to save PROSTATES!" print (CX0274) and banner (CX0466) ads communicate a message that "POM Juice treats, prevents, or reduces the risk of prostate cancer." (CCFF 588). This is a completely illogical inference. Nowhere do Complaint Counsel explain how they make the leap from POM Juice is "good for prostates" to "POM Juice treats, prevents, or reduces the risk of prostate cancer," especially in light of the fact that the Bovitz Survey

also allegedly found that (1) 31% of the general population and 48% of the POM population said the "main idea" of the "I'm off to save PROSTATES!" billboard was "healthy/health benefits/juice is good for you" and (2) 12% of the general population and 28% of the POM population said "antioxidants." (PX0295a15-0017, 45).

Complaint Counsel contend that 22% of the general population and 31% of the POM population in the Bovitz Survey stated that the "main idea" of the "Holy Health! $25 million in medical research" billboard was that "$25 million [was] spent on research/research based." (CCFF 588). From this finding Complaint Counsel erroneously contend that "a number of the challenged ads communicated that the claimed benefits were research based." (CCFF 588). Complaint Counsel, however, fail to identify which of the "challenged ads" these findings supported and omit that the Bovitz Survey also allegedly found that (1) 57% of the general population and 46% of the POM population said "healthy/health benefits/juice is good for you;" (2) 2% of the general population and 9% of the POM population responded "antioxidants". (PX0295z15-0017, 0045). Moreover, the fact that "Holy Health! $25 million in medical research" billboard included a reference to "$25 million in medical research" is irrelevant to the fact that similar references to investment in scientific resesearch in the Challenged Products were used in other Challenged Ads because different headlines and totally unique body copy were at issue. (*Compare* PX0295a15-0010 *with* CX0274).

589. Bovitz Survey respondents were also exposed to all five tested ads from the "Super Hero" campaign or all five tested ads from the "Dressed Bottle" campaign and asked an open-ended question, "Based on the ads you just saw, what are the specific benefits, if any, of drinking POM Wonderful?" (CX0369_0008-09; Stewart, Tr. 3214-16). This open-ended question was not leading. (Stewart, Tr. 3216).

Response to Finding No. 589:

Respondents do not dispute that the above-quoted question was part of the Bovitz Survey. It was Question 10 out of 18 questions in the Main Questionnaire. (CX0369_0009).

Before the survey participants were asked to answer Questions 7 through 18, they were shown a a series of five billboard ads from the Dressed Bottle campaign or five billboard ads from the Super Hero advertising campaign and asked to evaluate the five billboard ads as a group. (CX0369_0008).

Respondents contend that Question 10, as quoted above, is leading and biased. Indeed, Professor Reibstein testified that Question 10 was a leading, biased question because it directed the survey participants to select a "specific benefit" which pressures them to identify a "specific benefit" even if they had not perceived a "particular benefit." (Reibstein, Tr. 2515-16). He further testified that he did not find the results from Question 10 to be credible or reliable because the question was leading and biased and because the survey itself was methodologically flawed and unreliable for the reasons stated in above in Response to Finding No. 579. (Reibstein, Tr. 2515-16). At trial, Professor Reibstein used the questions regarding the "Decompress" billboard ad to exemplify that Question 10 inflated the results. (Reibstein, Tr. 2515-26). Question 10 says: "Based on the [group of five] ads you just saw, what are the specific benefits, if any, of drinking POM Wonderful." (CX0369_0009). Twenty-one percent of the general population responded "helping/lowering blood pressure." (PX00225-0014). When asked a general question regarding the main idea of the group of five Dressed Bottle billboards (*i.e.*, Question 9) and when respondents were not asked to select a "benefit," only 5% of the general population said it helps/lowers blood pressure. (PX00225-0011). When respondents were specifically asked about the main idea of the "Decompress" ad in Questions 5 and 6 and were not asked to select a "benefit," 14% of general population said the main idea of the billboard was about helping/lowering blood pressure. (PX00225-0013). Questions 5, 6 and 9, which did not ask survey participants to list a "specific benefit," resulted in much lower percentages than when Question 10, a leading, biased question was asked. (PX00225-0011, 0013, 0014).

590. Of the survey respondents exposed to the five "Dressed Bottle" ads, which included the images and headlines of the challenged "Decompress" print ad and the challenged "Heart Therapy" print and banner ads, 38% of the general target audience said that a benefit of drinking POM Juice was "good for your heart" and 21% said a benefit was "helps/lowers blood pressure." (PX0295a15-0011, 0020; Stewart, Tr. 3216-17). There were similar results among POM users. (PX0295a15-0048; Stewart, Tr. 3217).

Response to Finding No. 590:

Before the survey participants were asked to answer Question 10, they were shown a a series of five billboard ads from the Dressed Bottle campaign (*i.e.*, "Cheat death," "The Antioxidant Superpower," "Decompress," "Heart therapy" and "Forevery young") or five billboard ads from the Super Hero advertising campaign (*i.e.* ,"Holy Health!," "I'm off to save PROSTATES!," "100% PURE," "BACK OFF…impostor juices!" and "Reisk your health in this economy? NEVER!"). Bovitz asked the survey participants to evaluate the five billboard ads as a group. (CX0369_0008).

In response to the Question 10 in the Bovitz Survey, which was biased and leading as set forth in Response to Finding No. 589 because it asked survey participants to state a "specific benefit" of drinking POM Juice, 38% of the general population said "good for your heart," 37% said "antioxidants," 21% responded "healthy," 21% stated "helps/lowers blood pressure," 18% said "keeps you young," 13% said "extends your life,"9% responded "gives you more energy," 9% said "calming/relieves stress," 7% stated "strength/makes you feel strong." (PX0295015-0020). Responses for the POM User population broke down as follows: 47% said "good for your heart," 40% responded "antioxidants," 21% said "helps/lowers blood pressure," 20% said "keeps you young," 16% responded "healthy," 16% said "extends your life," 11% said "gives you more energy," 7% responded "calming/relieves stress," and 7% said "strength/makes you feel strong." (PX0295015-0048).

As set forth above in Response to Finding No. 589, Professor Reibstein testified that Question 10 was a leading, biased question because it directed the survey participants to

select a "specific benefit" which pressures them to identify a "specific benefit" even if they had not perceived a "particular benefit." (Reibstein, Tr. 2515-2516). He further testified that he did not find the results from Question 10 to be credible or reliable because the question was leading and biased and because the survey itself was methodologically flawed and unreliable for the reasons stated in above in Response to Finding No. 579. (Reibstein, Tr. 2515-16).

591. The Bovitz Survey's open-ended communication of "good for your heart" and "helps/lowers blood pressure" from the images and headlines of the "Dressed Bottle" campaign is consistent with findings that the challenged "Heart Therapy" print ad (CX0109_0001; CCFF ¶ B.1.h.363) and banner ad (CX0463; CCFF ¶ C.5.a.536) communicated a message that POM Juice prevents or reduces the risk of heart disease (see CCFF ¶ B.1.h.367, C.5.a.538) and a finding that the "Decompress" print ad (CX0103_0001; CCFF ¶ B.1.g.357) communicated a message that POM Juice treats, prevents, or reduces the risk of heart disease, including by reducing blood pressure (see CCFF ¶ B.1.g.361).

Response to Finding No. 591:

Respondents dispute that the Bovitz Survey is probative extrinsic evidence of the meaning of the Challenged Ads or what a reasonable person would take away from them. First, the Bovitz Survey is not probative because any comparisons between the Bovitz Stimuli (which had no body copy) and the Challenged Ad with the same headline is completely irrelevant because the Challenged Ads with the same headlines all have body copy, and the body copy of an ad drastically changes the meaning of an ad or what a reasonable person would take away from it. (*See supra* RRFF 585; D. Stewart, Tr. 3206). Second, the Bovitz Survey itself was methodologically flawed and unreliable for the reasons stated in above in Response to Finding No. 579. (*See supra* RRFF 579). Third, Respondents disagree with Complaint Counsel's conclusion that the "open-ended communication of 'good for your heart' and 'helps/lowers blood pressure'" are consistent with Complaint Counsel's assertion that the (a) challenged "Heart Therapy" print ad (CX0109_0001) and banner ad (CX0463) communicated a message that POM Juice prevents or reduces the risk of heart disease or (b) challenged "Decompress" print ad

(CX0103) communicated a message that POM Juice treats, prevents, or reduces the risk of heart disease. Nowhere do Complaint Counsel explain how they make the leap from POM Juice is "good for your heart" to "POM Juice treats, prevents, or reduces the risk of heart disease," especially in light of the fact that the Bovitz Survey also found that 37% of the general population said "antioxidants," 21% responded "healthy," 18% said "keeps you young," 9% responded "gives you more energy," 9% said "calming/relieves stress" and 7% stated "strength/makes you feel strong" when asked in Question 10 to list a "specific benefit" of drinking POM Juice. (PX0295015-0020). Moreover, the results from Question 10 are not credible or reliable because the question was leading and biased in that it directed the survey participants to select a "specific benefit" which pressures them to identify a "specific benefit" even if they had not perceived a "particular benefit." (Reibstein, Tr. 2515-2516).

592. Bovitz Survey respondents who were exposed to the five "Super Hero" ads, which included an ad picturing a POM Juice bottle saying, "HOLY HEALTH! $25 million in medical research," were asked a close-ended question, "Based on the ads you just saw, which of the following do you think are true about POM Wonderful?" Respondents were provided a multiple-choice list and told to select as many or as few that applied. (PX0295a15-0033).

Response to Finding No. 592:

Respondents do not dispute that the above-quoted question was part of the Bovitz Survey. It was Question 16 out of 18 questions in the Main Questionnaire. (CX0369_0010-11). Before the survey participants were asked to answer Questions 7 through 18, they were shown a a series of five billboard ads from the Dressed Bottle campaign campaign (*i.e.*, "Cheat death," "The Antioxidant Superpower," "Decompress," "Heart therapy" and "Forevery young") or five billboard ads from the Super Hero advertising campaign (*i.e.* ,"Holy Health!," "I'm off to save PROSTATES!," "100% PURE," "BACK OFF…impostor juices!" and "Risk your health in this economy? NEVER!"). (CX0369_0008; PX00225-0005-0006). Bovitz asked the survey participants to evaluate

the five billboard ads as a group. (CX0369_0008). Respondents agree that Question 16 was a closed-ended question and that the survey participants were told to select as many or as few from the following 14 choices that applied to the brand POM Wonderful:

a. Backed by medical research

b. Is good for cardiovascular health

c. 100% pure pomegranate juice

d. Contains all natural ingredients

e. Is good for prostate health

f. Like "health in a bottle"

g. Contains naturally occurring antioxidants

h. Is the original pomegranate juice

i. Is good for you

j. Will help you stay healthy

k. Will help you live longer

l. Is better than other pomegranate juices

m. Has proven health benefits

n. Tastes good

o. None of the above

(CX0369_0010-11).

593. In response to this closed-ended question, 63% of the general target audience and 78% of POM Juice users said based on the ads, POM Juice had "proven health benefits." (PX0295a15-0033-34).

Response to Finding No. 593:

Complaint Counsel completely mischaracterize the evidence. Question 16 of the Bovitz Survey asked "Based on the ads you just saw, which of the following do you think that are true about POM Wonderful? Please select as many or as few as you feel apply."

(PX0223-0401). The question clearly asked about impressions of the POM brand, not about POM Juice. (PX0223-0401). In response to Question 16, 63% of the general population and 78% of the POM User population marked that their impressions of the POM brand was that it "has proven health benefits." (PX0295a15-0033-34).

Respondents further contend that these percentages are unreliable and inflated. First, the Bovitz Survey as a whole is methodologically flawed and unreliable for the reasons stated in above in Response to Finding No. 579. (*See supra* RRFF 579). Second, the results from Question 16 are unreliable and inflated because the closed-ended question was leading in that the survey respondents were admittedly given only 14 choices and were forced to select from attributes they may not otherwise have thought of. (RFF 2724; *see also* Reibstein, Tr. 2551-52). Utilizing closed-end questions also results in the exclusion of potential answers that were not included on the list of choices because respondents often feel compelled to select one of the answers provided on the list of choices. (RFF 2725; Reibstein, Tr. 2519). The results of the Bovitz Survey are also biased because the use of a closed-ended question, like Question 16, heightened "yea saying," which is the tendency to give a yes or more socially desirable response in an effort to be agreeable to the exclusion of potential answers not included on the list. (RFF 2725; Rebistein, Tr. 2519; Stewart, Tr. 3218-19).

594. Because this was a closed-ended question, there is the possibility of yea-saying, *i.e.,* .the tendency to give a yes or more socially desirable response in an effort to be agreeable. (*See* Stewart, Tr. 3218-19). To analyze the responses conservatively, one of the other attributes can be used as a control. (Stewart, Tr. 3219). Here, following that approach, if one were to use the response option "Will help you live longer" as a control attribute, as none of the five "Super Hero" billboards explicitly addressed longevity (although they might have implied it), and deducted the responses for that attribute, 43% of the general target audience (*i.e.*, 63% minus 20%) and 46% of POM Juice users (*i.e.*, 78% minus 32%) thought that POM Juice had "proven health benefits." (PX0295a15-0010, 0033-34).

Response to Finding No. 594:

Complaint Counsel's admission that the five "Super Hero" billboards "might have implied" "longevity" destroys their argument because Mr. Stewart testified that one way "you might account for yea-saying" is to "look for a question or a response that is clearly not relevant to the content of a particular ad or set of ads." (Stewart, Tr. 3219). This means that the control attribute cannot be "relevant to the content" of the challenged advertisement. (Stewart, Tr. 3219).

Respondents further contend that these percentages are unreliable and inflated. First, the Bovitz Survey as a whole is methodologically flawed and unreliable for the reasons stated in above in Response to Finding No. 579. (*See supra* RRFF 579). Second, the results from Question 16 are unreliable and inflated because the closed-ended question was leading in that the survey respondents were admittedly given only 14 choices and were forced to select from attributes they may not otherwise have thought of. (RFF 2724; *see also* Reibstein, Tr. 2551-52). Utilizing closed-end questions also results in the exclusion of potential answers that were not included on the list of choices because respondents often feel compelled to select one of the answers provided on the list of choices. (RFF 2725; Reibstein, Tr. 2519). The results of the Bovitz Survey are also biased because the use of a closed-ended question, like Question 16, heightened "yea saying," which is the tendency to give a yes or more socially desirable response in an effort to be agreeable to the exclusion of potential answers not included on the list. (RFF 2725; Rebistein, Tr. 2519; Stewart, Tr. 3218-19). Third, the responses to Question 16 relate to the POM brand, not POM Juice. Question 16 asked "Based on the ads you just saw, which of the following do you think that are true about POM Wonderful? Please select as many or as few as you feel apply." (PX0223-0401). The question clearly asked about the POM brand, not about POM Juice. (PX0223-0401). In response to Question 16, 63% of the general population and 78% of the POM User population

marked that their impressions of the POM brand was that it "has proven health benefits." (PX0295a15-0033-34). Moreover, the fact that a certain percentage of the general and POM User populations marked "has proven health benefits" for their impressions of the POM brand does not mean those respondents believed that "POM Juice is proven to prevent, treat or reduce the risk of disease." These are two very distinct concepts. Moreover, what the survey participants thought was true about the POM brand may or may not be attributable to POM Juice. (PX0295a15-0033-34).

595. The Bovitz Survey's closed-ended communication of "proven health benefits" from the images and headlines of the "Super Hero" campaign is consistent with findings that many of the challenged advertisements communicated establishment claims. (*See, e.g.*, CCFF ¶¶ B.2.b.372-88, B.4.a.398-B.4.e.429).

Response to Finding No. 595:

Respondents disagree with Complaint Counsel's assertion. First, Complaint Counsel cannot rely on the Bovitz Survey as relevant extrinsic evidence on the meaning of the Challenged Ads or what a reasonable person would take away from them because Complaint Counsel is not challenging billboard advertisements (*i.e.,* ads without body copy) in this case. (RFF 2234, 2770; Reibstein, Tr. 2540, 2574). As set forth in Response to Finding No. 585, any comparisons between the Bovitz Stimuli and the Challenged Ad with the same headline is completely irrelevant because the Challenged Ads with the same headlines all have body copy, and the body copy of an ad can modify the meaning of the headlines and imagery. (D. Stewart, Tr. 3206).

Seccond, the responses to Question 16 relate to the POM brand, not POM Juice. Question 16 asked "Based on the ads you just saw, which of the following do you think that are true about POM Wonderful? Please select as many or as few as you feel apply." (PX0223-0401). The question clearly asked about the POM brand, not about POM Juice. (PX0223-0401). In response to Question 16, 63% of the general population and 78% of the POM User population marked that their impressions of the POM brand was that it

"has proven health benefits." (PX0295a15-0033-34). Moreover, the fact that a certain percentage of the general and POM User populations marked "has proven health benefits" for their impressions of the POM brand does not mean those respondents believed that "POM Juice is proven to prevent, treat or reduce the risk of disease." These are two very distinct concepts. Moreover, what the survey participants thought was true about the POM brand may or may not be attributable to POM Juice. (PX0295a15-0033-34).

Third, Complaint Counsel's conclusion is also erroneous because none of the Challenged Advertisements convey establishment claims that the Challenged Products treat, prevent or reduce the risk of heart disease, prostate cancer or erectile dysfunction. (RFF 2273, 2281-84, 2300, 2303-06, 2322, 2325-28, 2360, 2362-63, 2367-69, 2384, 2386, 2388-90, 2407, 2409-12, 2423, 2425-28, 2442, 2444-47, 2467-69, 2472-74, 2506, 2517, 2523, 2529, 2535, 2542-43; Respondents' Appendix of Advertisements).

Last, the results from the Bovitz Survey are unreliable because its is methodological flawed for the reasons stated in above in Response to Finding No. 579. Moreover, the results from Question 16 are completely unreliable and inflated for the reasons stated above in Response to Finding No. 593.

596. Respondents used the Bovitz Survey to make decisions regarding their advertising campaigns. Lynda Resnick used the Bovitz Survey to determine that POM would continue using the then-running "Super Hero" advertising campaign. (CX0313_0002; CX1378 (Kuyoomjian, OS Dep. at 205); CX1357 (Kuyoomjian, Dep. at 252), CX1359 (L. Resnick, Dep. at 236). The conclusions drawn from the Bovitz Survey applied across all media formats and were not limited to a narrow analysis of campaign billboards. As Mrs. Resnick wrote in her book, *Rubies in the Orchard*,

A concise, potent message travels well. You can publish it in a magazine and mount it on a billboard. You can put it on a Web site or embroider it on a baseball cap. The shorter the message, the more easily it adapts to different circumstances – and the more readily it travels between different media.

(CX0001_0020).

Response to Finding No. 596:

Complaint Counsel mischaracterizes the testimony of Ms. Kuyoomjian. Ms. Kuyoomjian did not testify that Lynda Resnick used the Bovitz Survey to determine that POM would continue using the then-running "Super Hero" advertising campaign. Rather, Ms. Kuyoomjian testified that based on the research, "the decision was made to stick with the [Super Hero] campaign." (CX1357 (Kuyoomjian, Dep. at 252-53); CX1378 (Kuyoomjian, OS Dep. at 205)). She never testified who made that decision.

Complaint Counsel completely mispresent Mrs. Resnick's statement from her book, *Rubies in the Orchard.* The quoted passage provides no support for Complaint Counsel's assertion that the "conclusions drawn from the Bovitz Survey applied across all media formats and were not limited to a narrow analysis of campaign billboard." For example, the quotation does not reference or analyze the results of the Bovitz Survey or the billboard stimuli used in the Bovitz Survey. (CX0001_0020). Nor does the quoted passages reference or analyze the Challenged Advertisements, the Challenged Claims, the Challenged Products or any specific ad, claim or product. It merely is a generalized statement espousing Mrs. Resnick's personal opinion about the importance of brevity in advertising. (CX0001_0020).

Moreover, as set for the in Response to Finding No. 585, the conclusions drawn from the Bovitz Survey do not apply to the Challenged Ads or what a reasonable person would take away from them. The Bovitz Survey is not probative extrinsic evidence because any comparisons between the Bovitz Stimuli (which had no body copy) and the Challenged Ad with the same headline is completely irrelevant because the Challenged Ads with the same headlines all have body copy, and the body copy of an ad drastically

changes the meaning of an ad or what a reasonable person would take away from it. (*See supra* RRFF 585; D. Stewart, Tr. 3206).

2. Butters and Stewart

597. Respondents called Dr. Ronald Butters as a linguistics expert to testify about the meanings of the challenged advertisements. (Butters, Tr. 2816-17). The Court recognized Dr. Butters as an expert in linguistics, including the meaning of language and symbols and the context in which they appear, but Dr. Butters admitted that he is not a marketing expert and does not have any expertise in advertising consumer products or in consumer buying behavior. (Butters, Tr. 2816, 2954-55). Dr. Butters also acknowledged that he had never previously testified as an expert in a case which involved alleged deceptive advertising. (Butters, Tr. 2956).

Response to Finding No. 597:

Respondents do not disagree that Dr. Butters is a linguistic expert, but note that Dr. Butters was also recognized as an expert on the meaning of language and symbols as well as written and oral communications. (Butters, Tr. 2816). Respondents agree only that Dr. Butters does not have a specialty in marketing aspects of consumer advertising or buying behavior, and they dispute Complaint Counsel's attempt to mischaracterize or minimize Dr. Butter's qualifications. As the materials attached to Dr. Butters's report demonstrate, Dr. Butters has significant expertise in linguistic science. (Butters Rep. 4-8 and Ex. 1).

598. Complaint Counsel called Dr. David W. Stewart as a rebuttal witness to respond to Dr. Butters. The Court recognized Dr. Stewart as an expert in advertising, marketing, consumer behavior, and survey methodology. (Stewart, Tr. 3168).

Response to Finding No. 598:

Respondents do not disagree that Complaint Counsel called Dr. Stewart as a rebuttal witness. However, Respondents note that Dr. Stewart is not a linguist and therefore did not undertake to rebut Dr. Butters from a linguistic perspective. (RFF ¶ 238). Dr. Stewart acknowledged that linguistics, of which Dr. Butters is an expert, is relevant to what an advertisement is likely to convey to consumers. (Stewart Dep. 38:7-11).

Respondents do not disagree that the Court recognized Dr. Stewart as an expert in advertising, marketing, consumer behavior, and survey methodology, but note that the Court recognized Dr. Stewart only as a rebuttal witness and that Dr. Stewart conducted no analysis as to how consumers understand or interpret messages or POM ads. (RFF ¶ 239).

599. Dr. Stewart is a full Professor of Marketing in the A. Gary Anderson Graduate School of Management, University of California at Riverside, where he served as Dean of the business school for four years. (PX295a01-0002, 0041; Stewart, Tr. 3161; CX1295 (Stewart, Report at 0002)). During his long and distinguished academic career, Dr. Stewart has taught a variety of graduate and undergraduate level courses related to advertising, consumer behavior, marketing research, and marketing strategy. (PX295a01-0050-51; Stewart, Tr. 3160-61; CX1295 (Stewart, Report at 0003-04)).

Response to Finding No. 599:

Respondents do not disagree that Dr. Stewart is a Professor of Marketing at University of California at Riverside. Although Dr. Stewart was once a Dean, Respondents note, as was revealed at trial (and curiously not mentioned in Complaint Counsel's findings), that Dr. Stewart was asked step down as Dean by the Chancellor of University of California. (Stewart, Tr. 3224-25). Respondents further note that Dr. Stewart initially denied that he was asked to step down as Dean, but recanted his testimony when faced with a document that established the inaccurate nature of his prior testimony. (Stewart, Tr. 3224-25.) Accordingly, Respondents dispute Complaint Counsel's characterization that Dr. Stewart has had a "distinguished" academic career.

600. Dr. Stewart has authored or co-authored eight books on advertising related issues and has written over 125 articles which have been accepted in peer reviewed academic journals. (Stewart, Tr. 3162-63; PX295a01-0002, 0005, 0008-17; CX1295 (Stewart, Report at 0002)). Dr. Stewart has served as the editor, associate editor, or member of the editorial board of numerous academic journals. (PX295a01-0043-47; CX1295 (Stewart, Report at 0002); Stewart, Tr. 3161). Dr. Stewart has served as the President of the Academic Council of the American Marketing Association and chairman of the Section on Statistics in Marketing of the American Statistical Association. (Stewart, Tr. 3161-62; PX295a01-0002, 43). He is a past president of the Society of Consumer Psychology of the American Psychological Association. (Stewart, Tr. 3162; PX295a01-0002, 0045; CX1295 (Stewart, Report at 0003)).

Response to Finding No. 600:

Respondents do not dispute the statements in paragraph 600.

601. According to Dr. Stewart, Dr. Butters's analysis of Respondents' advertising communication ignores an enormous body of theory and empirical research related to how consumers use information, process advertising messages, and make decisions in the market place. (CX1295 (Stewart, Report at 0006); Stewart, Tr. 3170-71).

Response to Finding No. 601:

Respondents do not dispute that Dr. Stewart holds this view of Dr. Butters's analysis, but note that Dr. Stewart himself admitted that linguistic analysis, which Dr. Butters performed, is relevant and useful to construing advertising claims. Respondents further note that Dr. Stewart did not perform his own analysis of the advertisements at issue. (RFF ¶ 239). In contrast to Dr. Stewart who did not analyze the claims, Dr. Butters applied a rigorous scientific linguistic methodology to his analysis of the claims. (RFF ¶¶ 182-85). In addition, Respondents note that Dr. Stewart testified that linguistics is a relevant to advertising analysis, that he is not a linguist, and that he did not perform an linguistic analysis. (Stewart Dep. 38:7-11).

602. For example, Dr. Butters analyzed the challenged ads from the perspective of the ordinary adult user of the English language in America. (Butters, Tr. 2831, 2833-34). Dr. Butter's total population framework ignores POM's practice of specifically targeting consumers who are very concerned about or already have health problems. (CX1295 (Stewart, Report at 0012-13); Stewart, Tr. 3182-84, 3186-87). Such consumers are likely to be both more attentive to health claims and more likely to draw specific inferences about the benefits of POM's products than the general universe of American speakers of English. (CX1295 (Stewart, Report at 0013); Stewart, Tr. 3187-88).

Response to Finding No. 602:

Respondents do not disagree with the first sentence of this paragraph. Respondents disagree with the second sentence of the paragraph and expressly dispute that POM has a practice of targeting only those consumers with health problems. (*See* RFF ¶¶ 2201-04). Respondents further dispute the last sentence of the paragraph and note that Complaint

Counsel's only support of this proposition is from Dr. Stewart who admittedly did not perform an analysis of the challenged advertisements. (Stewart Tr., 3168) (*see also* RFF ¶¶ 2201-04).

603. In his report and during his testimony, Dr. Butters asserted that the effect of humor in advertising for the POM Products is to reduce or block the communication of any serious health claims. (PX0158 (Butters, Report at 0004); PX0350 (Butters, Dep. at 62); Butters, Tr. 2864).

Response to Finding No. 603:

Respondents do not disagree with the statements in this sentence, but note that the statements are incomplete and taken out of context. Dr. Butters further testified and stated in his report that humor has, historically, been used in a variety of ways in advertising and that an analysis of an advertisement is needed to determine the way that humor interacts in any particular context. (Butters, Tr. 2825-27.).

604. Dr. Butter's assertion is contrary to research on the use of humor in advertising. (CX1295 (Stewart, Report at 0008-09); Stewart, Tr. 3200-01). There is no evidence in the marketing literature that consumers would be skeptical of claims that employ humor and the literature suggests that appropriately used humor disarms consumers, reduces counter arguing, and increases persuasion. (CX1295 (Stewart, Report at 0009); Stewart, Tr. 3200-01). This is consistent with the testimony of Lynda Resnick who said, "if you make someone laugh . . . you've broken through . . . their guard goes down a little and they listen to you." (CX1359_0242-44).

Response to Finding No. 604:

This finding is misleading. Dr. Butters's opinion regarding the way that humor interacts in the advertising context is consistent with and based on his rigorous linguistic analysis and his interpretation, using the methodologies and approaches he described in his report and at trial (including semantics, semiotics, and lexicology and pragmatics) (Butters Tr. 2825-30; Butters Rep. 6-7). Complaint Counsel's only support for their contention that Dr. Butters' contention is contrary to marketing literature are references relied upon by Dr. Stewart. Respondents note, however, that the literature relied on by Stewart does not address the specific type of advertising at issue in this case. (Stewart Tr. 3231-3233).

Indeed, one of the articles relied upon by Dr. Stewart does not even address American consumers, but rather discusses humor in a sub-set of advertising in the United Kingdom. (Stewart Tr. 3231-3233).

605. During redirect at trial, Dr. Butters changed his testimony and acknowledged that the humor in POM ads does not block the serious statements that are made in the body copy of the ads or in footnotes. (Butters, Tr. 2958).

Response to Finding No. 605:

Respondents disagree that Dr. Butters "changed" his testimony. Dr. Butters has consistently testified that interpretations of advertisements are context-dependent and that humor can work in various ways, depending on the particular advertisement at issue. (Butters, Tr. 2958; Butters Dep. 65:16-25). With regard to the POM ads at issue, Dr. Butters testified consistently that the exaggerated, humorous headlines and imagery, such as "I'm Off To Save Prostates…" contribute to the light hearted and less serious nature of the ads. Dr. Butters never testified -- in deposition or at trial -- that humor would work to block statements in the footnotes or full text of an advertisement.

606. During redirect, Dr. Butters still asserted that POM's exaggerated and humorous headlines and images will not be seen as making claims. (Butters, Tr. 2958).

Response to Finding No. 606:

Respondents do not disagree with this statement, but note that Dr. Butters has never testified that text referring to specific studies or in footnotes do not make verifiable claims. (Butters Tr. 2921-22).

607. The Bovitz Study, which tested POM's humorous headlines and images by themselves, contradicts Dr. Butters, showing significant communication of specific health benefits claims, including that POM Juice is good for prostates, good for your heart, and helps/lowers blood pressure. (Stewart, Tr. 3202, 3204-06, 3213-14, 3216-17, 3218-20; CCFF ¶¶ 588, 590).

Response to Finding No. 607:

The Bovitz Study does not contradict Dr. Butter's conclusion, as the Bovitz study did not concern the full advertisements themselves. (*See* RFF ¶¶ 2752-71). Complaint Counsel admitted during trial that they were not challenging the out-of-home advertisements (such as billboards) that were the subject of the Bovitz study. (RFF ¶ 2752). The Bovitz Survey also does not address materiality because, among other reasons, participants were not asked why they purchase POM Juice. (RFF ¶¶ 2754-55). Moreover, in contrast to Dr. Butters's careful and rigorous linguistic analysis of the advertisements at issue, the Bovitz Survey is methodologically flawed and unreliable because Question E imposed a stringent screening criteria, which created an overall bias in the survey towards extremely health-focused people, which is not representative of the overall population. (RFF ¶ 2759; PX0356 (Reibstein, Dep. at 173)). The sample size of only 100 POM users and 150 target consumers also was too small to reach statistical significance at the 95% confidence level. (RFF ¶¶ 2760-61; PX0356 (Reibstein, Dep. at 172-73); *see also* RFF ¶¶ 2766-68). The Bovitz Survey is also methodologically flawed and unreliable because participants were shown specific advertisements in a tightly controlled environment, which is not how consumers normally view ads. (RFF ¶¶ 2756, 2762; PX0356 (Reibstein, Dep. at 173-74)). Thus, the Bovitz Survey cannot be used to determine whether what was observed in the survey applies to a normal advertising viewing context. (RFF ¶¶ 2756, 2763). The Bovitz Survey also had no control and, thus participants might have had preconceived perceptions about pomegranate juice before being exposed to POM's billboard ads which could skew their perception of POM's billboard ads. (RFF ¶ 2757). Dr. Butters's analysis on the other hand concerned the actual advertisements at issue in this case and analyzed them from the perspective of speakers of the English language in America.

608. Dr. Stewart testified that although some humorous headlines like "Amaze your cardiologist" and "Floss your arteries" might not to be taken literally, they [can] still

communicate serious health messages, such as that POM Juice offers significant cardiovascular health benefits and such headlines contribute to the overall net impressions from the advertisements. (Stewart, Tr. 3202, 3204-06, 3230-31, 3240).

Response to Finding No. 608:

Respondents do not disagree that Dr. Stewart holds the views expressed, but note that he is not qualified to render this opinion because he did not analyze the advertisements at issue in the case. (Stewart Tr. 3168).

609. Contrary to a net impression analysis, Dr. Butters parsed the text of the challenged ads in analyzing individual elements or words. (Stewart, Tr. 3173; CX1295 (Stewart, Report at 0006)).

Response to Finding No. 609:

Respondents dispute that Dr. Butters failed to consider the entirety of the advertisement. As Dr. Butters testified extensively to at trial, his linguistic analysis involved various sub-fields of linguistics, including (without limitation) semiotics (the study of signs and images as they interact with words and expression), semantics (the study of the meaning of words), and lexicography. (Butters, Tr. 2813-2815; Butters Rep. 4-6). Dr. Butters testified that he considered the entire advertisement and the interactions between the words, images, and other symbols or imagery in performing his analysis. (RFF ¶¶ 181-82).

610. Dr. Butters asserted that POM's ads were sufficiently qualified by words such as "can," "may," "pilot" and "preliminary." (Butters, Tr. 2822-23, 2912-14, 2925; PX0158 (Butters, Report at 0023, 0043)). Dr. Butters, however, was not aware of any academic literature to support his position. (See Butters, Tr. 2915-16, 2921; PX0350 (Butters, Dep. at 93, 97)).

Response to Finding No. 610:

Respondents do not dispute the first sentence of this finding, but note that it only states a portion of Dr. Butters's entire opinion of the advertisement at issue. (*See generally* Butters Rep and Butters Tr.). Respondents disagree with Complaint Counsel's blatant

mischaracterization of the testimony cited in the second sentence. At trial, Dr. Butters testified that his opinions were based on rigorous linguistic research, literature, and methodology, including dictionaries and other texts in the field. Dr. Butters never stated that there was no academic literature to support his linguistic approach or analysis, he merely stated that there was not a particular piece of literature that analyzed Respondents' specific ads. (Butters Tr. 2916-17).

611. Asked whether reasonable consumers take the claim "can reduce" to mean "reduces," as alleged in the Complaint, Dr. Butters stated that there is no clear yes or no answer because of the intrinsic ambiguity of the word "reduces." (PX0350 (Butters, Dep. at 92-93)). Moreover, Dr. Butters admitted that there is no academic literature to support a conclusion that reasonable consumers will not take a claim like "can reduce" to mean "reduces." (PX0350 (Butters, Dep. at 93)).

Response to Finding No. 611:

Respondents vigorously dispute the contentions and characterization in this paragraph. The exchange that Complaint Counsel references is from Dr. Butter's deposition when Complaint Counsel, over the objection of Respondents' counsel, asked him to answer questions about the generic meaning of the word "reduces" separate and apart from any context. Not only was this question irrelevant to the underlying inquiry in this case (because the question did not apply to any specific ads or any context), but Dr. Butters himself noted that the term "can reduce" must be read in context to decipher its meaning. (Butters, Dep. at 92-94). Complaint Counsel's attempt to twist Dr. Butters's testimony should be rejected.

612. Dr. Stewart testified that the members of the audience for a POM ad are processing the totality of the ad, not nuances of individual words. (Stewart, Tr. 3172-74). Dr. Stewart asserted that the academic literature offers empirical evidence that the presence of qualifiers actually increases the credibility of claims. (Stewart, Tr. 3189-90; CX1295 (Stewart, Report at 0016-17); PX0295a07)).

Response to Finding No. 612:

Respondents do not dispute that Dr. Stewart testified to the statements made in paragraph 612.

613. Even a linguistics textbook frequently used by Dr. Butters for his introduction to linguistics course asserted, in a section titled "Language in Advertising," that the use of qualifiers, such as those noted by Dr. Butters, "encourage the audience of the advertisements to infer that a stronger claim is intended than the one that is actually entailed." (Butters, Tr. 2916-19).

Response to Finding No. 613:

Respondents do not dispute the specific language from "Language in Advertising," but they do dispute Complaint Counsel's attempt to take the language out of context. As Dr. Butters testified at trial, Dr. Butters disagrees with certain statements in the "Language in Advertising" textbook based on his linguistic expertise. (Butters, Tr. 2919).

614. Dr. Stewart believed that the typical consumer would likely have little understanding of what "initial" or "pilot" means. (Stewart, Tr. 3191).

Response to Finding No. 614:

Respondents do not disagree with the statement that Dr. Stewart testified to this conclusion, but note that Dr. Stewart admitted that he had not performed specific research and had not conducted an independent analysis of the ads at issue or the audience that would likely see the ads and therefore Dr. Stewart's opinion is not substantiated. (Stewart, Tr. 3169). As Dr. Butters testified, words in an advertisement must be read in context with the overall ad. Dr. Stewart's opinion about specific words devoid of context is not relevant to this case.

615. Furthermore, such terms as "initial" or "pilot" are often used in POM advertising in connection with mentions of a well-respected medical school (UCLA), "leading universities," reference to professional journals in which support of the claims is found, reference to a Nobel laureate, and reference to the sum of money spent on research that is represented as supporting the advertising claims (e.g., $25 million), all of which have the effect of establishing the credibility of claims for the POM Products. (CX1295 (Stewart, Report at 0017)). Dr. Butters conceded that if a "pilot" study is described in an ad as

having been published in a medical journal, it could affect how the consumer views it in the context. (Butters, Tr. 2925).

Response to Finding No. 615:

Respondents dispute that that Dr. Stewart is qualified to opine on the use of the words "initial" or "pilot" or their effect on POM customers because he admittedly did not conduct any analysis of the advertisements at issue in this case. (RFF ¶ 239). Respondents further dispute that Dr. Stewart can render an opinion as to the other statements in this finding, as he did not perform a specific analysis of the ads at issue. (RFF ¶ 239) As to the last sentence of this finding, Complaint Counsel has taken Dr. Butters's words out of context. Dr. Butters testified that if there are quotes from researchers, a description of a study, the results of the study in the ad, and additional information about what the study means that such information could affect how a consumer views the study and its implications. (Butters, Tr. 2925).

3. POM's Communications with Consumers and POM's Views on Consumer Takeaway

616. POM was aware from communications with consumers that people with heart disease or who were at risk for heart disease were drinking POM Juice for the purpose of treating, preventing, or reducing their risk of heart disease, arterial plaque, or high blood pressure, and that consumers believed that POM products could treat, prevent, or reduce the risk of heart disease, arterial plaque, or high blood pressure. The consumer comments included:

- "My dad has heart problems and I'd like to have him on a regimen of drinking POM juice daily[.]" (CX0485_0083);
- "I've started pomegranate juice to help with a small blockage in my heart." (CX0485_0649);
- "I need to buy your 48 ounce 100% POM juice to lower my blood pressure. A study in Israel revealed that 75 to 85 year old patients who drank 8 ounces of the juice for one year, reduced arterial plaque by thirty percent. Needless to say, I want to reduce my plaque and lower my blood pressure also. . . . I need to start drinking this right away." (CX0485_0510-11);
- "I want to continue using your product, please let me know because I do not mind paying for the juices you make, because they are nutritious, and I

need them because of my health problems with my blood pressure." (CX0485_1088-89);

- "If people's arterial plaque was decreased by 30% in one year, does that mean that after about 3 years and 4 months it would be all gone and your arteries would be clean as a whistle? . . . I am concerned about heart health because I am almost 59 and had a heart attack a year ago." (CX0485_2296); and

- "Caller said that he has been consuming the juice daily for three years, and he has not seen a reduction in his blood pressure. He believes that the studies shown on the website are inaccurate and false." (CX0485_1390).

Response to Finding No. 616:

It is not, as Complaint Counsel argue, apparent that consumers purchased POM Juice because they believed it would treat, prevent or reduce the risk of heart disease, arterial plaque or high blood pressure. (See infra BLANK section on Materiality). As such, POM could not have possibly been aware that its consumers were taking away this message, which they were not.

Indeed, consumers purchased POM's products for a variety of reasons unrelated to health. (PX0356 (Reibstein, Dep. at 114)). There exists absolutely no evidence that POM Juice was purchased to "treat, prevent or reduce the risk of heart disease, arterial plaque, or high blood pressure" as boldly claimed by Complaint Counsel. In fact, Dr. Reibstein's survey, for example, revealed that less than 1% purchased POM to prevent, cure, or treat any disease. (Reibstein, Tr. 2493). Additionally, to support their bold assertion, Complaint Counsel cite only to quite literally, a handful of consumer inquiries out of more than 24,000 inquires POM received, many of which pertained primarily to when or whether a product might be available in a certain location. (CCPTB at 59; CX0485).

Moreover, not only has POM never offered its products as a substitute for medical care, but it has written policies in place, that repeatedly make clear that its products are not

offered as substitutes for conventional medical care or therapies, and such practice would be a cause for termination. (Tupper, Tr. 3018; S. Resnick, Tr. 1871). Indeed, as a matter of practice, in responding to its consumer inquiries, POM encourages its consumers to consult with his or her doctor. (Tupper, Tr. 3018-19; CX0308_0003-0005).

617. POM also was aware from numerous communications with consumers that men with prostate cancer, or who were at risk for prostate cancer, were drinking POM Juice or taking POMx for the purpose of treating, preventing, or reducing their risk of prostate cancer, and that consumers believed that POM products could treat, prevent, or reduce the risk of prostate cancer. The consumer comments included:

- "I have read the UCLA study and have been unsuccessful in finding Pomegranate Juice. I have found a mixture but not 100% Pomegranate Juice. This is important to me since I have 2nd recurrence [sic] of prostate cancer." (CX0485_0155);

- "My problem is that I have prostate cancer and have been a cancer survivor for 10 years...It has recently flared-up [sic] I contacted UCLA about your sponsored study and was told that I didn't qualify....But I could 'go it alone' with the regimine [sic], and drink 8 oz of your product per day. 'Desperite [sic] situations need desperite [sic] actions.'" (CX0485_0165);

- "I'm doing a single subject, controlled study of the juice's efficacy in controlling the growth of my existing prostate cancer." (CX0485_0192);

- "I suffer from prostate cancer and presently drink a third of a bottle of Pomwonderful [sic] per day in the hope that this will reduce the rate of increase in my psa. It is too early to assss [*sic*] the results but in the meantime a routine blood check by my GP who is monitoring my high blood pressure has disclosed an increase in my potassium level and this will require medication. I understand that pomegranate is a source of potassium and I wonder if you are able to tell me if your product contains a sufficiently high element to cause the problem. Unless it is significant, I do not intend stopping drinking Pomwonderful [sic] in view of the important potential benefit to me [sic] cancer but will appreciate your advices." [sic] (CX0485_0193);

- "I have been drinking POM 100% Pomegranate juice for about 8 months for prostate cancer prevention." (CX0485_0384);

- "I'm an 89 year old man with prostate cancer. I've been treated with radiation but I have an aggressive cancer (Gleason 9) and my PSA is rising. I've just started using the POM wonderful 100% pomegranate

juice. . . . In checking your web site I saw that it is available in pill form. Has then [sic] been proven as effective as the liquid form in treating prostate cancer?" (CX0485_1049-50);

- "I just purchased a re-occurring monthly supply of POM Pills. My brother recently was diagnosed with advanced prostate cancer at 48 years old, which puts me (44) in a high risk category." (CX0485_1339-40).

Response to Finding No. 617:

It is not, as Complaint Counsel argue, apparent that consumers purchased POM Juice because they believed it would treat, prevent or reduce the risk of prostate cancer. (See infra BLANK section on Materiality). As such, POM could not have possibly been aware that its consumers were taking away this message, which they were not.

Indeed, consumers purchased POM's products for a variety of reasons unrelated to health. (PX0356 (Reibstein, Dep. at 114)). There exists absolutely no evidence that POM Juice was purchased to "treat, prevent or reduce the risk of prostate cancer" as boldly claimed by Complaint Counsel. In fact, Dr. Reibstein's survey, for example, revealed that less than 1% purchased POM to prevent, cure, or treat any disease. (Reibstein, Tr. 2493). Additionally, to support their bold assertion, Complaint Counsel cite only to quite literally, a handful of consumer inquiries out of more than 24,000 inquires POM received, many of which pertained primarily to when or whether a product might be available in a certain location. (CCPTB at 59; CX0485).

Moreover, not only has POM never offered its products as a substitute for medical care, but it has written policies in place, that repeatedly make clear that its products are not offered as substitutes for conventional medical care or therapies, and such practice would be a cause for termination. (Tupper, Tr. 3018; S. Resnick, Tr. 1871). Indeed, as a matter of practice, in responding to its consumer inquiries, POM encourages its consumers to consult with his or her doctor. (Tupper, Tr. 3018-19; CX0308_0003-0005). Mr. Resnick testified that if consumers are interpreting from Respondents' "Decompress" ad that

POM Juice lowers blood pressure, "[i]t's not my problem . . . it's their problem." (CX1376 (S. Resnick, OS Dep. at 309-10)).

618. Mr. Resnick testified that if consumers are interpreting from Respondents' "Decompress" ad that POM Juice lowers blood pressure, "[i]t's not my problem … it's their problem." (CX1376 (S. Resnick, OS Dep. at 309-10)).

Response to Finding No. 618:

Complaint Counsel have mischaracterized Mr. Resnick's testimony.

While it is true that, during a series of questions about the Bovitz survey, Mr. Resnick stated, "it's not my problem…it's their problem" if consumers interpret the Decompress ad that POM Juice lowers blood pressure, the basis for Mr. Resnick's statement was that he did not believe that the Decompress advertisement made any reference to blood pressure or that POM ever made blood pressure reduction claims. (CCPTB at 69; CX1377 (S. Resnick, Ocean Spray Dep. at 310)).

Indeed, nowhere in this ad do Respondents expressly (i.e., unequivocally and directly) state that (a) POM Juice "prevents," "treats," or "reduces the risk" of heart disease, prostate cancer and erectile dysfunction; or (b) POM Juice is "clinically proven" to "prevent," "treat," or "reduce the risk" of heart disease, prostate cancer and erectile dysfunction. (CX0103_0001; CX0459_0001). 2335. Moreover, Dr. Butters testified that it would be a gross exaggeration for anybody to think that the image of a blood pressure cuff around the POM Juice bottle and the headline "Decompress" could literally mean drink a glass of pomegranate juice and your blood pressure will go down. (Butters, Tr. 2933). Similarly, Mr. Resnick testified that the "Decompress" advertisement is a tongue-in-cheek way to show that POM is healthy and it will help your heart. (CX1376 (S. Resnick, Ocean Spray Dep. at 163-64)).

619. Similarly, Mr. Resnick testified that if POM's "ads communicate to consumers that POM can prevent or delay the onset of prostate cancer," he is very comfortable with that claim. (CX1376 (S. Resnick, OS Dep. at 156)).

Response to Finding No. 619:

Complaint Counsel have mischaracterized Mr. Resnick's testimony. To construct a story about "lack of remorse" Complaint Counsel also take statements that Mr. Resnick made in connection with advertising claims that he believed that POM never made. While Mr. Resnick does not believe that POM's advertisements communicate that the Challenged Products can prevent of delay the onset of prostate cancer, he, in fact, does believe that POM's science would support such claims. Mr. Resnick explained, "…the research we've done on not just humans and PSA, but on the actual cancer cells themselves in mice, I am totally comfortable that there's a good chance as any that this is helpful for prostate." (CX1376 (S. Resnick, Ocean Spray Dep. at 155)). Thus, Mr. Resnick's statements do not reflect a lack of remorse—instead they reflect his belief that POM never made the claims alleged, and that, in any event, such claims would be supported by the science.

620. POM itself boasted that its marketing efforts have caused consumers to associate pomegranate juice with certain nutritional and health benefits: "Due to POM's marketing efforts and funding of research, and substantial research not funded by POM, many consumers now associate pomegranate juice with certain nutritional and health benefits." (CX1404_0037; *see also* CX1395_0004 ("A key element of POM Wonderful's marketing campaign has been its concentration on the health benefits associated with pomegranates and pomegranate juice, and its emphasis on the high level of antioxidants contained in POM Wonderful brand juice.")).

Response to Finding No. 620:

Although POM may have marketed certain nutritional and health benefits of pomegranates, this aspect of POM's marketing philosophy alone does not show that Respondents intended to convey the broad "prevent or treat" claims Complaint Counsel attributes to the Challenged Ads.

621. Respondents paid close attention to the net impression of competitors' product claims that they believed to be misleading to the "average consumer." (*See, e.g.*, CX1364 (Tupper, TCCC Dep. at 141-43, 149-50, 155-58) (repeatedly referring to the "average consumer")).

Response to Finding No. 621:

Respondents object to this proposed finding as irrelevant, argumentative and conclusory. Mr. Tupper was not giving a net impression analysis of competitor's product during the deposition; rather he was answering specific questions about various aspects of the product's label.

622. For example, Mr. Tupper testified that "any reasonable consumer" in a grocery aisle would be drawn to the large font words ("[p]omegranate is in big font") and visual images ("pictures of . . . two big red pieces of fruit against this blobby green backdrop") and conclude from the label that the competitor's juice is healthy pomegranate juice. (CX1369 (Tupper, Welch Dep. at 178-79, 181); *see also* CX1364 (Tupper, TCCC Dep. at 148) ("You see pomegranate blueberry and your eyes is then drawn at the picture of pomegranate and blueberries. That is what your brain processes. As I'm sure you can see, in addition to those big things, a bunch of small stuff that I believe most consumers, if not all consumers, are going to gloss over and ever pay attention to it.")).

Response to Finding No. 622:

Respondents object to this proposed finding as irrelevant and misleading. Mr. Tupper was testifying about the label of a competitor's product, not about alleged health claims in the advertising of POM products. Complaint Counsel has asked the Commission to make several leaps in logic in order to conclude that that Mr. Tupper's comments about the label on a bottle of Minute Maid juice could, in some way, relate to health benefit claims in POM's advertising. This is not just illogical and misleading but also untrue. Furthermore, unlike the labels on the competitor's product, the Challenged Advertisements do not convey the messages that the FTC claim they make, and Respondents have a rational basis, and competent and reliable scientific evidence to support the claims that were expressly and implicitly made.

623. Mr. Tupper also acknowledges that a statement "may be factually true on the surface" and yet misleading because "it lends a level of credibility as to the healthfulness of the product" that may not be backed up. (CX1364 (Tupper, TCCC Dep. at 142)).

Response to Finding No. 623:

Respondents object to this proposed finding as irrelevant and misleading. Mr. Tupper was testifying about the label of a competitor's product, not about alleged health claims in the advertising of POM products. Complaint Counsel has asked the Commission to make several leaps in logic in order to conclude that that Mr. Tupper's comments about the label on a bottle of Minute Maid juice could, in some way, relate to health benefit claims in POM's advertising. This is not just illogical and misleading but also untrue. Furthermore, unlike the labels on the competitor's product, the Challenged Advertisements do not convey the messages that the FTC claim they make, and Respondents have a rational basis, and competent and reliable scientific evidence to support the claims that were expressly and implicitly made.

624. Likewise, Mr. Tupper recognizes that "many consumers may not read" or take the time to process information presented in small font on a label. (CX1364 (Tupper, TCCC Dep. at 125-26, 150, 164, 167-68) (noting that information about the competitor's juice blend is "small font, buried at the bottom, the label has a lot of information to process, and as I said before I think what the consumer is going to process is Minute Maid, help nourish your brain, pictures of the pomegranates and the blueberries and the name pomegranate-blueberry")).

Response to Finding No. 624:

Respondents object to this proposed finding as irrelevant and misleading. Mr. Tupper was testifying about the ingredient list on the label of a competitor's product, not about alleged health claims in the advertising of POM products. Complaint Counsel has asked the Commission to make several leaps in logic in order to conclude that that Mr. Tupper's comments about the size of font on a bottle of Minute Maid juice could, in some way, relate to health benefit claims in POM's advertising. This is not just illogical and

misleading but also untrue. Furthermore, unlike the labels on the competitor's product, the Challenged Advertisements do not convey the messages that the FTC claim they make, and Respondents have a rational basis, and competent and reliable scientific evidence to support the claims that were expressly and implicitly made.

VI. RESPONDENTS' CLAIMS ARE MATERIAL

A. Respondents' Challenged Claims Are Presumptively Material

625. The challenged ads present the POM Products as treating, preventing, and/or reducing the risk of heart disease, prostate cancer, and/or erectile dysfunction and therefore make significant health claims. (*See supra* Sections V.D – V.F).

Response to Finding No. 625:

Complaint Counsel's use of the term "present" is vague and ambiguous and in error if Complaint Counsel correlates "present" with "convey" to consumers. The Challenged Advertisements do not convey that the Challenged Products prevent, treat, or reduce the risk of heart disease, prostate cancer and erectile dysfunction. (RFF 2210-16, 2273, 2275-76, 2279, 2281-86, 2300-08, 2322, 2324-28, 2360-69, 2384-85, 2388-91, 2407-12, 2323-28, 2442-47, 2467-74, 2506, 2517, 2542; Appendix of Advertisements). The use of the term "significant" is vague and ambiguous and in error if Complaint Counsel correlates "significant" with "material." There is no evidence that the Challenged Claims are material to consumers' purchase decisions. (RFF 2219, 2613-46, 2678, 2696-2701). In fact, the Reibstein Survey demonstrates just the opposite – that only 1.48% (6 out of 406) of POM Juice buyers (i) bought, (ii) would buy again or (iii) would recommend to a friend POM Juice because they believe that it cures or prevents any specific disease. (PX0223-0020). Complaint Counsel failed to present any evidence to rebut the Reibstein Survey. (RFF 2680-84, 2719, 2721-80).

626. Health benefits are the central characteristic and purpose of using POMx and are a central characteristic of POM Juice as it was advertised. (*See supra* CCFF ¶¶ VIII.153-57, Sections V.C – V.F).

Response to Finding No. 626:

Respondents object to this proposed finding as conclusory and argumentative and further state that none of the cited evidence supports the assertion that "[h]ealth benefits are the central characteristic and purpose of using POMx." Respondents further object that the terms "health benefits" and "central characteristic" are vague and ambiguous. Respondents state that the Challenged Ads summarize some of Respondents' scientific research on the Challenged Products in the areas of cardiovascular, prostate and erectile health and talk about the healthful properties of the products, including that the Challenged Products contain abundant antioxidants and that they are wholly derived from pomegranate fruit. (RFF 493-99, 2478-2505, 2518-44). Respondents dispute that they ever intended to convey or that the Challenged Ads do convey the claim that the Challenged Products treat, prevent or reduce the risk of heart disease, prostate cancer and erectile dysfunction or that they are "clinically proven" to do so. (RFF 2209-11). Complaint Counsel presented no evidence directly contradicting this testimony.

627. Challenged claims were often made expressly or so strongly implied as to be virtually express. (*See supra* Sections V.D – V.F).

Response to Finding No. 627:

Respondents deny that they made the Challenged Claims. (RFF 2209-16). The Challenged Ads do not convey the disease claims that Complaint Counsel assert are expressly or virtually expressly made in the Challenged Advertisements. Nowhere do POM's ads expressly (*i.e.*, unequivocally and directly) state that the (a) Challenged Products "prevent," "treat," or "reduce the risk" of heart disease, prostate cancer and erectile dysfunction; or (b) Challenged Products are "clinically proven" to "prevent," "treat," or "reduce the risk" of heart disease, prostate cancer and erectile dysfunction. (RFF 2210, 2273-74, 2300-01, 2322, 2324, 2360-61, 2384-85, 2407-08, 2442-43, 2467-68, 2506, 2517, 2542; Appendix of Advertisements). Nor can Lynda Resnick or

Matthew Tupper be held liable under the FTC Act for the media interviews Complaint Counsel cites in Sections V.F.2.a-d. (RFF 2548-2595, 2610-21).

628. Respondents intended to make the challenged claims. (*See, e.g.,* CCFF ¶¶ IX.C.1.281-IX.C.3.318, IX.D.1.b.334, 337-38, IX.D.1.f.350, IX.D.1.f.354, IX.D.1.g.359-60, IX.D.2.a.369, IX.D.2.b.373-74).

Response to Finding No. 628:

Respondents genuinely believe in the health benefits of the Challenged products and in the scientific integrity of POM's sponsored research. (RFF 502-20). Thus, it is not surprising that POM's ads summarize some of Respondents' scientific research on the Challenged Products in the areas of cardiovascular, prostate and erectile health and talk about the healthful properties of the Challenged Products, including that the Challenged Products contain abundant antioxidants and that they are wholly derived from pomegranate fruit. (RFF 493-99, 2478-2505, 2518-44). However, Respondents strenuously dispute that they ever intended to convey or that the Challenged Ads do convey the claim that the Challenged Products treat, prevent or reduce the risk of heart disease, prostate cancer and erectile dysfunction or that they are "clinically proven" to do so. (RFF 496, 535, 538, 540, 545-50, 2209-11, 2280; CX1372 (S. Resnick, Trop. Dep. at 57-59); CX1375 (L. Resnick, Trop., Dep. at 79-81)). Complaint Counsel presented no evidence directly contradicting the Individual Respondents' testimony.

Moreover, POM never states, expressly or by implication, conspicuously on the face of any of the Challenged Ads that scientific tests "prove" that the Challenged Products "prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction," or even that they "prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction." (RFF 2209-11, 2467-68, 2506, 2517; Reply Ad Appendix; Appendix of Advertisements). Throughout its advertising, POM highlights that POM Juice is a 100% juice product wholly-derived from the pomegranate fruit, and that POMx

has the same content as the pomegranate fruit itself and is 100% derived from the exact same fruit. (RFF 493-94, 2518-44; Reply Ad Appendix). Indeed, Respondents have never advertised their products as a pharmaceutical drug, nor intended to advertise their products as drugs. (RFF 495-96, 524-30). Rather, Respondents have always marketed the Challenged Products for what they intrinsically are: whole-food products. (RFF 497-99). Accordingly, it is far more logical (and the evidence demonstrates) that reasonable consumers would view the Challenged Products the way they perceive any other extremely healthy whole food, like broccoli, blueberries, grapes or tomatoes, which may help prevent or improve your odds against disease, but which would not "stop" anything, like a drug with a single target of action against a particular disease or condition.

B. Respondents Admit the Health Benefits of the POM Products Are Important to Consumers' Purchase Decisions

629. Respondents' marketing strategy for the POM Products was premised on convincing consumers that the claimed health benefits are the reason to buy their expensive products. In March 2004, Mr. Regal, POM's then Vice-President of Marketing, sent an email to Mr. Tupper summarizing consumer research as showing "People are interested in . . . [h]ealth benefits – this is why they put up with the price." (CX0283_0002).

Response to Finding No. 629:

Respondents object to this proposed finding as conclusory and argumentative and further state that the cited does not evidence support the assertion that "Respondents' marketing strategy for the POM Products was premised on convincing consumers that the claimed health benefits are the reason to buy their expensive products." Respondents further object that the terms "marketing strategy" and "health benefits" are vague and ambiguous. Respondents state that the Challenged Ads summarize some of Respondents' scientific research on the Challenged Products in the areas of cardiovascular, prostate and erectile health and talk about the healthful properties of the products, including that the Challenged Products contain abundant antioxidants and that they are wholly derived from pomegranate fruit. (RFF 493-99, 2478-2505, 2518-44). Respondents dispute that they

ever intended to convey or that the Challenged Ads do convey the claim that the Challenged Products treat, prevent or reduce the risk of heart disease, prostate cancer and erectile dysfunction or that they are "clinically proven" to do so. (RFF 496, 531, 535, 538, 540, 545-50, 2209-11, 2280; CX1372 (S. Resnick, Trop. Dep. at 57-59); CX1375 (L. Resnick, Trop., Dep. at 79-81)). Complaint Counsel presented no evidence directly contradicting the Individual Respondents' testimony.

Complaint Counsel also mischaracterize the substance of Mr. Regal's email to Mr. Tupper. For example, Mr. Regal was merely commenting upon the raw consumer feedback obtained from a single survey conducted in July 2004, not espousing on a large body of consumer research commissioned by POM as implied by Complaint Counsel. Also, Complaint Counsel provided no evidence the survey's methodology and whether it was reliable or what questions were even asked of the survey participants. Moreover, in his email, Mr. Regal only referenced "health benefits" at the bottom of a long list of items that people were purportedly interested in regard to POM Juice, stating:

"People are interested in

- Larger sizes of POM
- Small 8oz
- Club store packages
- Concentrate
- Iced Teas
- Mixed with sparkling water
- Lower price - coupons
- Health benefits – this is why they put up with the price." (CX0283_0002).

Nowhere in his email does Mr. Regal state that "health benefits" are material to consumers' purchase decisions of POM Juice. (CX0283_0002). Therefore, Mr. Regal's

email is irrelevant to whether the Challenged Claims are material. (RFF 2690-93). On that point, Complaint Counsel utterly failed to sustain their burden of proving that the Challenged Claims were material to prospective consumers because they (1) never offered any affirmative proof or expert opinion to support a finding that the Challenged Claims were material (*see* RFF 2680-89), and (2) failed to discredit Professor Reibstein's Survey of POM Wonderful 100% Pomegranate Juice Users, which directly contradicted the initial presumption of materiality. (RFF 2219, 2623-57, 2678, 2696-2701).

630. Respondents' marketing presented statistics on the prevalence of heart disease, prostate cancer, and erectile dysfunction as a reason for consumers to be concerned, and presented POM Juice or POMx products as the solution to treat, prevent, or reduce the risk of these diseases or medical conditions. For example,

- "Remember: heart disease is America's number one killer. For women as well as men. . . . To keep your heart healthy: exercise regularly. Eat a healthy diet. And drink 8 ounces of POM Wonderful Pomegranate Juice." (CX0029_0002);
- "[A]t least 58.8 million Americans suffer from some form of heart disease. . . .To date, our scientists have found that pomegranate juice may help counteract factors leading to arterial plaque build-up, as well as inhibit a number of factors associated with heart disease." (CX1426_00047-48).
- "Prostate Cancer Affects 1 Out of Every 6 Men[.] Prostate cancer is the second leading cause of cancer related death in men in the United States. . . . New pomegranate research offers hope to prostate cancer patients." (CX1426_00050-51); and
- "POM Wonderful 100% Pomegranate Juice was found to have beneficial effects on erectile dysfunction (ED), a disorder that affects 1 in 10 men worldwide and 10 to 30 million men in the United States alone." (CX0128_0002).

Response to Finding No. 630:

Respondents object to this proposed finding as conclusory and argumentative and further state that none of the cited evidence support the assertions that the Challenged Ads presented statistics on the prevalence of certain disease "as a reason for consumers to be concerned" or that "Respondents presented POM Juice or POMx products as the solution" to treat, prevent or reduce the risk of disease. Respondents further object that the terms "concerned" and "solution" are vague and ambiguous. Complaint Counsel's

use of the term "present" is also vague and ambiguous and in error if Complaint Counsel correlates "present" with convey to consumers. Respondents state that the Challenged Ads summarize some of Respondents' scientific research on the Challenged Products in the areas of cardiovascular, prostate and erectile health and talk about the healthful properties of the products, including that the Challenged Products contain abundant antioxidants and that they are wholly derived from pomegranate fruit. (RFF 493-99, 2478-2505, 2518-44). Respondents dispute that they ever intended to convey or that the Challenged Ads do convey the claim that the Challenged Products treat, prevent or reduce the risk of heart disease, prostate cancer and erectile dysfunction or that they are "clinically proven" to do so. (RFF 496, 531, 535, 538, 540, 545-50, 2209-11, 2280; CX1372 (S. Resnick, Trop. Dep. at 57-59); CX1375 (L. Resnick, Trop., Dep. at 79-81)).

631. POM believes that the millions of dollars it has spent promoting pomegranate juice for health in fact created the market for the juice. (CCFF ¶ IX.A.176).

Response to Finding No. 631:

Complaint Counsel misstate Mrs. Resnick testimony. Mrs. Resnick testified: "Through its investment of millions of dollars to research and promote the nutritional qualities and health benefits associated with pomegranate juice, [POM] largely created the burgeoning market for genuine pomegranate juice that exists today. (CX1362 (L. Resnick, Coke Dep. at 120) (emphasis added)). Thus, Mrs. Resnick distinguishes between expenditures on research on the Challenged Products versus the advertising costs for the products. It is also clear that she believes POM advertised the general "nutritional qualities" of the Challenged Products as well as the "health benefits" POM' research supported.

The use of the term "health" is vague and ambiguous and in error if Complaint Counsel correlates "health" with treat, prevent or reduce the risk of heart disease, prostate cancer and erectile dysfunction. Respondents genuinely believe in the health benefits of the Challenged Products and in the scientific integrity of POM's research (RFF 502-20).

Thus, it is not surprising that POM's ads summarize some of Respondents' scientific research on the Challenged Products in the areas of cardiovascular, prostate and erectile health and talk about the healthful properties of the Challenged Products, including that the Challenged Products contain abundant antioxidants and that they are wholly derived from pomegranate fruit. (RFF 493-99, 2478-2505, 2518-44). However, the Individual Respondents testified expressly that they never intended to convey or that the Challenged Ads do convey the claim that the Challenged Products treat, prevent or reduce the risk of heart disease, prostate cancer and erectile dysfunction or that they are "clinically proven" to do so. (RFF 496, 535, 538, 540, 545-50, 2209-11, 2280; CX1372 (S. Resnick, Trop. Dep. at 57-59); CX1375 (L. Resnick, Trop., Dep. at 79-81)). Complaint Counsel presented no evidence directly contradicting their testimony.

Moreover, POM never states, expressly or by implication, conspicuously on the face of any of the Challenged Ads that scientific tests "prove" that the Challenged Products "prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction," or even that they "prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction." (RFF 2209-11, 2467-68, 2506, 2517; Reply Ad Appendix; Appendix of Advertisements). Even where medical research was referenced in advertising, the ads conveyed qualified messages about the health benefits of the Challenged Products, not definitive claims that the products will treat, prevent or reduce the risk of heart disease, prostate cancer or erectile dysfunction. (RFF 2517). Throughout its advertising, POM highlights that POM Juice is a 100% juice product wholly-derived from the pomegranate fruit, and that POMx has the same content as the pomegranate fruit itself and is 100% derived from the exact same fruit. (RFF 493-94, 2518-44; Reply Ad Appendix). Indeed, Respondents have never advertised their products as a pharmaceutical drug, nor intended to advertise their products as drugs.

(RFF 495-96, 524-30). Rather, Respondents have always marketed the Challenged Products for what they intrinsically are: whole-food products. (RFF 497-99).

632. Mr. Resnick acknowledged that the kinds of health benefits that POM's scientific research revealed are the primary reason people buy pomegranate juice. (CX1372 (S. Resnick, Trop Dep. at 31)). Stewart Resnick also stated that consumers buy pomegranate juice "because they believe and in fact it does postpone the onset of prostate cancer, which postpones the onset of death." (CX1376 (S. Resnick, OS Dep. at 217)).

Response to Finding No. 632:

Mr. Resnick's personal opinions about the reasons people buy pomegranate juice is pure speculation and irrelevant to the issue of whether the Challenged Claims are material. Moreover, Mr. Resnick's testimony cited by Complaint Counsel were not in response to questions about why people buy the Challenged Products or whether the Challenged Claims are material to consumers. (CX1372 (S. Resnick, Trop Dep. at 31; CX1376 (S. Resnick, OS Dep. at 217). Of course, as shown by the testimony and survey of Professor Reibstein, there is no evidence that the Challenged Claims are material to consumers. (RFF 2219, 2613-46, 2678, 2696-2701). Complaint Counsel presented no evidence to rebut Professor Reibstein's testimony and survey. (RFF 2680-84).

Even if consumers buy pomegranate juice "because they believe and in fact it does postpone the onset of prostate cancer, which postpones the onset of death," Mr. Resnick never testified that they hold this belief because of the Challenged Ads. (CX1372 (S. Resnick, Trop. Dep. 1-121); CX1376 (S. Resnick, OS Dep. at 1-337)). Moreover, even if consumers purchase POM Juice for "health benefits"–which there is no record evidence– Mr. Resnick never testified that consumers buy the Challenged Products to treat, prevent or reduce the risk of heart disease, prostate cancer or erectile dysfunction. (CX1372 (S. Resnick, Trop. Dep. 1-121); CX1376 (S. Resnick, OS Dep. at 1-337)).

633. Similarly, Mrs. Resnick stated that she knew "that 72 percent of the people who buy pomegranate juice buy it for health reasons." (CX1362 (L. Resnick, TCCC Dep. at 97)).

Response to Finding No. 633:

Although Mrs. Resnick testified that 72% of people who buy pomegranate juice buy it for "health reasons," she further testified "[n]ow, what health reason that is I'm not sure." (CX1362 (L. Resnick, TCCC Dep. at 97)). Complaint Counsel presented no evidence on where Mrs. Resnick obtained the 72% figure or whether it is accurate. Nor did Complaint Counsel present evidence on what "health reason" was relevant to the purported 72% of pomegranate juice buyers. Moreover, Mr. Resnick's testimony cited by Complaint Counsel was not in response to a question about why people buy the Challenged Products or whether the Challenged Claims are material. (CX1362 (L. Resnick, TCCC Dep. at 97)). Of course, as shown by the testimony and survey of Professor Reibstein, there is no evidence that the Challenged Claims are material to consumers. (RFF 2219, 2613-46, 2678, 2696-2701). Complaint Counsel presented no evidence to rebut Professor Reibstein's testimony and survey. (RFF 2680-84).

Even if consumers buy pomegranate juice for "health reasons," Mr. Resnick never testified that do so because of the Challenged Ads. (CX1362 (L. Resnick, TCCC Dep. at 1-310)). Moreover, even if consumers purchase POM Juice for "health reasons"–which there is no record evidence–Mrs. Resnick never testified that consumers buy the Challenged Products to treat, prevent or reduce the risk of heart disease, prostate cancer or erectile dysfunction. (CX1362 (L. Resnick, TCCC Dep. at 1-310)).

634. According to Lynda Resnick, POM was being purchased more by "people that have heart disease or prostate cancer in their family, or have a fear of having it themselves." (CX1368 (L. Resnick, Welch Dep. at 66-67)).

Response to Finding No. 634:

Complaint Counsel mischaracterize Mrs. Resnick's testimony. Mrs. Resnick testified that POM's consumers were generally people who "want a really healthy drink" and that POM was noticing that its consumers were "starting to migrate older, to people that have

heart disease or prostate cancer in their family, or have a fear of having it themselves." (CX1368 (L. Resnick, Welch Dep. at 67)). Moreover, Mr. Resnick's testimony cited by Complaint Counsel was not in response to a question about why people buy the Challenged Products or whether the Challenged Claims are material. (CX1368 (L. Resnick, Welch Dep. at 66-67)). Of course, as shown by the testimony and survey of Professor Reibstein, there is no evidence that the Challenged Claims are material to consumers. (RFF 2219, 2613-46, 2678, 2696-2701). Complaint Counsel presented no evidence to rebut Professor Reibstein's testimony and survey. (RFF 2680-84).

Even if there was an uptick in the number of people buying POM Juice that had "heart disease or prostate cancer in their family, or hav a fear of having it themselves," Mrs. Resnick never testified that reasons for that was relaed to the Challenged Ads. (CX1368 (L. Resnick, Welch Dep. at 1-178)). Moreover, even if some buyers of POM Juice had heart disease or prostate cancer, Mrs. Resnick never testified that they buy the Challenged Products to treat, prevent or reduce the risk of heart disease, prostate cancer or erectile dysfunction. (CX1368 (L. Resnick, Welch Dep. at 1-178)).

635. According to a September 2006 press article, Ms. Posell, POM's then vice president of corporate communications, said every time a new study was released touting a health benefit of pomegranate juice, there was a spike in sales, and she gave the example of a then-recent prostate cancer study. (CX0433_0004).

Response to Finding No. 635:

Respondents object to the proposed finding to the extent that Complaint Counsel construe the cited evidence to bolster their argument that Respondents intended to convey to consumers that the Challenged Products treat, prevent or reduce the risk of disease or that the Challenged Claims are material to consumers' purchase decisions. In the press article cited by Complaint Counsel, Ms. Posell never stated that the Challenged Claims are material to consumers' decision to buy the Challenged Products. (CX0433_0004). Of course, as shown by the testimony and survey of Professor Reibstein, there is no evidence

that the Challenged Claims are material to consumers. (RFF 2219, 2613-46, 2678, 2696-2701). Complaint Counsel presented no evidence to rebut Professor Reibstein's testimony and survey. (RFF 2680-84).

Moreover, even if there is a spike in sales after a new study is released, Ms. Posell never stated that the increase in sales was a result of the Challenged Ads or exclusively of Respondents' research. (CX0433_0004). Nor did she say that consumers buy the Challenged Products to treat, prevent or reduce the risk of heart disease, prostate cancer and erectile dysfunction or that POM conveys such claims. (CX0433_0004).

636. Respondents conducted a test of two POMx Pill ads and found that the one with medical copy discussing the specifics of heart and prostate cancer studies generated more orders than one with less medical copy. (CX0264_0001-02; CX0266_0002; Tupper, Tr. 1009-10).

Response to Finding No. 636:

Complaint Counsel presented no evidence regarding the "test" conducted on the POMx Pill ads, including the test's methodology and whether it was scientifically valid. Nor did Complaint Counsel present evidence showing that the medical copy in the ad was material to consumers. Of course, as shown by the testimony and survey of Professor Reibstein, there is no evidence that the Challenged Claims are material to consumers. (RFF 2219, 2613-46, 2678, 2696-2701). Complaint Counsel presented no evidence to rebut Professor Reibstein's testimony and survey. (RFF 2680-84).

As to Mr. Tupper's deposition testimony, he specifically answers "I don't recall" when asked whether POMx pill ads that had more specific copy about medical studies generate more orders. (Tupper, Tr. 1009). Being presented with CX0266 also did not refresh Mr. Tupper's recollection as to whether ads with more specific copy on medical studies generated more orders. Instead, he testified "Well, I take this (meaning CX0266) at face

value." (Tupper, Tr. 1009-10). Thus, Respondents object to Complaint Counsel's citation to Mr. Tupper's deposition on the ground that the document speaks for itself.

637. Mr. Perdigao, the head of Fire Station, noted in an email that the "consumer benefit" of proposed advertisements that did not reference prostate or heart health was less compelling than POM had hoped. (CX0320_0002; L. Resnick, Tr. 90; *see also* Perdigao, Tr. 670-73). He testified that in attempting to develop a television marketing campaign without reference to heart, cardiovascular, or prostate health, POM and its advertising agency found that the consumer benefit was not as compelling because the claims were more vague. (Perdigao, Tr. 670-73).

Response to Finding No. 637:

Complaint Counsel mischaracterizes Mr. Perdigao's statements in his email to Liz Leow and his trial testimony about the email. Mr. Perdigao stated in his email to Liz Leow:

> "Per the meeting today, we are still being asked to develop a humorous TV campaign …, but we cannot reference: – Heart/Cardio Health – Prostate Health …. The consumer benefit is not nearly as compelling as we had hoped, but our focus should be on the fact that POM is healthy. It offers antioxidants that are good for you, as they reduce free radicals …."

In regard to his statement not as "compelling as we had hoped," he testified that "in the world of advertising, the less specific you are, generally, the less interesting it is to develop proactive advertising. I like to have specific content and specific claims, that's ideal, and you can - - the creative people tend to have a better - - if you close the box a little bit, it gets a little bit more fertile for creative development. And when you're just talking so vague and so wide, generally, it's hard to keep creative ideation focused. So, I like more specific briefs. So, I was - - this is me subjectively saying, you now, I'm - - I wish it was not so vague." (Tupper, Tr. 672-73). Thus, Mr. Perdigao was expressing his personal opinion, as a creative person, about the type of ads he prefers. Mr. Perdigao in no way voiced POM's opinion about its advertising or any claims made therein.

638. Even Respondents' marketing expert, Dr. David Reibstein conceded that it was likely that consumers in POM's target audience who were concerned about heart disease would find

a claim that drinking a bottle of POM Juice a day prevents or treats heart disease to be important, that those concerned about prostate cancer would find a prostate cancer prevention or treatment claim important, and that those concerned about erectile dysfunction would find an erectile dysfunction prevention or treatment claim important. (PX0356 (Reibstein, Dep. at 117-19)).

Response to Finding No. 638:

Complaint Counsel mischaracterized Professor Reibstein's testimony. Professor Reibstein testified that a claim that drinking a bottle of POM juice a day prevents or treats heart disease, prostate cancer, or erectile dysfunction "might be" important to consumers in POM's target audience. (PX0356 (Reibstein, Dep. at 117-19)). He also testified that does not mean consumers would actually believe or act on the claim. (PX0356 (Reibstein, Dep. at 118-19)). Professor Reibstein never testified in deposition that the Challenged Claims are important to consumers in POM's target audience or that the Challenged Claims motivate or are a reason why consumers purchase the Challenged Products. (PX0356 (Reibstein, Dep. at 1-187)). Professor Reibstein confirmed at trial that he doesn't know whether consumers in POM's target audience who were concerned about prostate cancer, cardiovascular disease or erectile dysfunction would find important a claim that drinking a bottle of POM Juice a day would prevent or treat those diseases. (Reibstein, Tr. 2533). He further testified that if asked to "speculate" on the question, such a claim "might be" important to consumers. (Reibstein, Tr. 2533-35).

C. Respondents' Own Consumer Research Demonstrates the Importance of Specific Health Benefits to Consumers' Purchase and Use of POM Products

639. In the ordinary course of business, Respondents conducted consumer research to understand the motivations behind the purchase and use of pomegranate juice by consumers. (*See*, *e.g.*, CX0370; CX0292).

Response to Finding No. 639:

The evidence cited by Complaint Counsel does not show that the Individual Respondents or Roll conducted any consumer research. Rather, the evidence provided summaries of market research conducted by POM or commissioned by POM. (CX0292). Complaint

Counsel's characterization of the market research as "to understand the motivations behind the purchase and use of pomegranate juice by consumers" is inaccurate and fails to fully and accurately describe the market research that is summarized in the cited evidence. (CX0292). Indeed, the June 2009 Report for the Attitudes &Usages Study ("A&U Study") states the background of the study is to "better understand the attitudes and usage of POM Wonderful and its competitors to identify barriers and opportunities for increasing consumption." (CX0370). This is different than asking what motivates people to buy pomegranate juice. (PX0227-0003, 0006-08; CX0370_0011-12; PX0356 (Reibstein, Dep. at 158); Reibstein, Tr. 2557)).

640. In June 2009, OTX, a consumer research firm, conducted an Attitudes and Usage consumer survey ("A&U study") on POM's behalf. (CX0370_0002, 0004). The A&U study's sample of 218 then-current POM Juice drinkers was a sufficient and fairly normal sample size. (Mazis, Tr. 2689-90). The POM Juice drinkers were asked, "Which of the following reasons are why you personally drink pomegranate juice?" (CX0370_0011; PX0227-0006; Reibstein, Tr. 2557; Mazis, Tr. 2681; CX1297 (Mazis, Report at 0012)). They were presented with a list of five reasons and given the opportunity to give another reason not on the list. (CX0370_0011; PX0227-0006; Mazis, Tr. 2681-82).

Response to Finding No. 640:

Respondents do not dispute that OTX conducted the A&U Study and that the full report of the study was date June 2009. (CX0370). Respondents disagree with Complaint Counsel's assertion that the study's sample of 218 current POM juice users "was a sufficient and fairly normal sample size." On the contrary, Professor Reibstein testified the sample was very small, which created "huge confidence intervals or uncertainty about the particular numbers." (Reibstein, Tr. 2520). Although Complaint Counsel's expert, Professor Mazis opined that the small sample size was "fairly normal," he ultimately conceded on cross-examination at trial that the results of the A&U Study are not statistically significant. (RFF 2739; Mazis, Tr. 2751-52).

Respondents do not dispute that Question B1 asked current POM users or other pomegranate juice brand users, "Which of the following reasons are why you personally

drink pomegranate juice?" (PX0227-0006). Question B was a closed-ended question and cued respondents to select from the following list of attributes they may not otherwise have thought of:

- I like the taste
- It's healthy / good for my health
- It's a new / interesting food trend
- It's all natural
- I like pomegranates
- Other (specify)

(PX0227-0006; RFF 2723-24, 2740; *see also* Reibstein, Tr. 2551-52). Although yea-saying can be mitigated through a control question such as "don't know" or "no opinion," Question B1 failed to include such a control question. (RFF 2727; PX0227-006).

Complaint Counsel's expert, Professor Mazis, agreed that the A&U Study does not address whether POM ads are material to consumers' purchase decisions. (RFF 2722, 2738, 2748). Rather, he testified that the A&U Study participants were "influenced" by "other information out in the marketplace, on the Internet and other places." (RFF 2748). The A&U Study is also irrelevant to the issue of materiality because respondents were asked why they drink pomegranate juice, <u>not why they buy pomegranate juice</u>. (PX0227-0003, 0006-08; CX0370_0011-12; PX0356 (Reibstein, Dep. at 158); Reibstein, Tr. 2557)).

The A&U Study is methodologically flawed and unreliable because the sample size of 200 POM Juice users was too small to reach statistical significances. (RFF 2733; Reibstein, Tr. 2520). Although Complaint Counsel's expert, Professor Mazis opined that the small sample size was sufficient and fairly normal, he ultimately conceded on cross-examination at trial that the results of the A&U Study are not statistically significant. (RFF 2739; Mazis, Tr. 2751-52).

The A&U Study is further methodologically flawed because it "primed" or "cued" the survey respondents on the issue of health even before asking them why they drink pomegranate juice by using the phrase "antioxidant-rich fruit juices" in two of the screening questions and the phrase "antioxidant-rich fruit" in the Introduction of study. (RFF 2732, 2743; Reibstein, Tr. 2560-61; Mazis, Tr. 2687). This serious flaw in the A&U Study leads to biased and unreliable results. (RFF 2732, 2743; Reibstein, Tr. 2560-61).

The results of the A&U Study are unreliable and inflated because the closed-ended questions were leading in that survey respondents were given a limited number of choices and cued to select from attributes they may not otherwise have thought of. (RFF 2723-24, 2740; *see also* Reibstein, Tr. 2551-52). Utilizing closed-end questions also results in the exclusion of potential answers that were not included on the list of choices because respondents often feel compelled to select one of the answers provided on the list of choices. (RFF 2725).

The results of the A&U Study are also biased because the use of only closed-ended questions heightened "yea saying," which is the tendency to give the answer the participant believes the interviewer is seeking to the exclusion of potential answers not included on the list. (RFF 2723, 2725, 2740; Reibstein, Tr. 2518-20). Although yea-saying can be mitigated through the use of a control question offering a "don't know" or "no opinion" type of option, the A&U Study failed to include such a control question. (RFF 2727; PX0027-006). As Professor Mazis conceded at trial, "open-ended questions make it significantly less likely that the participant will be led into giving a particular answer." (RFF 2742; Mazis, Tr. 2732).

641. Eighty-five percent (85%) of then-current POM Juice drinkers chose "healthy/good for my health," which the given reason more often than "I like the taste," "It's a new/interesting food trend," "It's all natural," and "I like pomegranates." (CX0370_0011; Mazis, Tr. 2683; CX1297 (Mazis, Report at 0012)).

Response to Finding No. 641:

In response to closed-ended Question B1, of the current POM Juice user respondents, 85% said they drank pomegranate juice because "it's healthy / good for my health," 75% said "I like the taste," 59% said "I like pomegranates," 50% said "it's all natural," 29% said "it's new / interesting food trend," and 4% said "other." (CX0370_0011).

The results from Question B1 are unreliable and inflated because the questions are leading in that the respondents were given a limited number of choices and/or cued to select from attributes that they might otherwise have thought of. (RFF 2729; Reibstein, Tr. 2518-20). Utilizing closed-end questions also results in the exclusion of potential answers that were not included on the list of choices because respondents often feel compelled to select one of the answers provided on the list of choices. (RFF 2725; Reibstein, Tr. 2519).

Moreover, the results of the A&U Study are methodologically flawed, unreliable, biased and not statistically significant. *See* Response to Finding No. 640.

642. Those POM Juice drinkers who cited "health" as a reason for using pomegranate juice were asked a follow-up question, "Which specific health reasons below describe why you personally drink pomegranate juice?" and were presented with a list of nine or ten reasons, depending on whether they were male or female. (CX0370_0012; PX0227-0006; Reibstein, Tr. 2558-59; Mazis, Tr. 2682-83).

Response to Finding No. 642:

Question B1 asked respondents why they drink pomegranate juice and provided a limited number of choices, one of which was "it's healthy / good for my health." (RFF 2728; PX0227-006). Survey respondents who selected "it's healthy / good for my health" from the list of only 6 choices as a reason why they drink pomegranate juice were asked in Question B2, "Which specific health reasons below describe why you personally drink

pomegranate juice?" and were forced to select from a list of 9 or 10 reasons, depending on their gender:

- Helps promote heart health
- Helps protect against prostate cancer [ASK MALE ONLY]
- Helps protect against other cancers (besides prostate)
- Contains naturally occurring antioxidants
- Will help me live longer
- Helps improve thinking and memory
- Good for bone and joint health
- Helps protect against urinary tract infections
- Provides immunity from colds and flu
- Promotes healthy pregnancy [ASK FEMALE ONLY]
- Other (specify)

(RFF 2728; PX0227-006). Although yea-saying can be mitigated through a control question such as "don't know" or "no opinion," Questions B1and B2 both failed to include such a control question. (RFF 2727; PX0227-006).

The results from Questions B1 and B2 as are unreliable and inflated because the questions are leading in that the respondents were given a limited number of choices and/or cued to select from attributes that they might otherwise have thought of. (RFF 2729).

When questions are open-ended as in the survey conducted by Professor Reibstein ("Reibstein Survey"), many other reasons for purchase are given that are not listed in A&U Study, including recommended/others like it, price/on sale, mixer, quality and bottle design. (RFF 2730; PX0223-0006-07; PX0227-0006). Moreover, when cued as in the A&U Study, the survey answers are inflated. (Reibstein, Tr. 2518-19). For instance,

in the A&U Study, 88-91% of the respondents answered that they drink pomegranate juice because it had antioxidants, which contrasts significantly with the Reibstein Survey, which showed that less than 10% of respondents purchase pomegranate juice for that reason. (RFF 2731; Reibstein, Tr. 2519; CX0370_0012).

Moreover, the results of the A&U Study are methodologically flawed, unreliable, biased and not statistically significant. *See* Response to Finding No. 640.

643. These survey respondents cited "contains naturally occurring antioxidants" (91%), "helps promote heart health" (57%), and "helps protect against prostate cancer" (47%) (males only) as the top three reasons why they drank pomegranate juice. (CX0370_0012; Mazis, Tr. 2683-84; CX1297 (Mazis, Report at 0012-13); *see also* Reibstein, Tr. 2559-60).

Response to Finding No. 643:

Of the current POM Juice user respondents who had selected "it's healthy / good for my health" from the list of closed-ended choices in Question B1 as a reason why they drink pomegranate juice, in response to closed-ended Question B2 which asked for a specific health reason describing why they drank pomegranate juice, 91% said "contains naturally occurring antioxidants," 57% said "helps promote heart health," 47% of men said "helps protect against prostate cancer," 45% said "provides immunity from colds and flu," 435 said "helps protect against other cancers (besides prostate); 38% said "helps protect against urinary tract infections," 28% said "will help me live longer," 28% said "good for bone and joint health," 25% said "helps improve thinking and memory," 14% said "promotes menopausal /post menopausal health," 6% said "promotes healthy pregnancy," and 2% said "other." (CX0370_0012).

Complaint Counsel mischaracterize the three percentages they cite above. As Complaint Counsel's own experts testified, to eliminate the effect of yea-saying, inattention and other noise, and to get the true impact of ads on the test group, the responses to the control group are subtracted from the responses to the test group. (RFF 2735, 2745;

Stewart, Tr. 3238; Mazis, Tr. 2735-36). For example, when the responses of the control group of other pomegranate brand juice drinkers are subtracted from the responses of the test group of current POM Juice drinkers in regard to Question B2, the percentage of POM Juice drinkers who mentioned "promotes heart health" and "helps protect against prostate cancer" is exceedingly low at only 8% and 7%, respectively. (RFF 2736-37; PX0224-0012). Moreover, Professor Reibstein testified that this type of question was a leading, biased question because it directed participants to select a "specific health reason" which pressures them to identify a "specific health reason" even if they did not perceive any of the choices as a "particular benefit" of drinking POM Juice. (RFF 2767-68; PX0227-0006). The results from Question B2 are thus unreliable and inflated, as discussed above. Moreover, the A&U Study is further methodologically flawed and unreliable as set forth in Response to Finding No. 641. *See* Response to Finding No. 640.

644. POM's Senior Vice-President of Marketing testified that she was not surprised by OTX survey results that 47 percent of male POM users buy POM Juice because it helps protect against prostate cancer. (CX1357 (Kuyoomjian, Dep. at 259-60)).

Response to Finding No. 644:

Complaint Counsel mischaracterize Ms. Kuyoomjian's testimony. Ms. Kuyoomjian merely testified that it did not surprise her that prostate health benefits "would be part of the reason" why the male respondents drank POM Juice or other antioxidant juices. (CX1357 (Kuyoomjian, Dep. at 259-60)). However, Ms. Kuyoomjian did not testify that the Challenged Claims are material to consumers. (CX1357 (Kuyoomjian, Dep. at 1-272)). Nor did she testify that consumers buy the Challenged Products to treat, prevent or reduce the risk of heart disease, prostate cancer or erectile dysfunction. CX1357 (Kuyoomjian, Dep. at 1-272)). Also, there evidence that the Challenged Claims are material to consumers' purchase decisions. (RFF 2219, 2613-46, 2678, 2696-2701). Additionally, the results of the A&U Study are methodologically flawed, unreliable, biased and not statistically significant. *See* Response to Finding No. 640.

645. According to Dr. Mazis, because "helps promote heart health" and "helps protect against prostate cancer" are second and third ranked, after "contains naturally occurring antioxidants," they are important health benefits motivating drinkers of POM Juice. (Mazis, Tr. 2686; *see also* CX1297 (Mazis, Report at 0013)).

Response to Finding No. 645:

Even though Professor Mazis conceded that the A&U Study was not "perfect" and "had some flaws," (Mazis, Tr. 2686-87), with respect to closed-ended Question B2, Professor Mazis testified that based on the relative ranking of the attributes "helps promote heart health," (57%) which was second, and "helps protect against prostate cancer," (47%) which was third, "I would take from that that those are pretty important health benefits to the drinkers of pomegranate juice generally and of POM Wonderful 100 percent pomegranate juice." (Mazis, Tr. 2686). Based on this testimony, in light of the fact that 91% said "contains naturally occurring antioxidants," Professor Mazis would apparently agree that the antioxidant attribute is an extremely important health benefit to pomegranate juice and POM Juice drinkers. (Mazis, Tr.2686).

Professor Mazis agreed, however, that the A&U Study does not address whether POM ads are material to consumers' purchase decisions. (RFF 2722, 2738, 2748). Rather, he testified that the A&U Study respondents were "certainly influenced" by "other information out in the marketplace, on the Internet and other places." (RFF 2748). Also, there evidence that the Challenged Claims are material to consumers' purchase decisions. (RFF 2219, 2613-46, 2678, 2696-2701).

Professor Mazis also conceded that the A&U Study was flawed because it "primed" the survey respondents by asking numerous screening questions about "antioxidant juices" and the word "antioxidant" was repeated a few times throughout the screening questions so that in considering the main survey questions, the respondents may have been focused on health and health issues. (RFF 2743). Professor Reibstein concurred that the use of the word "antioxidant" in the screening questions was a serious design flaw. (RFF 2732).

Complaint Counsel also mischaracterize the results of the A&U Study. As Complaint Counsel's own experts testified, to eliminate the effect of yea-saying, inattention and other noise, and to get the true impact of ads on the test group, the responses to the control group are subtracted from the responses to the test group. (RFF 2735, 2745). For example, when the responses of the control group of other pomegranate juice drinkers is subtracted from the responses of the test group of current POM Juice drinkers, the percentage of current POM Juice drinkers who mentioned "promotes heart health" and "helps protect against prostate cancer" is only 8% and 7%, respectively. (RFF 2736-37). Additionally, the results of the A&U Study are methodologically flawed, unreliable, biased and not statistically significant. *See* Response to Finding No. 640.

646. The A&U study shows that consumers would find claims that drinking POM Juice treats, prevents or reduces the risk of heart disease or prostate cancer to be important to their purchase or use decisions. (Mazis, Tr. 2688-89; CX1297 (Mazis, Report at 0013)).

Response to Finding No. 646:

Respondents dispute this conclusion. Because the current POM Juice drinkers cited "contains naturally occurring antioxidants" (91%), "helps promote heart health" (57%) and "helps protect against prostate cancer" (47% (males only)) as the top three reasons why respondents drank pomegranate juice when asked to choose from a list of twelve choices in response to Question B2, Complaint Counsel erroneously assert that these results show that "consumers would find claims that drinking POM Juice treats, prevent or reduces the risk of heart disease or prostate cancer to be important to their purchase or use decisions." (CX0370_0012). Just because a certain percentage of consumers allegedly drink POM Juice because it "helps promote heart health" does not mean the Challenged Claims (*i.e.*, prevent, treat or reduce the risk of disease) were material to consumers. (RRFF 643, 646-47). Indeed, Professor Mazis testified: "an advertising claim may involve information important to consumers, but to be material it has to be important to their decision to buy." (RFF 2692). To the extent any conclusion can be

drawn from the unreliable A&U Study, it is certainly not that the Challenged Claims are material to consumers. (RRFF 643, 646-47).

Moreover, the Reibstein Survey demonstrates that that the Challenged Claims are not material to consumers' purchase decisions. (RFF 2219, 2613-46, 2678, 2696-2701). Complaint Counsel presented no evidence to rebut the Reibstein Survey. (RFF 2680-88). Indeed, Professor Mazis conceded that there is no evidence in the record regarding whether "it's probable that any POM Juice or POMx advertisement was likely to affect anyone's belief about POM." (RFF 2689). He also testified that the A&U Study participants were "influenced" by "other information out in the marketplace, on the Internet and other places." (RFF 2748). The results of the A&U Study also are methodologically flawed, unreliable, biased and not statistically significant. *See* Response to Finding No. 640.

647. Respondents' marketing expert, Dr. Reibstein, acknowledged that he would not completely disregard the responses to "helps protect against prostate cancer" as a reason that consumers consume POM Juice. (PX0356 (Reibstein, Dep. at 158).

Response to Finding No. 647:

Complaint Counsel did not accurately represent the full substance of Professor Reibstein's testimony on this topic. Professor Reibstein also testified that the results for the response "helps protect against prostate cancer" are overinflated (PX0356 (Reibstein, Dep. at 157). Moreover, Professor Reibstein repeatedly stated that the results of the A&U Study were methodologically flawed, unreliable, biased and not statistically significant. *See* Response to Finding No. 640. He also testified that the A&U Study was not relevant to the issue of materiality because respondents were asked why they consume or drink pomegranate juice, not why they buy pomegranate juice. (PX0356 (Reibstein, Dep. at 158); PX0227-0003, 0006-08; CX0370_0011-12). The parties'

experts also agree that the results of the A&U are not statistically significant. (RFF 2633, 2639).

648. The 2009 A&U results are consistent with an August 2007 Zoomerang online study commissioned by Respondents. (*See* CX0292_0025; CX0136_0001). Among 287 heavy pomegranate juice drinkers in the Zoomerang study, the leading reason for purchase was long-term health (74%), which was ahead of taste (67%). (CX0292_0026).

Response to Finding No. 648:

Respondents agree that the results of Question B1 of the A&U Study, which asked respondents why they personally drink pomegranate juice, shared some consistencies with the results of the Zoomerang Study, which asked why respondents used pomegranate juice. In response to closed-ended Question B1 of the A&U Study, of the current POM Juice user respondents, 85% said they drank pomegranate juice because "it's healthy / good for my health," 75% said "I like the taste," 59% said "I like pomegranates," 50% said "it's all natural," 29% said "it's new / interesting food trend," and 4% said "other." (CX0370_0011). Of the heavy pomegranate juice drinkers in the Zoomerang Study, 74% said they drank pomegranate juice for long term health benefits, 67% said taste, 40% said quench thirst, 31% said energy boost and 10% said as a cocktail mixer (10%). (CX0292_0026). Also, particularly notable is that almost 70% of all respondents could not identify any health benefit of drinking pomegranate juice. (CX0136_0005; CX0292_0025). Additionally, when the total survey population in the Zoomerang Study were asked to rate a list of attributes, survey respondents rated the following attributes as "extremely important": an all natural 100% juice (63%), flavor/taste (60%), no added sugars and preservatives (59%), health benefits (56%), juice is shelf stable (25%), fruit is grown in the U.S.A. (24%) and fruit is grown in California (12%). (CX0292_0026).

As with the A&U Study, the Zoomerang Survey is irrelevant to whether the Challenged Claims are material to consumers' purchase decisions. Instead of examining why

consumers purchase pomegranate juice, including POM Juice, the objective of the Zoomerang Survey was to understand, among other reasons, consumers "consumption habits," a different concept than why consumers purchase pomegranate juice. (CX0136_0003; CX0292_0025-26). Moreover, the Zoomerang Survey does not associate long-term health benefits to treating, preventing or reducing the risk of disease. (CX0292_0025-26).

649. Asked to rank six health benefits of drinking pomegranate juice in order of importance to them personally, heavy pomegranate juice drinkers in the Zoomerang study ranked cardiovascular health as the most important benefit, "followed by [anti]aging & prostate" health. (CX0136_0006; CX453_0004).

Response to Finding No. 649:

Complaint Counsel's statement can be stated with more precision. When asked to rank the six listed health benefits of drinking pomegranate juice in order of importance, the male respondents in the Zoomerang Study said cardiovascular followed by prostate health and the women respondents said cardiovascular followed by anti-aging. (CX0136_0007-0008).

The results of the Zoomerang Survey are unreliable and inflated because the closed-ended question was leading in that respondents were given a limited number of choices and forced to rank health benefits they may not otherwise have thought of. (RFF 2724; *see also* Reibstein, Tr. 2551-52). The use of the closed-ended question also resulted in the exclusion of potential health benefits that were not included on the list of choices because respondents were compelled to rank the health benefits listed. (RFF 2725; Reibstein, Tr. 2519). Complaint Counsel also presented no evidence that the results of the Zoomerang Survey are statistically significant. Nor did Complaint Counsel present evidence that the health benefits listed in the Zoomerang Survey were material to the respondents' decision to drink pomegranate juice, let alone their decision to buy the juice. Of course, even if the health benefits listed in the Zoomerang Survey are "important" to

the respondents does mean they are material. As Professor Mazis conceded, "an advertising claim may involve information important to consumers, but to be material it has to be important to their decision to buy." (RFF 2692; *see also* RFF 2693).

650. Among a larger sample population, which included drinkers of other juices, over 60% of Zoomerang study participants ranked cardiovascular health as the first or second most important benefit, 40% of males ranked prostate health as the first or second most important benefits, and approximately 18% of males did so for erectile dysfunction. (CX0136_0002, 07-08; CX453_0004).

Response to Finding No. 650:

Complaint Counsel's statement can be stated with more precision. Of the total Zoomerang study population, in response to an open-ended question, 31% said they knew any specific health benefits of pomegranate juice. (CX0292_0026; CX0453_0004). Of these 31%, in response to a question asking them to rank a list of six health benefits in order of importance, the male respondents responded as follows: approximately 60% said cardiovascular, 40% said prostate health; approximately 30% said anti-aging, approximately 30% said anti-inflammatory, 18% said erectile dysfunction and approximately 17% said oral health. (CX0136_0007). Of these 31%, the women ranked the same list as follows: approximately 65% said cardiovascular, almost 45% said anti-aging, approximately 40% said anti-inflammatory, 20% said oral health, approximately 15% said prostate health and 12% said erectile dysfunction. (CX0136_0008).

The results of the Zoomerang Survey are unreliable and inflated because the closed-ended question was leading in that respondents were given a limited number of choices and forced to rank health benefits they may not otherwise have thought of. (RFF 2724; *see also* Reibstein, Tr. 2551-52). The use of the closed-ended question also resulted in the exclusion of potential health benefits that were not included on the list of choices because respondents were compelled to rank the health benefits listed. (RFF 2725; Reibstein, Tr. 2519). Complaint Counsel also presented no evidence that the results of

the Zoomerang Survey are statistically significant. Nor did Complaint Counsel present evidence that the health benefits listed in the Zoomerang Survey were material to the respondents' decision to drink pomegranate juice, let alone their decision to buy the juice. Of course, even if the health benefits listed in the Zoomerang Survey are "important" to the respondents does mean they are material. As Professor Mazis conceded, "an advertising claim may involve information important to consumers, but to be material it has to be important to their decision to buy." (RFF 2692; *see also* RFF 2693.

D. Respondents' Litigation Survey Does Not Measure the Materiality of Respondents' Claimed Health Benefits

651. To attempt to rebut the presumption of materiality of the claims for POM Juice, Respondents presented a purchase motivation study designed by Dr. David Reibstein, a marketing professor at The Wharton School, University of Pennsylvania. (Reibstein, Tr. 2481, 2487, 2525-26). The Court recognized Dr. Reibstein as an expert in marketing and marketing research. (Reibstein, Tr. 2486).

Response to Finding No. 651:

Respondents do not dispute that the Court recognized Professor Reibstein as an expert in marketing and marketing research, (Reibstein, Tr. 2486), and that Respondents presented a survey designed by Professor Reibstein, which surveyed why POM Juice buyers (i) bought, (ii) would buy again and (iii) would recommend POM Juice to a friend. (PX0223_0005). The Reibstein Survey rebutted the intial presumption of materiality because it unequivocally demonstrated that because consumers purchase POM Juice for non-disease related reasons. (RFF 2623-28). Specifically, only 1.48% of POM Juice buyers and 1.74% of non-POM Juice buyers bought, would buy again or would recommend to a friend POM Juice because it prevents or cures disease. (RFF 2623-24, 2630). In fact, in response to the key question why did you buy POM Juice, only 1% of respondents volunteered that they bought because the juice would prevent or cure disease. (RFF 2631, 2635). Similar results were found for why would you buy POM Juice again and why would you recommend the juice to a friend. (RFF 2636, 2640-41,

2645). The Reibstein Survey also showed that that less than 1% of pomegranate juice buyers who saw a POM advertisement purchased the juice because they believe it cures or prevents a specific disease. (RFF 2646, 2650, 2652).

On the other hand, Complaint Counsel neither presented affirmative evidence or expert opinion that the Challenged Claims are material to consumers' purchase decisions nor a consumer survey to discredit the Reibstein Survey results. (RFF 2680-84).

652. At the time he designed his study, Dr. Reibstein was neither familiar with the FTC's Deception Policy Statement nor was he familiar with the concept of materiality in an FTC case. (PX0356 (Reibstein, Dep. at 13, 41-42)).

Response to Finding No. 652:

Complaint Counsel mischaracterizes Professor Reibstein's testimony. Professor Reibstein testified that because "[materiality] is not a term that [he] would commonly use," he was not "fully aware of what the legal definition [was] of materiality" at the time he designed his survey. (PX0356 (Reibstein, Dep. at 42)). During his deposition, Professor Reibstein testified that his understanding of materiality is as follows:

> As statement of counsel, this is not my domain in terms of the legal terminology as being used. But it is my understanding of whether or not the actions taken by the defendant led to some subsequent behavior, was material in leading to some subsequent behavior; that is, had a significant impact on.

(PX0356 (Reibstein, Dep. at 43). Respondents do not dispute that Professor Reibstein testified that he was not familiar with the FTC Deception Policy Statement. (PX0356 (Reibstein, Dep. at 13). Respondents, however, dispute the relevance of Complaint Counsel's assertions because materiality is a legal term of art. Respondents do not offer Professor Reibstein as an expert on the legal definition of materiality and contend that such legal definitions are conclusions of law.

653. Complaint Counsel called Dr. Michael Mazis as an expert rebuttal witness to address Dr. Reibstein's testimony, and the Court recognized Dr. Mazis as an expert in marketing and marketing research. (CX1297 (Mazis, Report at 0002, 004-05); Mazis, Tr. 2659). Dr. Mazis is a Professor Emeritus of Marketing at the Kogod School of Business, American University. (PX0296a01-0001; Mazis Tr. 2653). He was a Professor of Marketing at American University from 1981 to 2008, serving ten years as chair of the Department of Marketing. (PX0296a01-0001; Mazis, Tr. 2653). Dr. Mazis is a former director of the Association for Consumer Research. (PX0296a01-0010). He was Editor of the Journal of Public Policy & Marketing from 1992 to 1995 and Associate Editor of The Journal of Consumer Affairs from 1998 to 2001. (PX0296a01-0002; Mazis, Tr. 2654). Among his duties as an editor and associate editor, Dr. Mazis would review and critique survey research. (Mazis, Tr. 2655-56). Dr. Mazis has conducted hundreds of surveys and research studies, including over one hundred surveys for use in legal proceedings. (Mazis, Tr. 2657).

Response to Finding No. 653:

Respondents do not dispute the above statements but contend that they do not provide a full picture of Professor Mazis' background and bias against Respondents. Complaint Counsel notably omit that Professor Mazis has repeatedly served as a paid consultant for numerous federal government agencies, including the FTC, FDA, Consumer Product Safety Commission, Department of Justice, Federal Deposit Insurance Corporation, Bureau of Alcohol, Tobacco and Firearms and U.S. Mint. (RFF 2706; Mazis, Tr. 2656, 2697). Complaint Counsel also omit the fact that (a) Professor Mazis was employed by the FTC from July 1997 through August 1979, (b) in the mid 1990's, he worked a day a week for the FTC's offices in Washington, D.C. for five to six years, (c) he served as the FTC's principal marketing witness in several cases and (d) during the past four years, Professor Mazis has been a testifying expert witness in at least 24 legal proceedings. (RFF 2707-10; Mazis, Tr. 2696-98; PX096a0001 at 0001-0002, 0012; PX0359 (Mazis, Dep. at 22-24)).

654. Dr. Reibstein's survey has no relevance to either the materiality of the challenged POMx claims or the purchase motivations of POMx purchasers. (Reibstein, Tr. 2565-66; CX1297 (Mazis, Report at 0004, 07)).

Response to Finding No. 654:

Respondents dispute that the Reibstein Survey has no relevance to the materiality of the challenged POMx claims or the purchase motivations of POMx purchasers for two reasons. First, the primary target audience for POMx is existing POM Juice consumers. (CX0409_0015). Second, the scientific studies on POM Juice support the same health benefits of POMx, and the POMx ads piggyback on the health benefits of POM Juice. (*E.g.,* CX0120; CX0122, CX0169, CX0180, CX0279, CX0280, CX0328, CX0331, CX0337, CX0342, CX353, CX0348, CX0350, CX0351, CX0355 and CX1426, Exh. I). Even Complaint Counsel concede that POM advertises not only that POMx is equivalent to POM Juice but also that the studies on POM Juice also support the same health benefits of POMx. (CCFF 412, 414-15). Moreover, where POM has referenced studies in POMx ads, it has consistently noted that the studies were done on POM Juice, and that one POMx Pill is equivalent to 8 ounces of POM Juice. (Appendix of Advertisements; CX0120, 0122, 0169, 0180, 0279, 0280, 0328, 0331, 0337, 0342, 0348, 0350-51, 0353, 0355, 1426).

655. Dr. Reibstein's survey was conducted in October 2010. (Reibstein, Tr. 2541). Dr. Reibstein did not expose consumers to the challenged ads. (Reibstein, Tr. 2494). He surveyed individuals who had purchased POM Juice in the prior six months and asked them to state why they purchased, would repurchase, or recommend POM Juice. (PX0237-0002; PX0223 (Reibstein, Report at 0004-05)). In response to these three open-ended questions, 35.2% of POM Juice purchasers volunteered that they bought or would repurchase POM Juice because it was "healthy" and 46.8% stated that they would recommend it to a friend because it was "healthy." (PX0223 (Reibstein, Report at 0006-08)).

Response to Finding No. 655:

Respondents do not dispute the statements above, but contend that they could be stated with more precision. Professor Reibstein testified that it was not necessary to show the respondents in his survey advertisements because his survey was not a copy test designed to establish what messages the Challenged Ads conveyed, but to discover purchase

motivations – *i.e*, why consumers buy POM Juice. (RFF 2660, 2675). For example, the introduction to the survey questionnaire stated that respondents will be asked questions about what types of beverages they drink and "the reasons why [they] drink them." (PX0237-0001). The key open-ended questions were also designed to elicit information about consumers' purchase decisions by asking "Why did you purchase," "Would you consider purchasing again" and "Would you recommend" POM Juice to a friend. (RFF 2665-67; *see also* 2669-71). Thus, the Reibstein Survey exclusively focused on the information which actually affected respondents' choice of, or conduct regarding POM Juice, which is the essence of materiality.

Moreover, Complaint Counsels' proposed approach of exposing consumers to the challenged claim or the challenged ad is a completely artificial approach because it is a forced exposure and inaccurately reflects how consumes react to ads or advertising claims in the real world. (RRFF 655, 657-59; RFF 2756, 2762-63). Professor Reibstein also testified that ad testing would not measure materiality. (Reibstein, Tr. 2525; RRFF 2756, 2762-63). Complaint Counsel's expert, Professor Mazis, also concedes that a survey on materiality does not need to show respondents actual ads. (RFF 2694). Although Professor Mazis contends that the Challenged Claims must be shown to the respondents, his testimony is rebutted by Professor Reibstein (*see* RFF 2675) and defies common sense because the respondents in the Reibstein Survey were asked directly to identify all reasons affecting their decision to buy POM Juice. (RFF 2665-67).

Additionally, Complaint Counsel's expert, Professor Mazis, declined to rule out the Reibstein Survey "as probative evidence" on materiality. (RFF 2718). Nor could he based on his own article entitled *Copy-Testing Issues in FTC Advertising Cases* in which he suggested, as one way of proving that an advertisement was immaterial to consumers, a survey asking why the participants buy the advertised product. (RFF 2713). The open-ended questions Professor Mazis used as examples of how to prove the claim was not

material were: (1) "what are the reasons you buy cheese?"; (2) "what are the reasons for your buying individually wrapped cheese food slices?"; and (3) what are "'all the reasons you can think of as to why you buy Kraft singles?'' (RFF 2713). No follow up questions were suggested. Professor Mazis testified that, while these open-ended questions might underestimate the importance of calcium in selecting cheese, they would nevertheless have "probative value" in proving that the ads in question were not material. (RFF 2713). The open-ended questions suggested by Professor Mazis are almost identical to the open-ended questions in the Reibstein Survey. (RFF 2665-2671, 2713).

656. Very few respondents, however, volunteered that they purchased POM Juice because it would treat, prevent, or reduce the risk of heart disease, prostate cancer, or erectile dysfunction. (PX0223 (Reibstein, Report at 0010-11, 0020)).

Response to Finding No. 656:

Respondents do not disagree that very few respondents purchase POM Juice becase it cures or prevents a specific disease. (RFF 2623-28). As Professor Reibstein found, only 1.48% of POM Juice buyers and 1.74% of non-POM Juice buyers bought, would buy again or would recommend to a friend POM Juice because it prevents or cures disease. (RFF 2623-24, 2630; PX0223-0020). In fact, in response to the key question why did you buy POM Juice, only 1% of respondents volunteered that they bought because the juice would prevent or cure disease. (RFF 2631, 2635). Similar results were found for why would you buy POM Juice again and why would you recommend the juice to a friend. (RFF 2636, 2640-41, 2645). The Reibstein Survey also shows that that less than 1% of pomegranate juice buyers who saw a POM advertisement purchased the juice because they believe it cures or prevents a specific disease. (RFF 2646, 2650, 2652). On the other hand, Complaint Counsel neither presented affirmative evidence or expert opinion that the Challenged Claims are material to consumers' purchase decisions nor a consumer survey to discredit the Reibstein Survey results. (RFF 2680-84).

657. Dr. Reibstein's assessment of consumer motivations does not provide a valid measure of the likely importance that the challenged POM Juice claims would have to consumers' purchase or use decisions. (CX1297 (Mazis, Report at 0008-09); Mazis, Tr. 2673).

Response to Finding No. 657:

Respondents dispute Complaint Counsel's assertion. The Reibstein Survey provides a valid measure of materiality because it revealed: (1) consumers' reasons for purchasing POM Juice; and (2) whether having previously seen POM advertisements in the normal sequence of viewing ads, and not in an artificial setting, whether the ads affected the consumers' reasons for purchasing POM Juice. (RFF 2660; PX0223-0005; Reibstein, Tr. 2487; PX0356 (Reibstein, Dep. at 11, 39, 51)). Professor Reibstein testified that it was not necessary to show respondents advertisements because his survey was not a copy test designed to establish what messages the Challenged Ads conveyed, but to discover purchase motivations – *i.e*, why consumers buy POM Juice. (RFF 2660, 2675). For example, the introduction to the survey questionnaire stated that respondents will be asked questions about what types of beverages they drink and "the reasons why [they] drink them." (PX0237-0001). The key open-ended questions were also designed to elicit information about consumers' purchase decisions by asking "Why did you purchase," "Would you consider purchasing again" and "Would you recommend" POM Juice to a friend. (RFF 2665-67; *see also* 2669-71). Thus, the Reibstein Survey exclusively focused on the information which actually affected respondents' choice of, or conduct regarding POM Juice, which is the essence of materiality.

Moreover, the Reibstein Survey's examination of the impact of POM's advertisements on buyers' purchasing decisions proves that POM's ads had no impact on buyers' beliefs that pomegranate juice can or will cure or prevent disease. (RFF 2646-47, 2649-57). A total of 12 unique respondents out of 750, including non-POM Juice buyers, mentioned a specific disease as a reason they bought, would buy, or would recommend pomegranate juice. (RFF 2646, 2650, 2655; PX0223-0016-0020; PX0233-0012; Reibstein, Tr. 2507).

Among these respondents, only 4 of them have seen a POM advertisement at some point and 8 never have. (RFF 2646; PX0223-0016-0020). The data, therefore, show that the portion of buyers believing in the curative or preventive attributes of pomegranate juice is very similar between the two groups of buyers: the ones who have seen a POM advertisement and the ones who have not. (RFF 2646-57; PX0223-0016-0020; PX0233-0012; Reibstein, Tr. 2507-08)

Conversely, Complaint Counsels' proposed approach of exposing consumers to the challenged claim or the challenged ad is a completely artificial approach because it is a forced exposure and inaccurately reflects how consumes react to ads or advertising claims in the real world. (RRFF 655, 657-59; RFF 2756, 2762-63). Professor Reibstein also testified that ad testing would not measure materiality. (Reibstein, Tr. 2525; RRFF 2756, 2762-63). Complaint Counsel's expert, Professor Mazis, also concedes that a survey on materiality does not need to show respondents actual ads. (RFF 2694). Although Professor Mazis contends that the Challenged Claims must be shown to the respondents, his testimony is rebutted by Professor Reibstein (*see* RFF 2675) and defies common sense because the respondents in the Reibstein Survey were asked directly to identify all reasons affecting their decision to buy POM Juice. (RFF 2665-67).

Additionally, Complaint Counsel's expert, Professor Mazis, declined to rule out the Reibstein Survey "as probative evidence" on materiality. (RFF 2718). Nor could he based on his own article entitled *Copy-Testing Issues in FTC Advertising Cases* in which he suggested, as one way of proving that an advertisement was immaterial to consumers, a survey asking <u>why</u> the participants buy the advertised product. (RFF 2713). The open-ended questions Professor Mazis used as examples of how to prove the claim was not material were: (1) "what are the reasons you buy cheese?"; (2) "what are the reasons for your buying individually wrapped cheese food slices?"; and (3) what are "'all the reasons you can think of as to why you buy Kraft singles?'' (RFF 2713). No follow up questions

were suggested. Professor Mazis testified that, while these open-ended questions might underestimate the importance of calcium in selecting cheese, they would nevertheless have "probative value" in proving that the ads in question were not material. (RFF 2713). The open-ended questions suggested by Professor Mazis are almost identical to the open-ended questions in the Reibstein Survey. (RFF 2665-2671, 2713).

658. In order to measure whether a particular claim is likely to affect consumers purchase behavior, survey respondents must be exposed to the claim and asked how important they think that claim would be in their potential purchase decision. (Mazis, Tr. 2728; CX1297 (Mazis, Report at 0008-09)). Dr. Reibstein acknowledged that his survey did not explicitly ask respondents to evaluate the importance of any of the challenged claims at issue in this matter in terms of whether those claims were likely to have an effect on their decision to purchase or to use POM Juice. (Reibstein, Tr. 2526-28).

Response to Finding No. 658:

Professor Reibstein testified that it was not necessary to show respondents advertisements because his survey was not a copy test designed to establish what messages the Challenged Ads conveyed, but to discover purchase motivations – *i.e*, why consumers buy POM Juice. (RFF 2660, 2675). For example, the introduction to the survey questionnaire stated that respondents will be asked questions about what types of beverages they drink and "the reasons why [they] drink them." (PX0237-0001). The key open-ended questions were also designed to elicit information about consumers' purchase decisions by asking "Why did you purchase," "Would you consider purchasing again" and "Would you recommend" POM Juice to a friend. (RFF 2665-67; *see also* 2669-71). Thus, the Reibstein Survey exclusively focused on the information which actually affected respondents' choice of, or conduct regarding POM Juice, which is the essence of materiality.

Moreover, Complaint Counsels' proposed approach of exposing consumers to the challenged claim or the challenged ad is a completely artificial approach because it is a forced exposure and inaccurately reflects how consumes react to ads or advertising

claims in the real world. (RRFF 655, 657-59; RFF 2756, 2762-63). Professor Reibstein also testified that ad testing would not measure materiality. (Reibstein, Tr. 2525; RRFF 2756, 2762-63). Complaint Counsel's expert, Professor Mazis, also concedes that a survey on materiality does not need to show respondents actual ads. (RFF 2694). Although Professor Mazis contends that the Challenged Claims must be shown to the respondents, his testimony is rebutted by Professor Reibstein (*see* RFF 2675) and defies common sense because the respondents in the Reibstein Survey were asked directly to identify all reasons affecting their decision to buy POM Juice. (RFF 2665-67).

Additionally, Complaint Counsel's expert, Professor Mazis, declined to rule out the Reibstein Survey "as probative evidence" on materiality. (RFF 2718). Nor could he based on his own article entitled *Copy-Testing Issues in FTC Advertising Cases* in which he suggested, as one way of proving that an advertisement was immaterial to consumers, a survey asking <u>why</u> the participants buy the advertised product. (RFF 2713). The open-ended questions Professor Mazis used as examples of how to prove the claim was not material were: (1) "what are the reasons you buy cheese?"; (2) "what are the reasons for your buying individually wrapped cheese food slices?"; and (3) what are "'all the reasons you can think of as to why you buy Kraft singles?'' (RFF 2713). No follow up questions were suggested. Professor Mazis testified that, while these open-ended questions might underestimate the importance of calcium in selecting cheese, they would nevertheless have "probative value" in proving that the ads in question were not material. (RFF 2713). The open-ended questions suggested by Professor Mazis are almost identical to the open-ended questions in the Reibstein Survey. (RFF 2665-2671, 2713).

659. Thus, there is a disconnect between what Dr. Reibstein sought to assess, which is why people bought, and materiality, which is how important a particular claim is to a potential purchaser and whether that claim would affect decision-making if the person knew of the claim. (See Mazis, Tr. 2673).

Response to Finding No. 659:

Respondents dispute this assertion. (*See* RCL 92). The Reibstein Survey properly measured materiality. *See* Response to Finding No. 657.

Moreover, Complaint Counsel's expert, Professor Mazis, declined to rule out the Reibstein Survey "as probative evidence" on materiality. (RFF 2718). Nor could he based on his own article entitled *Copy-Testing Issues in FTC Advertising Cases* in which he suggested, as one way of proving that an advertisement was immaterial to consumers, a survey asking why the participants buy the advertised product. (RFF 2713). The open-ended questions Professor Mazis used as examples of how to prove the claim was not material were: (1) "what are the reasons you buy cheese?"; (2) "what are the reasons for your buying individually wrapped cheese food slices?"; and (3) what are "'all the reasons you can think of as to why you buy Kraft singles?'' (RFF 2713). No follow up questions were suggested. Professor Mazis testified that, while these open-ended questions might underestimate the importance of calcium in selecting cheese, they would nevertheless have "probative value" in proving that the ads in question were not material. (RFF 2713). The open-ended questions suggested by Professor Mazis are almost identical to the open-ended questions in the Reibstein Survey. (RFF 2665-2671, 2713).

Additionally, Complaint Counsel wrongly focuses exclusively on whether a factor is "important" generally whereas Complaint Counsel's expert, Professor Mazis testified: "an advertising claim may involve information important to consumers, but to be material it has to be important to their decision to buy." (RFF 2692). The Reibstein Survey focused on factors important to respondents' decision to buy POM Juice and, thus, properly measure materiality. (RFF 2660, 2665-67; PX0237-0001).

660. The Reibstein survey only asked broad open-ended questions with no probing. (CX1297 (Mazis, Report at 0009-10); Mazis, Tr. 2731). Consumers' beliefs that pomegranate juice is a healthy drink is a major reason they purchase the juice. (Reibstein, Tr. 2553; CX1297 (Mazis, Report at 0009-10)). The Reibstein survey should have explored what

Respondents meant by their healthy response and whether there were specific reasons or benefits that underlay "healthy" responses. (Mazis, Tr. 2709).

Response to Finding No. 660:

Respondents dispute this assertion. Because close-end questions suggest the desired answer and elicit bias, all three key questions in the Reibstein Survey were asked in an open-ended format to reduce the likelihood of biased results. (RFF 2672; Reibstein, Tr. 2551-52). Complaint Counsel's expert, Professor Mazis, agreed that open-ended questions make it "significantly less likely that the respondents will be led into giving a particular answer. (RFF 2715).

The Reibstein Survey also contained sufficient probing into the respondents' decision-making process. For example, by asking respondents in each of the key primary questions to "*include as many specific details*" in each answer as to why they did or would act as they indicated (RFF 2665-67), the Reibstein Survey proactively sought to probe the specific reasons underlying the respondents' responses. (Reibstein, Tr. 2546). Moreover, Professor Reibstein's survey design was more impactful and reliable because he effectively asked the same question three different ways: (1) Question E: Why did you purchase POM; (2) Question F: "Would you consider purchasing POM Wonderful 100% Pomegranate Juice again" and "Why" and (3) Question G: "Would you recommend POM Wonderful 100% Pomegranate Juice to a friend" and "Why". (Reibstein, Tr. 2554, 2585-86; RFF 2665-67). Questions H, I and J asked non-POM Juice pomegranate juice buyers the same questions as Questions E, F and G, respectively. (RFF 2669-71). Indeed, Professor Reibstein testified that his triangular approach was a very reliable design and, in effect, asked follow-up questions:

> Q. Okay. So you asked why they bought, if they would repurchase, and if they would recommend to a friend and why in three different sets of questions.
>
> A. Right.

Q. Okay. So why did you ask so many similar-sounding questions with –

A. So I wanted to try and triangulate and to give them as many opportunities as possible to articulate what their motivations were for purchasing. And it is often common in doing marketing research that what you want to do is have multi-questions, not identical questions but sort of surrounding the same area so that you could gain some reliability in the answers that you have.

* * *

Q. Without follow-up questions and without closed-ended questions, your 35.2 percent may be a very low estimate of the percentage of purchasers who are motivated by health reasons; correct?

A. I don't think that is really a fair way to characterize what I believe because I -- you said "without follow-up questions." There really are follow-up questions. And the follow-up questions are, you know, I ask why do you buy, and then I also ask sort of related questions that are follow-ups. So, first of all, I ask why do you buy and please provide all the detail, and then I ask follow-up questions that say would you buy again and why, and so that's giving them more opportunity to be expansive, and would you recommend this to a friend and why, and so in each of those cases it really is follow-up and follow-up with an opportunity for them to be expansive without saying, Well, you're wrong in your previous answer and you're going to have to be providing us some more. So I'm going to say that's incorrect as you characterized it of having no follow-up questions.

(Reibstein, Tr. 2492, 2553-54). Likewise, if curing or preventing heart disease, prostate cancer or erectile dysfunction were important factors in respondents' decision to buy POM Juice, Professor Reibstein testified that his survey gave them more than ample opportunity to express that belief by asking them in multiple ways what information was likely to affect their choice of, or conduct regarding POM Juice. (Reibstein, Tr. 2585-86; RRFF 655, 657-59).

Additionally, Complaint Counsel's expert, Professor Mazis, declined to rule out the Reibstein Survey "as probative evidence" on materiality. (RFF 2718). Nor could he based on his own article entitled *Copy-Testing Issues in FTC Advertising Cases* in which he suggested, as one way of proving that an advertisement was immaterial to consumers, a survey asking why the participants buy the advertised product. (RFF 2713). The open-ended questions Professor Mazis used as examples of how to prove the claim was not material were: (1) "what are the reasons you buy cheese?"; (2) "what are the reasons for your buying individually wrapped cheese food slices?"; and (3) what are "'all the reasons you can think of as to why you buy Kraft singles?'' (RFF 2713). No follow up questions were suggested. Professor Mazis testified that, while these open-ended questions might underestimate the importance of calcium in selecting cheese, they would nevertheless have "probative value" in proving that the ads in question were not material. (RFF 2713). The open-ended questions suggested by Professor Mazis are almost identical to the open-ended questions in the Reibstein Survey. (RFF 2665-2671, 2713).

661. The Reibstein survey failed, however, to follow-up its purchase motivation questions to determine whether some or all of these consumers believed that pomegranate juice is "healthy" because it treats, prevents, or reduces the risk of heart disease, prostate cancer, and/or erectile dysfunction. (CX1297 (Mazis, Report at 0010); *see also* Mazis, Tr. 2705-06, 2707-08).

Response to Finding No. 661:

Respondents dispute this contention and assert that the Reibstein reliably and effectively probed into the respondents' decision-making process, including the "healthy" response. *See* Response to Finding No. 660.

E. Respondents' Persistence in Using the Challenged Claims after Receiving Warnings That the Claims Are Deceptive Is Evidence of Materiality

662. In March 2005, the New York Attorney General's office sent POM a letter expressing concerns that POM's advertising was false or misleading. The letter asked for POM's substantiation regarding several claims, including those related to atherosclerosis and reduction of plaque. Moreover, the letter stated that the phrase "Amaze your cardiologist" was "an implication that drinking POM Wonderful Pomegranate juice will provide substantial benefits to a consumer's heart" and similarly, that the phrase "Floss

your arteries" was "an implication that drinking POM Wonderful Pomegranate Juice will reduce plaque build-up in a consumer's arteries." (CX1419_0002-0003).

Response to Finding No. 662:

As an initial matter, the letter states only that "[w]e have concerns that such advertising may be false or misleading," not that it was false or misleading as proposed finding no. 662 incorrectly states. (CX1409-0002-0003) (emphasis added). The Attorney General's Office did not challenge the validity of the underlying science or draw any conclusions about the representations made in the advertisements. (CX1419_0002-0003). Complaint Counsel's contention that this was a "warning that the claims are deceptive" is thus erroneous. The Attorney General simply requested information about POM's advertising, and at no point contended that POM was violating the law. (CX1419_0002-0003). Moreover, in April 2005, counsel for POM responded to the letter. That was the last word on the subject--the New York Attorney General never followed up or suggested it had issues with POM's response. (CX1419_0004-0013). *The inquiry letter was sent to POM over five years before Complaint Counsel initiated this action and addresses advertisements that ceased running in that same time period*. For example, the "Amaze Your Cardiologist" and "Floss Your Arteries. Daily" advertisements have not run since 2004 and 2005. (Tupper, Tr. 2996-97; CX1353 (Tupper, Dep. at 131)). If anything, the evidence suggests that POM responded appropriately, at least in part, by making changes in its advertising. Notably, Complaint Counsel also does not (and cannot) cite any testimony regarding this inquiry. They only raise this contention for the first time now, after one and a half years of litigation, and after trial. Thus no evidence or testimony supports Complaint Counsel's argument that this inquiry serves as evidence of Respondents' alleged "intentional disregard of the law" or of materiality.

663. Respondents' health claims for POM Juice have been the subject of two decisions by the Council for Better Business Bureaus' National Advertising Division (NAD). In March 2005, the NAD, as part of its regular monitoring program, reviewed the "Amaze your cardiologist" and "Floss your arteries" advertisements, along with the Aviram CIMT/BP Study (2004) cited therein. The NAD concluded that POM's use of the Aviram study in

the "Amaze your cardiologist" advertisement did not clearly articulate the preliminary nature of the study or its details; and furthermore, that the "Floss your arteries" advertisement carried the message that healthy people could prevent buildup of arterial plaque with POM Juice. (CX0037_0008-0010).

Response to Finding No. 663:

The NAD's decisions directly refute Complaint Counsel's contention that Respondents "persisted in using the challenged claims after receiving warnings that the claims are deceptive." In 2005, the NAD found only that POM did not adequately "qualify" the science that was being described in the "Amaze your cardiologist" and "Floss your arteries" advertisements. The NAD recognized, in part, that the advertisements were supported by competent and reliable science. For example, the NAD expressed satisfaction that Dr. Aviram's 2004 CIMT study, which served as the basis for these ads, was "sufficiently powered and did not find that the number of participants here rendered the results unreliable. (Tupper, Tr. 2983; CX0037_0007; CX0611). The NAD further "acknowledged the promising research, offering encouraging results suggesting that pomegranate juice consumption can offer a wide protection against cardiovascular diseases." (CX0037_0010). Similarly, the NAD also acknowledged "the role that antioxidant pomegranate juice can play in the reduction in the risk of free radical-related diseases, in particular, *the reduction* of artery-clogging plaque. (CX0037_0010). The NAD also stated that, in connection with the statement "Just eight ounces a day can reduce plaque by up to 30%!" it "was not an "establishment claim" (i.e., a "clinically proven" claim), which is traditionally held to a higher standard of scientific proof." (CX0037_ 0007). The NAD also stated in connection with the "Amaze Your Cardiologist" advertisement that it

> **"acknowledged that for those individuals in the marketplace that suffer from carotid artery stenosis (severe arterial plaque buildup), elderly or otherwise, the message conveyed contains *valuable information* for that population, information that the advertiser *should be free to tout.*"**

(CX0037_0009, emphasis added). Despite disagreeing with the overall ruling, POM responsibly took the findings into account in its future advertising. (CX0037_0011; Tupper, Tr. 2996). POM, in fact, completely stopped running the "Floss Your Arteries" and "Amaze Your Cardiologist" advertisements in 2004 and 2005. (Tupper, Tr. 2996-97; CX1353 (Tupper, Dep. at 131)).

Despite disagreeing with the NAD, POM began describing POM's research in less general terms as noted by the NAD, as a matter of company policy. (Tupper, Tr. 2986-87). Additionally, *as a result* of the NAD's decisions, Respondents now also direct consumers back to their website to read the full scientific study. (Tupper, Tr. 2985).

Thus the 2005 NAD decision and POM's response to it refute Complaint Counsel's contention that POM "persist[ed] in using the challenged claims after receiving warnings that the claims are deceptive," as well as Complaint Counsel's contention that such purported persistence somehow establishes materiality.

664. The NAD recommended that the "Amaze your cardiologist" advertisement be modified and that the "Floss your arteries" advertisement be discontinued or modified to avoid misleading consumers. (CX0037_0010-11).

Response to Finding No. 664:

Respondents object to this proposed finding for the same reasons articulated in Response to proposed finding no. 663. Despite disagreeing with the ruling, POM responsibly took the findings into account in its future advertising. (CX0037_0011; Tupper, Tr. 2996). POM completely stopped running the "Floss Your Arteries" and "Amaze Your Cardiologist" advertisements in 2004 and 2005. (Tupper, Tr. 2996-97; CX1353 (Tupper, Dep. at 131)). Additionally, as testified to by Mr. Tupper at trial, despite disagreeing with the NAD, POM began describing POM's research in less general terms as noted by the NAD, as a matter of company policy. (Tupper, Tr. 2986-87). Further, *as a result* of the NAD's decisions, Respondents now direct consumers back to their website to read the

full scientific study. (Tupper, Tr. 2985). Thus the 2005 NAD decision and POM's response to it refute Complaint Counsel's contention that POM "persist[ed] in using the challenged claims after receiving warnings that the claims are deceptive," as well as Complaint Counsel's contention that such purported persistence somehow establishes materiality.

665. Mr. Tupper stated that POM implemented the NAD's 2005 requests and suggestions, although it disagreed with them ("[T]hey had some requests and suggestions for what I think amounted to some minor modifications in phraseology and such, which we respectfully disagreed with, but implemented nonetheless."). (CX1364 (Tupper, TCCC Dep. at 305-06)).

Response to Finding No. 665:

Respondents object to this finding for the same reasons articulated in Response to finding No. 663. Despite disagreeing with the ruling, POM responsibly took the findings into account in its future advertising. (CX0037_0011; Tupper, Tr. 2996). POM, in fact, completely stopped running the "Floss Your Arteries" and "Amaze Your Cardiologist" advertisements in 2004 and 2005. (Tupper, Tr. 2996-97; CX1353 (Tupper, Dep. at 131)). Additionally, as testified to by Mr. Tupper at trial, despite disagreeing with the NAD, POM began describing POM's research in less general terms as noted by the NAD, as a matter of company policy. (Tupper, Tr. 2986-87). Additionally, *as a result* of the NAD's decisions, Respondents now also direct consumers back to their website to read the full scientific study. (Tupper, Tr. 2985). Thus the 2005 NAD decision and POM's response to it refute Complaint Counsel's contention that POM "persist[ed] in using the challenged claims after receiving warnings that the claims are deceptive," as well as Complaint Counsel's contention that such purported persistence somehow establishes materiality.

666. POM, however, continued to cite the Aviram CIMT/BP Study (2004), and specifically the 30% plaque reduction finding, in its advertising until at least 2009. (*See, e.g.,* CCFF ¶¶ IX.D.4.b.406-IX.D.4.c.418, IX.D.4.f.430-IX.D.4.g.437, IX.E.1.449, IX.E.1.451, IX.E.1.453-IX.E.1.454, IX.E.4.520, IX.E.4.527). The NAD later determined that POM failed to discontinue the "prevent arterial plaque build-up" claim that was challenged in

2005, and had even disseminated new advertising making the same express claim, a fact that "particularly disturbed" the NAD. (CX0055_0044).

Response to Finding No. 666:

Complaint Counsel grossly mischaracterize the recommendation of the 2006 NAD decision. The NAD expressly noted that POM had, since the time of the 2005 decision been "avoiding the quantified 30% reduction claim." (CX0055_0044). Furthermore, the NAD did not take issue with the fact that Respondents continued to cite the Aviram 2004 study; the NAD recommended that the Aviram study be described in *qualified terms*. Specifically, the NAD emphasized the language "may prevent atherosclerosis" and "may promote sustained correction of atherosclerosis" and suggested describing the parameters of the study. (CX0055_0045). The NAD also recommended that POM "qualify the claims in a manner that "ensures that consumers understand the extent of the support for the claim" and explained that it took "no issue with the advertiser discussing and/or educating the public as to the state of this science." (CX0055_0046).

Moreover, despite respectfully disagreeing with the NAD, POM made the changes recommended in the 2005 decision. Mr. Tupper testified at trial that despite believing that it had adequate support, POM altered the 30% reduction claim by simply describing the study and directing consumers to the full publication available on a related website. (Tupper, Tr. 2984-86) For example, in subsequent POMx pill advertisements POM identified Dr. Aviram's study as "preliminary" and represented the details of the study:"Pomegranate juice consumption resulted in a significant IMT reduction by up to 30% after one year" and cited to a footnote explaining that the number, age, and health condition of the participants, and the length of time that they drank the juice. (CX0279-0001).

Thus the 2006 NAD decision and POM's response to that decision refute Complaint Counsel's contention that POM "persist[ed] in using the challenged claims after receiving

warnings that the claims are deceptive," as well as Complaint Counsel's contention that such purported persistence somehow establishes materiality.

667. In April 2006, the NAD reviewed POM's advertising again in response to a challenge from Welch Foods, Inc. (CX0055_0001).

Response to Finding No. 667:

Respondents do not dispute this proposed finding except insofar as the phrase "POM's advertising" is vague and ambiguous, and insofar as the document cited is actually an NAD decision issued on April 5, 2006, not a "review" conducted by the NAD in April of 2006. (CX0055_0001). Respondents further object that the proposed finding is irrelevant to the issues of intent and materiality that Complaint Counsel asserts them as putative evidence of.

668. Some of the advertising claims reviewed in the 2006 NAD decision included claims that are found in the "Cheat Death" advertisement ("Cheat death…. [POM Juice] can help prevent premature aging, heart disease, stroke, Alzheimer's, even cancer. Eight ounces a day is all you need.") (CX0036) as well as the "10 Out of 10 People Don't Want to Die" advertisement ("98% of heart attacks are due to atherosclerosis . . . . To keep your heart healthy . . . drink 8 ounces of POM Wonderful Pomegranate Juice.") (CX0029).

Response to Finding No. 668:

Complaint Counsel misrepresent the 2006 NAD decision by cobbling together claims and advertisements to construct an argument of notice and intent. The 2006 NAD decision did not review the claim "Cheat death…. [POM Juice] can help prevent premature aging, heart disease, stroke, Alzheimer's, even cancer. Eight ounces a day is all you need." Nor did the 2006 NAD decision review the "10 out of 10 People Don't Want to Die" advertisement.

> Rather than those advertisements, the NAD reviewed these specific claims:
>
> "[POM Juice] can help prevent premature aging, heart disease, stroke, Alzheimer's, even cancer. Eight ounces a day is all you need."

> "Remember: heart disease is America's number one killer. For women as well as men. 98% of all heart attacks are due to atherosclerosis, or too much plaque in the arteries….To Keep your heart healthy:…drink 8 ounces of POM Wonderful Pomegranate Juice."

These specific statements appeared in other advertisements that the NAD discussed, not the "Cheat Death" or "10 out of 10" advertisements cited in Complaint Counsel's fallacious proposed finding. In fact, the NAD decision did not even discuss the "Cheat Death" ad (CX0036) or the "10 out of 10" (CX0029) ad. Respondents thus object to the proposed finding because it false.

Respondents further object to the proposed finding as irrelevant to the extent that Complaint Counsel seek to use it as evidence to bolster their argument about alleged persistence by POM in making claims that it was notified were deceptive. The 2006 NAD decision did not make any findings about the validity of the underlying science referenced in POM's advertising. (Tupper, Tr. 2983-84; CX0055_0038-39). While the NAD did find that POM discussed its research in terms that were too general, it also found that POM's scientific evidence on cardiovascular health might be sufficient to support more narrowly tailored qualified claims. (CX0055_0039, 0047).

669. In this 2006 decision, the NAD rejected many of POM's assertions attempting to minimize its claims, which are similar to the arguments made in this matter. For example, the NAD rejected the notion that POM's advertising claims were puffery, finding that POM made "objectively provable claims requiring substantiation." (CX0055_0047).

Response to Finding No. 669:

Respondents object that this proposed finding is an inaccurate and misleading lawyer's argument, rather than a finding of fact.

The NAD accepts and articulates recommendations similar to Respondents' arguments, and has agreed with Respondents' position in many respects. The 2006 NAD decision

suggested that POM's claims would not be deceptive if sufficiently qualified and also found that qualified claims could be supported by basic science alone. (CX0055_0047, 0039, 0045).

The NAD primarily took issue with the fact that some of POM's advertisements were *not sufficiently qualified* and suggested the same type of qualified language *that Complaint Counsel argues should be ignored in this case and is inconsequential*. For example, the NAD made the following recommendations:

> NAD recommended that POM modify and disclose "the emerging nature of the scientific findings as they concern the role of pomegranate juice in one's diet and the association between antioxidants and heart health." (CX0055_0047).
>
> "[I]t is an advertiser's responsibility to present the whole story regarding the available scientific data by *qualifying its claims* in such a manner that employs the weight of the evidence properly and ensures that consumers understand the extent of the support for the claim." (CX0055_0039, emphasis added).

Indeed, the NAD, unlike Complaint Counsel, did not construe Respondents' representations about their science to be "clinically proven." (CX0055).

Furthermore, the NAD, unlike Complaint Counsel, determined that POM could properly make qualified health benefit claims in its advertising based on in vitro and in vivo evidence alone. For example, the NAD stated, "Although results of one recent study conducted in vitro in cultured human coronary artery and in vivo in hypercholesterolemic mice tended to show that pomegranate juice may prevent atherosclerosis and *may promote* a sustained correction of atherosclerosis in vitro and in vivo" that evidence could not support unqualified claims—the type of claims that POM has never made. (CX0055_0045; RFF 2457, 2463, 2465, 2478, 2534, 2542, 2215, 2216, 2347, 2466, 2469). In fact, since the 2006, when discussing the benefits of its products, POM's

policy has been to discuss and describe what research was done, where it was done and to summarize the results of the specific scientific studies described in its advertisements. (Tupper, Tr. 2986-87). 481. For example, POM now uses the following language, "A recently published preliminary medical study followed 46 men previously treated for prostate cancer, either with surgery or radiation. After drinking 8 ounces of POM Wonderful 100% Pomegranate Juice daily for two years, these men experienced significantly longer PSA doubling times" to describe the results of the Pantuck study and convey the qualified message that the results were "preliminary." (CX0471).

Finally, even with respect to the puffery issue that Complaint Counsel identifies in this proposed finding of fact, the NAD found only that the specific headlines "**when accompanied by language** [like] POM Wonderful prevents or reduces the risk of heart disease, Alzheimer's, stroke … etc." was not puffery. (CX0056_0047). The NAD further found that such claims either required substantiation or "recommended that they be modified or discontinued in accordance herein." (CX0056_0047). As discussed above, POM responded by modifying its use of specific accompanying language, and introduced qualifications. Thus, again, the 2006 NAD decision cuts directly against the proposition that Complaint Counsel cites it for.

670. Moreover, the NAD rejected POM's argument that its advertisements merely stated that POM Juice has high levels of antioxidants and therefore simply claimed that it is beneficial to one's health: "[T]his is a generous reading of the challenged advertisements. . . . [T]hese claims are not as tentative as the advertiser suggests[.] . . .[T]he advertiser most assuredly makes strong unqualified performance claims – claims requiring concomitant supporting evidence." (CX0055_0035-36).

Response to Finding No. 670:

Respondents object to the proposed finding because it mischaracterizes the 2006 NAD decision. That decision noted that POM took the position that its advertising conveyed three different messages, not the single message that Complaint Counsel selectively quotes in its misstatement. (CX0055_0035).

Respondents further object that the cited quotations are extraordinarily partial and deceptive excerpts which deliberately omit the portion of the sentence that cuts against Complaint Counsel. If the statements are to be cited, they should be complete and accurate, not misleading sentence fragments. For example, Complaint Counsel's proposed last sentence omits the detailed introductory text of the actual quoted sentence: "Thus, to the extent that the advertiser asserted that the challenger mischaracterized its claims as making quantified performance claims about the health benefits of POM Wonderful juice, NAD concluded that, while perhaps not specifically *quantified* performance claims, the advertiser most assuredly makes strong unqualified performance claims – claims requiring concomitant supporting evidence" (CX0055_0035). Complaint Counsel omits the core of the sentence, in which the NAD found that POM's position was correct, and that the challenger's position was erroneous.

In its 2006 Decision, contrary to Complaint Counsel's partial quotations, the NAD primarily took issue with the fact that some of POM's advertisements were *not sufficiently qualified* and suggested the same type of qualified language that Complaint Counsel argues should be ignored in this case and is inconsequential. (CX055_0039, 0047). For example, the NAD made the following recommendations:

> NAD recommended that POM modify and disclose "the emerging nature of the scientific findings as they concern the role of pomegranate juice in one's diet and the association between antioxidants and heart health." (CX0055_0047).
>
> "[I]t is an advertiser's responsibility to present the whole story regarding the available scientific data by *qualifying its claims* in such a manner that employs the weight of the evidence properly and ensures that consumers understand the extent of the support for the claim." (CX0055_0039, emphasis added).

Despite the fact that the NAD did not making any findings about the validity of the underlying science referenced in POM's advertising, it recognized that POM's research could be supportive of POM's advertising claims if the language was sufficiently qualified. (Tupper, Tr. 2983-84; CX0055_0038-39). For example, the NAD noted that it did not want to undercut the value of POM's sponsored research or discount or diminish "the value of the promising scientific research provided by" POM. (CX0055_0038). Furthermore, the NAD also noted that "nothing in this decision precludes the advertiser from making truthful claims regarding the state of science of antioxidants, free radicals, and the *encouraging results* of preliminary research regarding the impact that antioxidants have on heart health, cancer, etc., and to accurately reflect what this research may suggest. NAD takes no issue with the advertiser discussing and/or educating the public as to the state of this science or promoting the fact that its product is an excellent source of antioxidants which, *undisputedly, may be beneficial to one's health*." (CX0055_0039, emphasis added).

Additionally, the NAD articulated a scientific substantiation standard for advertising claims that is entirely different than Complaint Counsel's unscientific contentions in this case. The NAD explained that "actual product testing is the most direct and affirmative means by which to assess the performance capability of a specific product" and "advertisers making health-related claims in food advertising should present claims in a manner that ensures consumers understand the extent of the scientific support for the claim." (CX0037_0037). Respondents clearly meet that NAD standard. Indeed, POM has sponsored more than a hundred studies on the Challenged Products, have, over time, changed aspects of its advertising to reflect the details of the parameters of the science supporting the advertisements, and make available the full copy of the supporting science available to consumers through a related website. (Tupper, Tr. 2984-86).

Thus, the plain language of the 2006 NAD decision reflects that the NAD recommends the very type of qualified language that Respondents articulate in their advertisements, rather than mandating the rigid bureaucratic rule now advocated by Complaint Counsel.

671. The NAD stated that it "had concerns about the sufficiency of [POM's] research to substantiate the claims which promise specific results from use of the advertised product" and recommended that its claims regarding cardiovascular benefits be "substantially modified to clearly disclose the limitations of the scientific findings[.]" (CX0055_0038, 0046).

Response to Finding No. 671:

In its zeal to misconstrue the evidence, Complaint Counsel presents a misleading partial quotation of the document, combined with another misleading partial quotation from a much later part of the document. The NAD's actual first quoted sentence was "While not discounting or diminishing the value of the promising scientific research provided by the advertiser, NAD had concerns about the sufficiency of this research to substantiate the claims which promise specific results from use of the advertised product." (CX0055_0038). In a proposed finding that allegedly shows POM's bad intent, Complaint Counsel deliberately attempts to hide the fact that the NAD, in the quoted sentence, found that POM's scientific research was "promising," and that it did not discount or diminish the value of that scientific research. Complaint Counsel's disingenuity contravenes the "intent" argument they attempt.

Similarly, the actual second quoted sentence, which followed seven pages later, included the key concluding portion of that sentence, which Complaint Counsel omitted, followed by two other key sentences: "As such, NAD recommended that the advertiser's claims regarding its POM Wonderful and its cardiovascular benefits be substantially modified to clearly disclose the limitations of the scientific finding **- in particular, the emerging nature of the scientific findings as they concern the role of its pomegranate juice in one's diet and the association between antioxidants and heart health. NAD believes**

its recommendation is consistent with an advertiser's responsibility to qualify claims in a manner that 'ensures that consumers understand the extent of the support for the claim.'' NAD takes no issue with the advertiser discussing and/or educating the public as to the state of this science." (CX0055_0046) (emphasis added). The bolded language was entirely omitted by Complaint Counsel's misleading proposed finding. The Respondents' wrongful intent cannot be established by manipulating and distorting the evidence in this manner.

Indeed, the 2006 NAD decision found that Respondents science, even the in vitro and animal studies alone, could meet the NAD's required level of substantiation so long as the science was sufficiently qualified in a manner that "ensures that consumers understand the extent of the support for the claim." (CX0055_0042). For example, the NAD stated, "Although results of one recent study conducted in vitro in cultured human coronary artery and in vivo in hypercholesterolemic mice tended to show that pomegranate juice *may* prevent atherosclerosis and *may promote* a sustained correction of atherosclerosis in vitro and in vivo" that evidence could not support unqualified claims—the type of claims that POM has never made. (CX0055_0045; RFF 2457, 2463, 2465, 2478, 2534, 2542, 2215, 2216, 2347, 2466, 2469). Indeed, the "substantial modification" that the NAD recommended is the very type of qualifiers that POM uses in its advertising.

672. The NAD decision specifically stated that it "harmonize[s] its own efforts with the regulatory framework developed by the FDA and FTC regarding food labeling and advertising." (CX0055_0034).

Response to Finding No. 672:

This is another incredibly misleading partial quotation. The actual statement is that "NAD **attempts to harmonize** its own efforts with the regulatory framework developed by the FDA and FTC regarding food labeling and advertising." (CX0055_0033). While

the NAD usually attempts such harmonization to the degree that is possible and desirable – or at least did back in 2006 – the NAD does so within the confines of its role as a voluntary industry organization. It certainly does not attempt anything like the draconian imposition of an "FDA prior approval rule" that Complaint Counsel now attempts. The 2006 FDA decision is replete with statements that contradict Complaint Counsel's attempted imposition of a new rule requiring two randomized controlled trials before health claims can be made in advertising. The NAD has never indicted anything other than opposition to that position, as exemplified by the statements in its two decisions involving POM. In fact, The NAD's articulated standard for food advertising and supporting substantiation requires actual product testing and that the advertiser present the claims in a manner that ensures "consumers understand the extent of the scientific support for the claim. (CX0055_0037).

Furthermore, the NAD stated that Respondents' science, even the in vitro and animal studies alone, could meet the NAD's substantiation standard so long as it was qualified in a manner that "ensures that consumers understand the extent of the support for the claim." (CX0055_0042). For example, the NAD stated, "Although results of one recent study conducted in vitro in cultured human coronary artery and in vivo in hypercholesterolemic mice tended to show that pomegranate juice *may* prevent atherosclerosis and *may promote* a sustained correction of atherosclerosis in vitro and in vivo" that evidence could not support unqualified claims—the type of claims that POM has never made. (CX0055_0045; RFF 2457, 2463, 2465, 2478, 2534, 2542, 2215, 2216, 2347, 2466, 2469). Indeed, the "substantial modification" that the NAD recommended is the very type of qualifiers that POM makes in its advertising. That position directly contradicts Complaint Counsel's position that POM's qualifying terms are inadequate to offset the alleged violations in its challenged advertisements.

673. Even after NAD specifically recommended in 2006 that POM "discontinue its claims, either express or implied, that simply drinking eight ounces of POM Wonderful daily can

reduce one's risk of cancer or that, with respect to cancer, consumers can 'Cheat Death' by drinking POM Wonderful," (CX0055_0042), Mr. Tupper has testified that POM continued to run advertisements with that exact headline: "I don't think we were ever making claims that consumers can cheat death. We continue to run the headline, I believe, but I don't think that's what this refers to. . . . We used the headline cheat death, as a headline by itself. I'm not sure how that relates to this [the NAD's] paragraph." (CX1364 (Tupper, TCCC Dep. at 335-36)).

Response to Finding No. 673:

The proposed finding of fact is a patent misstatement because the NAD decision never recommended that the headline "Cheat Death" by itself be discontinued. Rather it recommended discontinuing the specific claim that "**with respect to cancer, consumers can 'Cheat Death' by drinking POM Wonderful**." (CX0055_0041) (emphasis added). That statement was made in reference to "Cheat Death" advertisements which also mentioned cancer in the body text. Complaint Counsel, however, falsely asserts in this proposed finding of fact that Matt Tupper testified that POM continued to run advertisements "with that exact headline." In fact POM ran the "Cheat Death" headline by itself, but – **perfectly consistent with the NAD recommendation –** did not use that headline "with respect to cancer" anywhere in the ad, thereby avoiding any implication that "Cheat Death" meant the product cured cancer. (CX1364 (Tupper, TCCC Dep. at 335-36)). POM followed the NAD recommendation precisely. And yet again, Complaint Counsel therefore resorts to deliberately distorting and misstating the record in an attempt to build a record for intent when the actual record powerful refutes that claim.

674. Although Mr. Tupper stated that he was aware of NAD's 2006 recommendation to discontinue express claims that drinking POM can prevent arterial plaque build-up, and has testified that POM changed its communication accordingly after the NAD decision came out (CX1364 (Tupper, TCCC Dep. at 336-37), in fact POM continued to cite the Aviram CIMT/BP Study (2004), and specifically the 30% plaque reduction finding, in its advertising until at least 2009. (*See, e.g.*, CCFF ¶¶ IX.D.4.b.406-IX.D.4.c.418, IX.D.4.f.430-IX.D.4.g.437, IX.E.1.449, IX.E.1.451, IX.E.1.453-IX.E.1.454, IX.E.4.520, IX.E.4.527).

Response to Finding No. 674:

Complaint Counsel's proposed finding mischaracterizes Mr. Tupper's testimony in the Coke deposition and POM's response to the NAD decision. Mr. Tupper testified that POM changed its advertisements in accordance with the NAD's recommendations. (CX1364 (Tupper, Coke, Dep. at 337). POM did continue to cite the Aviram 2004 study in its advertising but did so in accordance with NAD's suggestion that POM summarize the study's specifics and parameters in appropriately qualified language. For example, POMx pill advertisements identified Dr. Aviram's study as "preliminary" and represented the details of the study: "Pomegranate juice consumption resulted in a significant IMT reduction by up to 30% after one year" and cited to a footnote explaining that the number, age, and health condition of the participants, and the length of time that they drank the juice. (CX0279-0001).

Furthermore, Dr. Aviram's 2004 study constitutes competent and reliable scientific support for POM's heart health. Dr. Aviram's study found a 30% reduction in arterial plaque of individuals who consumed pomegranate juice dialy for one year. (RFF 1118). Specifically, the authors wrote: "We thus conclude that, as previously shown in atherosclerotic mice, also in humans pomegranate juice consumption (by patients with carotid artery stenosis) possess anti-atherosclerotic properties, as it substantially decreased serum oxidative stress and, in parallel, reduced common carotid intima-media thickness." (CX0611-0009). Thus, Dr. Aviram's study constitutes competent and reliable evidence that the consumption of POM Juice is beneficial to cardiovascular health by, among other things, reducing arterial plaque and lowering blood pressure. (CX0611; Heber, Tr. 1962-64).

675. In May 2008, POM sought clearance from NBC for a television commercial, which included a line stating that POM Juice contained antioxidants that may promote prostate health. NBC reviewed POM's prostate cancer study, and found that it failed to meet the network's clinical testing guidelines. NBC required human studies for health claims, but the prostate cancer study relied upon by POM was neither randomized nor controlled, and

clearly stated the need for further research to prove validity. Therefore, NBC did not consider the prostate health claim to be adequately documented. (CX0193; Tupper, Tr. 1056-59; Perdigao, Tr. 662-63).

Response to Finding No. 675:

Respondents object to Complaint Counsel's proposed finding to the extent it is offered to support their argument that Respondents persisted in making deceptive health benefit claims after receiving warnings. NBC's internal guidelines are not "legal" guidelines, and are completely inappropriate to cite as evidence of Respondents' intentions. There is absolutely no evidence in the record establishing what NBC's policies actually are, or how they are applied. (*See* CX0193_0001). Indeed, despite the fact that NBC stated that one of POM's studies did not meet its own *internal standards*, NBC suggested that POM use the very type of qualified language that Complaint Counsel argues is ineffective. (CX0193_0002-0003). Complaint Counsel cannot cite NBC's statements as evidence of POM's alleged bad intent, while ignoring NBC's statements as evidence of POM's good intent. For example, from the exhibits cited by Complaint Counsel, NBC also revised POM's proposed language "Pomegranate contains powerful antioxidants needed to promote prostate and heart health" to read "Pomegranate contains powerful antioxidants that *may* promote prostate health and heart health." (CX0193_0002-0003) (emphasis added). This does not help Complaint Counsel's position on the proposed order, which asks the Commission to ignore either (1) the effectiveness of qualifiers in POM's current advertising or (2) ignore the possibility of the mandated use of certain qualifying language in POM's health benefit advertising, as an alternative to the more severe aspects of the proposed order. *Pearson v. Shalala*, 130 F. Supp. 2d 105, 122 (D.D.C. 2001) (court concluded that FDA suppressed First Amendment rights in suppressing Plaintiff's claim rather than proposing a clarifying disclaimer to accompany the claim). NBC also took no issue with and approved the phrase "Pomegranate contains powerful antioxidants needed to keep you health[y]." and "Pomegranate contains powerful antioxidants to keep

you healthy." (CX0193_0002 [sic]). Indeed, NBC, unlike Complaint Counsel, did not construe Respondents' representations about their science to mean "clinically proven." (CX0193).

Thus the cited evidence establishes, at most, that NBC notified POM that many of its advertising statements were acceptable under internal NBC policies, but that NBC believed appropriate qualification should be used for other statements. That refutes Complaint Counsel's contentions about POM's alleged persistence in using deceptive claims after receiving notification.

676. Although POM did not run this particular television advertisement, it continued to run advertising making claims citing the prostate cancer study after May 2008. (*See, e.g.*, CCFF ¶¶ IX.D.2.c.377-81, IX.D.4.c.415, IX.D.4.d.419, IX.D.4.e.425, IX.F.2.b.572).

Response to Finding No. 676:

Respondents object to the proposed finding on the same basis as discussed in the response to CCFF No. 675. POM's continued use of advertising that cites to the prostate cancer study does not illustrate or constitute evidence supporting Complaint Counsel's arguments regarding intent or materiality.

677. Similarly, in 2008 Comcast objected to a proposed POM television advertisement showing the bottle with noose and the tagline "Cheat Death." Comcast's lawyers wanted to know whether POM had substantiation that drinking POM would extend a person's life. (CX0242).

Response to Finding No. 677:

Comcast lawyers' request to see POM's science, asserted in the type of review that internal counsel for media companies routinely applies to advertising they run, is hardly evidence that Respondents deliberately persisted in making deceptive claims after receiving notice. In the cited letter, Comcast's sales manager specifically states that "Do they have any medical research that shows drinking POM will extend a person's life? Sounds silly to me but the lawyers wanted to know if you can substantiate the claim."

(CX0242). In that very letter, Comcast described this issue as "silly," reflecting the fact that the headline "Cheat Death" is obviously puffery. (CX0242).

Comcast's lawyers did not attempt to assess of the validity of POM's science or whether the asserted implied claim of extending one's life was sufficiently substantiated. Rather Comcast's attorneys merely requested what studies POM has that would address such a message, in the type of exhaustive check that is commonly conducted by counsel, no matter how "silly" or minor the issue. (CX0242). Thus, the cited evidence does not support Complaint Counsel's argument that POM was warned that the "Cheat Death" headline is inherently "deceptive," or that it is "material." Instead, the letter underscores the headline's puffery.

678. In January 2008, the FTC sent POM a letter alerting the company to its concerns about the advertising claims for POMx. (JX 0001).

Response to Finding No. 678:

Respondents have no specific response.

679. POM stated to the FTC in April 2008 that POM's scientific findings

The company also stated that it had

(CX0967_0004, 0008, *in camera*) (emphasis added). As set forth in CCFF ¶¶ 879-949, POM was aware of inconsistent study results at the time of its statement to the FTC.

Response to Finding No. 679:

Complaint Counsel cite POM's response to the FTC's 2008 inquiry letter to POM (which only addressed POMx, not POM Juice) as evidence that Respondents have disregarded the law and intended to mislead consumers. (JX0001). Complaint Counsel thus effectively argues that Respondents "intentionally" flouted the law because Respondents believe strongly in their defense, and have chosen to litigate it in federal court rather than

accede to Complaint Counsel's defective allegations. That position is logically and legally absurd. The general statements that Complaint Counsel cites from POM's response letter are plainly supported by the evidence, and by the vast body of science in support of POM's claims. (CX0967_0008, *in camera*). There is no question whatsoever that POM believes in that science. RFF 510-550. Nor is there any question that POM did not believe – and does not believe – that scientific evidence calls into question the benefits of pomegranate juice for prostate and heart health. As set forth in detail in POM's proposed findings of fact, the evidence and testimony in this action establishes exactly the opposite. RFF 1040-1573; RFF 1574-1922.

680. Dr. Liker kept in his files a printout (dated September 26, 2005) of an FTC press release, complaint and settlement with Tropicana Products, Inc., in which the FTC had alleged that Tropicana had made unsubstantiated health claims (including cholesterol and blood pressure reduction claims) about its orange juice. (CX0747). Dr. Liker testified that this document was likely sent to him from someone at POM or Roll who wanted him to be aware of it. (CX1350 (Liker, Dep. at 259-60)).

Response to Finding No. 680:

Complaint Counsel severely overreaches in trying to patch together an argument about alleged intent that the actual record does not support. The fact that Dr. Liker kept an FTC press release about a competitor's settlement with the FTC is not evidence that Respondents themselves persisted in making deceptive claims after receiving warnings. The fact that Complaint Counsel even attempts this argument demonstrates the bankruptcy of their effort to prove intent. Every company has many pieces of information about competitors being hit with legal allegations, and various settlements that result. The fact that Dr. Liker knew that Tropicana settled a lawsuit with the FTC does not somehow establish that POM was on notice that its own claims were deceptive -- anymore than POM learning about a competitor's class action settlement means that POM is on notice that it has "done wrong."

This printout involves a completely unrelated company making claims unrelated to the alleged violations at issue here. Complaint Counsel cannot construe their own practice of threatening companies and settling with them as *de facto* notice to competing companies that their own advertising is deceptive. First, because a settlement does not establish anything by itself; companies settle for many different reasons. Second, because false advertising claims are very fact-specific, and intent deceive is not across an industry just because Complaint Counsel decides to file an action.

Respondents further object to the cited deposition testimony because it lacks foundation and calls for speculation. Dr. Liker testified that "I don't have specific recollection as to why this particular document was in my file." (CX1350 (Liker, Dep. at 259). Dr. Liker also testified that he did not have any recollection of who at POM or Roll would have sent this to him. (CX1350 (Liker, Dep. at 260)). Thus, the fact that Dr. Liker kept this press release, complaint, and settlement in his files should be disregarded.

681. In February 2010, the FDA issued a warning letter to POM, finding POM made therapeutic claims on its website about POM Juice and that it was intended for use in the cure, mitigation, treatment, or prevention of diseases such as prostate cancer, erectile dysfunction, and heart disease. The FDA drew the same conclusion about POM's website claims for POMx Pills, including claims about heart disease and prostate cancer. (CX0344_0001-05).

Response to Finding No. 681:

In February 2010, POM received a warning letter from the FDA expressing concerns about consumer testimonials and the reprints and summaries of the published studies available on POM's website. (Tupper, Tr. 2981-2981; CX0344_0001). However, the FDA 2010 Warning Letter did not take issue with POM's underlying science and, despite disagreeing with the FDA's position, POM responsibly and adequately responded to the letter. (Tupper, Tr. 2981; CX0344; CX0346, *in camera*). POM provided a written response to the FDA stating that it respectfully disagreed with the FDA's contention that POM was marketing its product as a drug by making the studies available on its website.

(Tupper, Tr. 2982-83). Additionally, out of an abundance of caution, POM also made other changes to its website in accordance with the FDA's letter. (Tupper, Tr. 2982-83). Indeed, since POM made those changes, the FDA has not expressed any further concerns. (Tupper, Tr. 2983).

Moreover, by its plain terms, the warning letter does not evaluate the scientific studies or assess the strength of the scientific evidence supporting claims made by POM. Indeed, nowhere in the warning letter does the FDA state or even suggest that POM's statements are false, misleading, or that the scientific studies cited fail to substantiate them. (CX0344). The warning letter also does not establish that POM has violated any law or regulation and has no legal effect as the FDA itself has declared that a "Warning Letter is informal and advisory." FDA, *Regulatory Procedures Manual* § 4-1-1, *available at* http://www.fda.gov/ICECI/Compliance Manuals/RegulatoryProceduresManual/ucml76870.htm. Thus, the FDA's warning letter is certainly not, as Complaint Counsel argue, evidence of Respondents' willingness to violate the law and does not support the argument that Respondents persisted in making their unsupported health benefit claims after inquiries and warnings is not evidence that the health benefit claims are material, or serve as a basis for justification of the proposed order.

682. Mr. Tupper testified that he considered the FDA's warning letter "very unimportant because my view is that the FDA is totally off base for singling us out. I think it's actually an extreme example of urgent and not at all important in the greater scheme of things." (CX1369 (Tupper, Welch Dep. at 198-99)). He said of FDA, "They're off their rocker." (CX1371 (Tupper, Trop. Dep. at 190)).

Response to Finding No. 682:

Complaint Counsel take Mr. Tupper's statements out of context. When Mr. Tupper testified that the FDA was off base but that matter was important and urgent, he was testifying as to his personal view.

> "Q. Using the dichotomy you've drawn between the important and the urgent, which category would you *personally* put the FDA's letter into?
>
> A. I would *personally* put it in the bucket of urgent, because there's a demand for a response and action and very unimportant because my view is that the FDA is totally off base singling us out. I think it's actually an extreme example of urgent and not at all important in the greater scheme of things."

(CX1369 (Tupper, Welch's Dep. at 198-99) emphasis added).

Both statements that the FDA was "off its rocker" or that it was an "extreme example of urgent and not all important" are supported. The FDA's position that by the the simple virtue of the fact that POM had posted its research on the POM website as opposed to a related website accessible through multiple clicks that POM's products suddenly became a drug. Since POM responded in a letter and made changes to its website whereby the research is accessible through multiple clicks, the FDA has not expressed any further concerns. (Tupper, Tr. 2983).

Further, in its warning letter the FDA took issue with the fact that POM posted consumer testimonials on its website and cited to statements from consumers that had absolutely nothing to do with any representations that POM made about the health benefits of its products. (CX0344). For example, "Since drinking the POM every time I feel a lump they have amazingly gone down." (CX0344_0002).

Moreover, Mr. Tupper's statements are supported because Respondents, in fact, have not and never intended to market POM's products as drugs. Throughout its advertising, POM highlights that POM Juice is a 100% juice product wholly-derived from the pomegranate fruit, and that POMx has the same content as the pomegranate fruit itself and is 100% derived from the exact same fruit. (*See* RFF 494). Indeed, Respondents have never advertised their products as a pharmaceutical drug, nor intended to advertise their products as drugs. (RFF 495-96). Rather, Respondents have always marketed the

Challenged Products for what they intrinsically are: whole-food products. (RFF 497-99). Accordingly, it is far more logical (and the evidence demonstrates) that reasonable consumers would view the Challenged Products the way they perceive any other extremely healthy whole food, like broccoli, blueberries, grapes or tomatoes, which may help prevent or improve your odds against disease, but which would not "stop" anything, like a drug with a single target of action against a particular disease or condition.

Thus, Mr. Tupper's statement do not support Complaint Counsel's position that Respondents persisted in making their unsupported health benefit claims after inquiries and warnings is not evidence that the health benefit claims are material, or serve as a basis for justification of the proposed order.

683. POM could have sought FDA approval for a qualified health benefit claim for pomegranate juice with a certain level of polyphenols. In 2001, Respondents' then Medical Director acknowledged the importance of conducting research on how the product works for purposes of substantiation "as we go to the FDA or the FTC for claims." (CX0003_001). In a 2003 proposal to POM, a consultant noted that a qualified health claim "allow[s] food and dietary supplement manufacturers to communicate emerging scientific information about the health benefits of their products, as long as it is truthful and not misleading." (CX0017_0002). POM chose not to go through this process because it would have provided no benefit to POM against its competitors. (Tupper, Tr. 3032-33). Mr. Tupper also expressed concern, in an 2009 internal summary he drafted, that although POM could seek a "reduced risk of prostate cancer" health claim from the FDA, unless POM's cancer data was "outstanding, the resulting claim could be weak, [e.g.], the tomato claim is: '*Preliminary scientific research suggests that eating ½ cup of tomatoes / tomato sauce a week may reduce the risk of prostate cancer. FDA concludes that there is little scientific evidence supporting this claim*.'" (CX1029_0004) (emphasis in original). Similarly, in the 2009 summary, Mr. Tupper noted POM could seek a "reduced risk of heart disease" health claim from the FDA, but indicated it was "[p]robably not worth pursuing" because, among other reasons, "[t]he claim would not be specific to POM, but rather it would be generic to all pomegranate products meeting a minimum level of polyphenol content[.]" (CX1029_0003 (emphasis omitted)).

Response to Finding No. 683:

Mr. Resnick's purpose in sponsoring research has always been to seek out the truth as to whether and to what extent there are health benefits from consuming pomegranate. RFF 510. His purpose in sponsoring the research was not simply to use the studies to get "marketing claims," especially given that getting such claims approved has little value for

a company selling a natural food product. The competitors of such a company reap the benefits of the expensive and time consuming process of getting claims approved – which the FDA rarely does anyways in useable form, due to its notorious preference for paternalistic suppression. The *Pearson* line of cases, extending from 1999 to 2002, demonstrate how outrageously obstructive the FDA was at the precise time when Complaint Counsel now contends POM should have sought approval of claims, and implies was wrongful for not doing. As the D.C. Circuit memorably put it in *Pearson I*,

> As best we understand the government, its first argument runs along the following lines: that health claims lacking "significant scientific agreement" are inherently misleading because they have such an awesome impact on consumers as to make it virtually impossible for them to exercise any judgment at the point of sale. It would be as if the consumers were asked to buy something while hypnotized, and therefore they are bound to be misled. We think this contention is almost frivolous. We reject it.

Pearson v. Shalala, 164 F.3d 655-56 (D.C. Cir. 1999). Yet the FDA continued to improperly obstruct health claim approvals, and was in consequence repeatedly rebuked by federal courts. *See Pearson v. Shalala*, 130 F. Supp. 2d 105, 112-13, 118-19 (D.D.C. 2001); *Pearson v. Thompson*, 141 F. Supp. 2d 105, 112 (D.D.C. 2001); *Whitaker v. Thompson*, 248 F. Supp. 2d 1, 14 (D.D.C. 2002). It thus defies credulity for Complaint Counsel to depict the fact that POM did not seek FDA approval as being evidence of alleged bad intent. The FDA's approval process for health claims was unworkable and (at that time) so restrictive that it was held unconstitutional.

Indeed the Resnicks, years before ever selling POM juice, began collaborating with scientists to determine what benefits pomegranate juice has. (CX1374 (Tupper, Ocean Spray Dep. at 87); CX1358 (Aviram Dep. at 4); CX1363 (S. Resnick, Coke Dep. at 61-63, 65-66); CX1367 (S. Resnick, Welch Dep. at 15); CX0001_0010-0011; L. Resnick, Tr. 150; PX0004). Mr. Resnick testified at trial that his motivation in sponsoring the

research was to "do well by doing good" or in other words to "help society" by exploring where the Challenged products "can do the most good." (S. Resnick, Tr. 1862-63).

As part of its internal preparation to potentially submit an application to the FDA for drug approval, POM reviewed its entire science portfolio to examine whether and to what extent POM's research would meet the FDA's requirements for *drug approval*, with its current limited recognition of surrogate markers used in POM's research.[3] (Tupper, Tr. 3011). During this preparation, as a discussion piece for an internal meeting with Mr. Resnick and his advisors, Respondent Matt Tupper and POM's Chief Science Officer, Mark Dreher, drafted a document titled, "Medical Portfolio Review" dated January 13, 2009. (Tupper, Tr. 942, 939, 3008-09; CX1353 (Tupper, Dep. at 248-49); Dreher, Tr. 556). Both Mr. Tupper and Mr. Dreher testified that the document was used solely to evaluate the strength of POM's science under the narrow parameters of FDA drug approval—not for the strength of the science generally, or as support for POM's health claims.

Lastly, Complaint Counsel implies that POM had wrongful intent because it could have sought FDA approval before making health claims regarding its natural food products, but Complaint Counsel makes no attempt to address (a) the FDA's traditional hostility towards granting such approvals even when strong science exists; (b) the tremendous costs associated with obtaining such approvals, including funding the research; and (c) the fact that for food products (as opposed to patented pharmaceuticals), the entity paying to fund the research and obtain the approval ordinarily has no ability whatsoever to recover its costs. The benefits of such research naturally accrue to competitors and the general public. Few companies are willing, like POM, to sponsor expensive scientific research on the health benefits of natural food products because of that fact.

[3] Again, the fact that POM was interested in obtaining FDA drug approval at this time does not mean that POM believed it was making "drug" claims, but only that it wanted an edge against competitors. (Tupper, Tr. 3007-08).

684. Mr. Tupper testified that POM did not make any specific changes to its marketing in response to receiving the letters from the FTC and the FDA. (Tupper, Tr. 1059-60). Moreover, Mr. Resnick testified at trial that he does not refer to any FDA or FTC standards in considering whether to make a claim. He stated that "Well, I haven't seen any standard that we can adhere to for what we're doing, so I can't say that we're hitting your standard or not. We're hitting my standard, and my standard I think is a very, very critical one. . . . [W]e don't make any claims unless we're very comfortable that we've done adequate work and the results are adequate enough to make those claims." Mr. Resnick further testified that he believes his standard is "an adequate standard . . . [o]r more than adequate." (S. Resnick, Tr. 1655-56).

Response to Finding No. 684:

Complaint Counsel patently misstate the record as to POM's response to the FDA warning letter. Mr. Tupper did not testify "That POM did not make any specific changes to its marketing in response to receiving the letters from **the FTC and the FDA**." (emphasis added). In the cited trial testimony, Mr. Tupper testified only that he did not recall any specific discussion with his marketing team regarding changes in response to the **FTC's** letter, although POM was always evaluating and changing its advertising based on the science. (Tupper, Tr. 1059-1060). Furthermore, During Respondents case-in-chief, Mr. Tupper, in fact, testified that POM had in fact made changes in accordance to the concerns expressed in the FDA's letter. (Tupper, Tr. 2982-830.

Also, contrary to Complaint Counsel's erroneous proposed finding, Mr. Tupper testified at trial that despite disagreeing with the FDA's position, POM responsibly and adequately responded to the letter. (Tupper, Tr. 2981; CX0344; CX0346, in camera). POM provided a written response to the FDA stating that it respectfully disagreed with the FDA's contention that POM was marketing its product as a drug by making the studies available on its website. (Tupper, Tr. 2982-83). Additionally, out of an abundance of caution, POM also made other changes to its website in accordance with the FDA's letter. (Tupper, Tr. 2982-83). Indeed, since POM made those changes, the FDA has not expressed any further concerns. (Tupper, Tr. 2983).

Complaint Counsel's citations regarding Mr. Resnick's belief about when a claim is substantiated do not evidence any wrongful intent, because Mr. Resnick's quoted testimony was perfectly consistent with the "competent and reliable scientific evidence" that governs substantiation in this proceeding of claims made in POM's advertising. By contrast, Complaint Counsel's recent attempt to adopt a "two RCT" standard of proof from FDA pharmaceutical regulation and enforce it against all health claims is unscientific and unlawful, as shown by the expert testimony presented at trial, the documentary evidence, and Respondents' legal citations. Complaint Counsel's attempt here to newly impose a strictly RCT standard for a food, in fact, proves Mr. Resnick's point—the standard as defined by Complaint Counsel is a moving target, especially when deviating from scientific principles; Mr. Resnick's principled response is to appropriately adhere to scientific principles in determining what shows a real health benefit, with reasoned consultation with the best medical research experts in the field to help guide him. (Liker, Tr. 1889-94). There is nothing flip or irreverent about this principle, as suggested by Complaint Counsel. Science is the best guide to what does and does not show a health benefit—not Complaint Counsel's rigid, enforcement based motivation for what that evidence should be.

685. The fact that Respondents persisted in making their unsupported health benefit claims after inquiries and warnings from the New York Attorney General's office, the NAD, NBC, the FDA, and the FTC is evidence that the health benefit claims are material. (CCFF ¶¶ 666, 673-74, 676, 684).

Response to Finding No. 685:

Respondents object to this finding as conclusory, argumentative, and unsupported by the record. See discussion in replies to CCFFs 666, 673-74, 676, and 684. Materiality in a false advertising case is determined by whether an advertising claim is likely to affect consumer purchasing decisions – not by whether the defendant was sufficiently responsive to notifications that its advertising might be misleading. The alleged fact that

Respondents persisted in making unsupported claims, even if it was true, has no bearing whatsoever on whether those claims *were likely to affect consumers' purchasing decisions*. Complaint Counsel's argumentative proposed finding of fact is a blatant *non sequitur*. Moreover, it is not even a proposed finding of fact at all, because it proposes a finding that facts are "evidence" of materiality, which is a legal determination.

F. POM Assured Researchers and Research Institutions That It Would Not Promote Disease Treatment, Cure, or Prevention Claims, but Did So Anyway

686. On several occasions, the Institutional Review Boards (IRBs) for at least five research institutions have questioned whether POM's prostate cancer studies were intended to support a significant change in advertising in the product, or whether POM intended to market its tested product for the treatment, cure, or prevention of disease, which would require an Investigational New Drug application (IND) on file with the FDA. (JX0003 ¶¶ A.10-11; *see, e.g.*, CX0774_0001 [2005 inquiry from UCLA]; CX0811_0001 [2006 inquiry from MD Anderson]; CX0936_0001-02 [2007 inquiry from Johns Hopkins]; CX0975_0001 [May 2008 inquiry from UCLA]; CX1020_0002 [December 2008 inquiries from University of Miami and University of Indiana]; CX1056_0001 [2009 email from Johns Hopkins]).

Response to Finding No. 686:

There is no evidence that Respondents sought to market the Challenged Products as anything other than whole fruit or whole fruit-derived products – not drugs.

Complaint Counsel completely mischaracterizes the university requests for INDs as "notice" that POM's advertisements were making "disease" claims. IRBs have in the past requested that POM file an IND with the FDA because of the science, i.e., the study design and protocols—not because of POM's advertising. The purpose of an IRB is to review protocols and factors associated with a study and to ensure the safety of the study participants—not to regulate advertising claims. (Dreher, Tr. 578). POM did not intend to market the POM products as drugs. (CX0774; CX0811; CX0936; CX0975; CX1020; CX1056; CX1340 (Carducci, Dep. at 179-80)). When the IRB looks at the study's endpoints, and it sees that it is measuring effects on a cancer population of participants, for example, it (and/or the FDA) will sometimes request an IND to further ensure the

safety of the conduct of the study. Contrary to Complaint Counsel's outrageously false suggestion that POM refused to comply with FDA requirements until forced, POM responded appropriately to these requests by indicating that, despite the study design, the product was not an "unsafe" drug and there is no basis for asserting that POM's dialogue with IRBs regarding the necessity of INDs for the safety of a study design put POM on notice that it was making "disease" claims in its advertising. All of the IRBs except for the IRB at Johns Hopkins University were satisfied with POM's response and did not require that an INDA be filed. (CX1340 (Carducci, Dep. at 179-80)).

687. In the May 2008 correspondence from UCLA, Dr. Pantuck noted that the IRB was concerned about POM's marketing because "the company previously assured the IRB that the studies would not be used as marketing for prostate cancer treatment." He also noted that he had sent POM an example "where it looked like POM was saying PJ [POM Juice] was beneficial for a disease – prostate cancer." (CX0975_0001).

Response to Finding No. 687:

Respondents object to the proposed finding to the extent Complaint Counsel construe it as evidence of POM's intent to mislead consumers or to market the Challenged Products as anything other than whole fruit or whole fruit-derived products.

First, the record does not reflect that UCLA ever required that an IND be filed for Dr. Pantuck's study or that the IRB was unsatisfied with POM's response.

Second, the purpose of an IRB is to review protocols and factors associated with a study and to ensure the safety of the study participants—not to regulate advertising claims. (Dreher, Tr. 578). POM has not and has never intended to advertise the Challenged Products as a drug. Throughout its advertising, POM highlights that POM Juice is a 100% juice product wholly-derived from the pomegranate fruit, and that POMx has the same content as the pomegranate fruit itself and is 100% derived from the exact same fruit. (*See* RFF 494). Indeed, Respondents have never advertised their products as a pharmaceutical drug, nor intended to advertise their products as drugs. (RFF 495-

96). Rather, Respondents have always marketed the Challenged Products for what they intrinsically are: whole-food products. (RFF 497-99). Accordingly, it is far more logical (and the evidence demonstrates) that reasonable consumers would view the Challenged Products the way they perceive any other extremely healthy whole food, like broccoli, blueberries, grapes or tomatoes, which may help prevent or improve your odds against disease, but which would not "stop" anything, like a drug with a single target of action against a particular disease or condition.

688. In December 2008, the University of Miami IRB obtained guidance from FDA that since the objective of POM's proposed study was to determine the effect of POMx treatment on PSA levels in prostate cancer patients, its use would be considered a drug and would require an IND. Similarly, the University of Indiana IRB stated they needed confirmation of IND exemption from the FDA in order to proceed. These conclusions were relayed to Dr. Liker at POM. (CX1020_0007).

Response to Finding No. 688:

Respondents object to the proposed finding to the extent Complaint Counsel construe it as evidence of POM's intent to market the Challenged Products as anything other than whole fruit or whole fruit-derived products, or that the IRBs at the University of Indiana or the University of Miami took any issue with POM's marketing as opposed to *objectives of a study as stated in the in study protocols*. (CX1020_0005).

The evidence does not reflect that the any IRB (including the University of Miami and the University of Indiana), with the exception of Johns Hopkins, was unsatisfied with POM's response or that it ultimately required that an IND be filed with the FDA.

Additionally, POM has not and has never intended to advertise the Challenged Products as a drug. Throughout its advertising, POM highlights that POM Juice is a 100% juice product wholly-derived from the pomegranate fruit, and that POMx has the same content as the pomegranate fruit itself and is 100% derived from the exact same fruit. (See RFF 494). Respondents have never advertised their products as a pharmaceutical drug, nor

intended to advertise their products as drugs. (RFF 495-96). Rather, Respondents have always marketed the Challenged Products for what they intrinsically are: whole-food products. (RFF 497-99). Accordingly, it is far more logical (and the evidence demonstrates) that reasonable consumers would view the Challenged Products the way they perceive any other extremely healthy whole food, like broccoli, blueberries, grapes or tomatoes, which may help prevent or improve your odds against disease, but which would not "stop" anything.

Lastly, the evidence does not show that the IRBs at the University of Indiana or the University of Miami took any issue with POM's marketing as opposed to *objectives of a study as stated in the in study protocols*. (CX1020_0005). For example, the University of Miami stated, "the Medical Sciences IRB B *reviewed a protocol*" and then obtained guidance from the FDA, which then looked at "the *objective of* the proposed 1-year clinical study." (CX1020_0007).

689. To mollify the IRBs, POM typically sent a response (either directly or through the principal investigator) stating that it would not make claims associated with the treatment, cure, or prevention of any disease, and therefore was exempt from IND filing requirements. (*See, e.g.*, CX0762_0002; CX0976_0006; CX0811_0001; CX0939_0001; CX0942_0007; CX1012_0001; Dreher, Tr. 581-82).

Response to Finding No. 689:

Respondents object to the term "mollify" as vague, ambiguous and argumentative. The cited responses to IRBs is evidence that Respondents neither believed nor intended to make claims associated with the treatment, cure, or prevention of any disease. Further, all of the IRBs except for the IRB at Johns Hopkins were satisfied with POM's response and did not require that an IND be filed. (CX1340 (Carducci, Dep. at 179-80).

690. For example, in May 2008, Dr. Dreher of POM sent a letter to Dr. Pantuck at UCLA stating that POM "strictly adheres to the Food and Drug Administration (FDA) and Federal Trade Commission (FTC) claims guidelines for foods and dietary supplements. . . . As a policy, POM does not make drug related disease claims associated with treatment, cure, prevention or diagnosis. I continually reaffirm this with our Marketing team." (CX0255_0034). Dr. Dreher's May 2008 letter to Dr. Pantuck

attached a full copy of the FTC's publication "Dietary Supplements: An Advertising Guide For Industry." (CX0255_0002-33).

Response to Finding No. 690:

Dr. Dreher's responding letter to Dr. Pantuck is evidence that Respondents neither believed nor intended to make claims associated with the treatment, cure, or prevention of any disease and does not do so as a matter of policy.

691. Rather than heed Dr. Pantuck's concern about POM's misuse of his prostate cancer study in its advertising, POM attempted to placate him with false claims of regulatory compliance. (*See* CCFF ¶ 690). Perhaps the more candid view of POM's attitude about regulatory compliance comes from Mrs. Resnick when she testified that if she heard of Dr. Pantuck's concerns (*see* CCFF ¶ IX.D.4.a.402), she would have disregarded them as "Dr. Pantuck is not a marketing person." (L. Resnick, Tr. 212).

Response to Finding No. 691:

Respondents object to the proposed finding as it does not support the proposition that POM intentionally disregarded warnings by outside parties that there were problems with POM's advertising. (CX0072; CX1080). First, Dr. Pantuck's statements on marketing have no bearing on this case. Second, Complaint Counsel intentionally distort the meaning of the emails by cherry-picking statements from the documents to artificially construct a story about warning and intent.

Complaint Counsel cite to an August 2006 email from Dr. Pantuck for their argument that Dr. Pantuck was concerned about "POM's misuse of his prostate cancer study in their advertising." (CCPTB at 60). But that is not what happened, and Dr. Pantuck never said that in his deposition or testified to that.

In August 2006, POM drafted a press that adopted quotes made by Dr. Pantuck in articles featured on WebMD and in the New York Times in July 2006. (CX0071). The title of the August 2006 draft press release was "Wonderful variety pomegranate juice shows promise for prostate cancer." (CX0071_0001). That press release was the basis for the

August 2006 email discussion between Dr. Liker and Dr. Pantuck cited to by Complaint Counsel. (CX0071_0001; CX0072). Indeed, Complaint Counsel misconstrue the meaning of the statements made by Dr. Pantuck in the August 2006 email. (CX0072). Dr. Pantuck was not concerned with POM's marketing claims or the further publicizing his study generally. (CX0072_0001). Dr. Pantuck, in fact, never raised any issue with his very favorable quotes about the health benefits of pomegranates in an article featured on WebMD. In the WebMD article, "Pomegranate Slows Prostate Cancer," Dr. Pantuck made the following statements:

- "The juice seems to be working[.]
- "Pantuck says that pomegranate juice may allow 65-to 70-year old men treated for prostate cancer to outlive their risk of dying from their cancer." (*available at* http://www.webmd.com/prostate-cancer/news/20060705/pomegranate-slows-prostate-cancer).

Dr. Pantuck also did not take issue with the following description of his study in a 2006 New York Times Article, also referenced in the email: "Findings from a small study suggest that pomegranate juice may one day prove an effective weapon against prostate cancer." (CX0071_0001; *available at* http://www.nytimes.com/2006/07/04/health/04test.html?scp=1&sq=testing:%20linking%20pomegranates%20to%20prostate%20health&st=cse). Dr. Pantuck was not concerned about the claims POM was making about his research—he was concerned about POM's use of his quotes *on POM's website*. He therefore writes, "I am very concerned that my legitimacy will be affected by displaying my name in such a manner: am I a spokesperson for the company, am I independent from the company? I was just quoted in Newsweek saying that Pom was not using the study merely to sell juice, now I am on their website making claims?" (CX0072_0001). Thus, the main concern expressed by Dr. Pantuck in this email exchange was that he did not want to be considered a

spokesperson for POM, which is what he thought consumers would take away from the website, because doing so might affect his credibility as an objective researcher. (CX0072_0001). His concern was not about a disagreement with the substantive statements he made in the articles that were thereafter copied on the press release. Consequently, Mrs. Resnick's statement that Dr. Pantuck was "not a marketing person" makes absolute sense when her statement is put in context—Mrs. Resnick did not think consumers would take away that he would be deemed a "spokesperson" for the Company. (L. Resnick, Tr. 212). Thus, the cited evidence and finding does not support Complaint Counsel's implied argument that Respondents received notice from Dr. Pantuck that their claims were not supported.

692. In May 2009, the Vice Dean for Clinical Investigation at Johns Hopkins informed Dr. Carducci, the principal investigator of a POMx prostate cancer study, that because POMx was being used to treat a medical condition (rising PSA), an IND was required. The Dean ordered Dr. Carducci to stop enrolling patients. (CX1056_0001).

Response to Finding No. 692:

Respondents object to this proposed finding as misstating the evidence.

First, the Vice Dean at Johns Hopkins required an IND be filed with the FDA not because of statements made by POM's marketing but because of statements made in the protocol of Dr. Carducci's study. The email written by the Vice Dean states, "We just completed a call with the FDA where they clarified for us *when a protocol* using a dietary supplement requires an IND."

Second, as Dr. Harley Liker testified, Johns Hopkins, unlike any previous IRBs, required POM to file an IND, but did not do so because Johns Hopkins perceived POM to intend to market a treatment for a disease or to market POMx. Dr. Liker testified that an IND was initially not required for Dr. Carducci's but that another study being conducted at Johns Hopkins, that *was completely unrelated to POM* and that was looking at the effects

of a natural product on cancer was brought to the attention of Johns Hopkins. (CX1350 (Liker, Dep. at 250). This prompted Johns Hopkins to require INDs for all studies conducted using natural products, across the board, *regardless of statements in the protocols or the company's marketing history*. (CX1350 (Liker, Dep. at 250).

Third, Complaint Counsel mischaracterizes Johns Hopkins request for an IND as "notice" that its advertisements were making "disease" claims or that POM intended to use the Challenged Products to "treat disease." POM did not intend to market the POM products as drugs. (CX0774; CX0811; CX0936; CX0975; CX1020; CX1056; CX1340 (Carducci, Dep. at 179-80)). Throughout its advertising, POM highlights that POM Juice is a 100% juice product wholly-derived from the pomegranate fruit, and that POMx has the same content as the pomegranate fruit itself and is 100% derived from the exact same fruit. (*See* RFF 494). Respondents have never advertised their products as a pharmaceutical drug, nor intended to advertise their products as drugs. (RFF 495-96). Rather, Respondents have always marketed the Challenged Products for what they are: whole-food products. (RFF 497-99).

693. The FDA rejected POM's standard argument against an IND, informing Dr. Carducci that "even if the company has no plan to make any claim, the objective of the study is to prevent the recurrence of cancer and that is a drug use and a serious clinical claim. Thus an IND is required." Nevertheless, POM continued to take the position that an IND was not required. (CX1066_0001-03).
(CX1349 (Gillespie, Dep. at 50); CX1074_0002, *in camera*).

Response to Finding No. 693:

Respondents object to the proposed finding as it mischaracterizes the cited evidence.

First, The FDA did not require an IND for the Johns Hopkins study because of POM's past or present marketing claims. In response to an email from Dr. Carducci, Dr. Shaw Chen of the FDA wrote, "Whether an IND is required for a marketed dietary supplement depends on the "intended use" in the proposed protocol, not on"…"*its marketing*

history." (CX1066_0002 emphasis added). Dr. Chen also wrote, "*In your case, even if the company has no plan to make any claim, the objective of the study is to prevent recurrence of prostate cancer...*" (CX1066_0002).

Second, POM objected to filing the IND because it believed the Challenged Products are not drugs and do not fall under the definition of a drug under the FDA's intended-use definition. Although Respondents genuinely believe in the health benefits of the Challenged Products and in the scientific integrity of POM's sponsored research (CX1406 (Tupper, Tropicana Tr. 182-83); CX1363 (S. Resnick, Coke Dep. at 83; CX1360 (S. Resnick, Dep. at 200, 229, 246); PX1372 (S. Resnick, Tropicana Dep. at 42-43); CX1371 (Tupper, Tropicana Dep. at 171); CX1362 (L. Resnick, Coke Dep. at 51, 80); CX1375 (L. Resnick, Dep. at 8, 209)), Stewart Resnick, Lynda Resnick, and Matt Tupper testified specifically that POM never intended *to convey the claim* that the Challenged Products are "clinically proven" to treat, prevent, or reduce the risk of disease, and certainly not in the same sense as a drug treats, prevents, or reduces the risk of disease. (Tupper, Tr. 992, 3008; L. Resnick, Tr. 194, 196-97, 217-19; CX1363 (S. Resnick, Coke Dep. at 81); CX1376 (S. Resnick, Ocean Spray Dep. at 135); CX1372 (S. Resnick, Tropicana Dep. at 52, 56-59); CX1364 (Tupper, Coke Dep. at 297, 299); CX1374 (Tupper, Ocean Spray Dep. at 7); CX1362 (L. Resnick, Dep. at 283-84)). Moreover, none of the of the Challenged Ads ever states that scientific tests "prove" that the Challenged Products "prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction," or even that they "prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction." (Appendix of Advertisements). Throughout its advertising, POM highlights that POM Juice is a 100% juice product wholly-derived from the pomegranate fruit, and that POMx has the same content as the pomegranate fruit itself and is 100% derived from the exact same fruit. (*See* RFF 494). Respondents have never advertised their products as a pharmaceutical drug, nor intended

to advertise their products as drugs. (RFF 495-96). Rather, Respondents have always marketed the Challenged Products as what they are: whole-food products. (RFF 497-99). Accordingly, it is far more logical (and the evidence demonstrates) that reasonable consumers would view the Challenged Products the way they perceive any other extremely healthy whole food, like broccoli, blueberries, grapes or tomatoes, which may help prevent or improve your odds against disease, but which would not "stop" disease like a drug.

Third, Respondents also object to the proposed finding to the extent that Complaint Counsel construe POM's filing of an IND with the FDA as an admission that Respondents believe or intend to convey to consumers that the Challenged Products drugs or a substitute for conventional medical care.

VII. ANALYSIS OF THE SCIENTIFIC EVIDENCE AS PURPORTED SUBSTANTIATION FOR RESPONDENTS' CLAIMS

A. Testifying Experts

1. Complaint Counsel's Experts

a. Stampfer

694. Dr. Meir J. Stampfer is a Professor of Epidemiology and Nutrition, Harvard School of Public Health; Faculty Member, Division of Biological Sciences, Harvard School of Public Health; Professor of Medicine, Harvard Medical School; and Faculty Member, Dana Farber Harvard Cancer Center. (Stampfer, Tr. 689-91; CX1293 (Stampfer, Report at 0001)). He teaches epidemiology, advanced epidemiology, and preventive medicine. (CX1293 (Stampfer, Report at 0001)). Epidemiology is the study of the determination and distribution of disease in humans. (Stampfer, Tr. 691).

Response to Finding No. 694:

It is an overstatement to say that Dr. Stampfer 'teaches' preventive medicine, which incorrectly implies that he teaches a course on that subject; Dr. Stampfer testified only that he "also give[s] lectures in connection with a preventative medicine course." (Stampfer, Tr. 691). Likewise, his report states only that he "give[s] lectures in the preventive medicine course." (CX1293 (Stampfer, Report at 0001)).

695. Dr. Stampfer has been an investigator in several large studies focused on the relationship between nutrition and cancer and cardiovascular disease ("CVD"), and their precursors. (CX1293 (Stampfer, Report at 0003-04)). These include:

- Nurses' Health Study (started 1976, 121,700 women, cancer prevention, CVD, diabetes, other health issues);
- Nurses' Health Study II (started 1989, 116,800 women, same as above);
- Physicians' Health Study (started 1982, 29,000 men, multivitamin supplements, and aspirin, and beta carotene for prevention of CVD and cancer); and
- Health Professionals Follow-up Study (started 1986, 51,529 men, nutritional factors as related to cancer, including prostate cancer, and heart disease).

(CX1293 (Stampfer, Report at 0003-04); Stampfer, Tr. 692-94)). Additionally, he has participated in research investigating risk factors (including food intake and dietary factors) associated with prostate cancer and conducted randomized clinical trials involving nutrition and health, including dietary interventions to reverse atherosclerosis. (Stampfer, Tr. 698-700).

Response to Finding No. 695:

Complaint counsel's proposed statement distorts the specifics of these studies, incorrectly claiming that they are all "studies focused on the relationship between nutrition and cancer and cardiovascular disease," and mischaracterizing their focuses.

For the two Nurses Health Studies, rather than complaint counsel's biased paraphrase, the precise language of Dr. Stampfer's report describes their scope: "While the prevention of cancer is a primary focus, these studies have produced landmark data on cardiovascular disease, diabetes, and other major health problems." (CX1293 (Stampfer, Report at 0003-0004)).

For the Physicians' Health Study, rather than complaint counsel's biased paraphrase, the precise language of Dr. Stampfer's report describes its scope: a randomized trial on physicians testing "the benefits of aspirin and beta carotene in the primary prevention of cardiovascular disease and cancer." (CX1293 (Stampfer, Report at 0004)).

For the Health Professionals Follow-Up Study, rather than complaint counsel's biased paraphrase, the precise language of Dr. Stampfer's report describes its scope: an all-male cohort study that tests "a series of hypotheses about men's health relating nutritional factors to the incidence of serious illness such as cancer, heart disease, and other vascular disease." (CX1293 (Stampfer, Report at 0004)).

Complaint counsel's last proposed sentence is inappropriately compound. As to the first part of the compound sentence, Dr. Stampfer testified that he was an author or co-author on a report addressing intakes of meat, fish, poultry, and eggs and the risk of prostate cancer progression. (Stampfer, Tr. 699).

As to the second part, Dr. Stampfer testified that he has been involved in just three randomized controlled trials involving nutrition and health: the VISP study of B-vitamins in relation to incidence of recurrent stroke, the DIRECT study which looked at comparing different diets for weight loss, and a randomized trial of moderate alcohol consumption among diabetics to look at glucose metabolism. (Stampfer, Tr. 699). By omitting the number and specifics of these studies, complaint counsel's proposed finding falsely implies that Dr. Stampfer has extensive experience with randomized controlled trials in the field of nutrition and health. Complaint counsel further falsely implies that the three such trials he has been involved with were closely related to the facts disputed here, which they were not. A full and accurate description of Dr. Stampfer's involvement, consistent with his trial testimony, should therefore be used instead.

696. Dr. Stampfer has published more than 850 articles in medical journals, including the *New England Journal of Medicine*, *American Journal of Epidemiology*, *Epidemiology*, and *Journal of American Medical Association*. (CX1293 (Stampfer, Report at 0002)). Over 300 of these articles relate to the relationship between nutrition and the prevention or treatment of CVD or prostate cancer. (Stampfer, Tr. 701; *see also* CX1293 (Stampfer, Report at 0002)).

Response to Finding No. 696:

Not disputed.

697. In 2003, the Institute for Scientific Information identified Dr. Stampfer as the most cited researcher in clinical medicine and epidemiology in the world during the past 20 years. (CX1293 (Stampfer, Report at 0002)). In 2005, the Institute for Scientific Information identified him as the most cited researcher in clinical medicine over the previous decade. (CX1293 (Stampfer, Report at 0002)).

Response to Finding No. 697:

This is correct, except that complaint counsel's phrasing misleadingly implies that Dr. Stampfer was cited separately in two different fields, "clinical medicine" and "epidemiology." All of the citations to Dr. Stampfer's research were made in the specific subfield of epidemiology, not in other subfields like oncology. The Institute for Scientific Information classified epidemiology citations as also being citations within the broader field of clinical medicine. For that reason, the same citation counted twice, once in the subfield and once in the umbrella category of clinical medicine.

Dr. Stampfer's report is more clear on this point than is complaint counsel's proposed finding. His report states that Dr. Stampfer was identified "as the most often cited research in clinical medicine in the world over the previous 20 years. I was also identified as the most often cited researcher in the field of Epidemiology during that same time period." (CX1293 (Stampfer, Report at 0002)). The report's more specific phrasing should be used instead.

698. Dr. Stampfer currently is an editor for leading medical journals, including the Journal of the *American College of Nutrition, American Journal of Epidemiology*, *American Journal of Medicine*, and *Clinical Chemistry*. Dr. Stampfer also had editorial positions on the *American Journal of Clinical Nutrition*, *New England Journal of Medicine*, and *American Journal of Medicine*. (Stampfer, Tr. 701; CX1293 (Stampfer, Report at 0001-02)). In connection with his positions on these journals, he has had the opportunity to evaluate articles involving the design and conduct of clinical trials, and articles relating to the relationship between nutrition and CVD or cancer. Dr. Stampfer is a member of professional organizations relating to epidemiology, cancer, and CVD, including the Society of Epidemiological Research, the American College of Nutrition, the American Heart Association, and the American Association for Cancer Research. (Stampfer, Tr.

701-03). He also has consulted for the government on the U.S. Dietary Guidelines. (Stampfer, Tr. 703).

Response to Finding No. 698:

Complaint counsel incorrectly describes Dr. Stampfer's role as "editor," implying that he substantively edited articles, when for most of the listed journals he either just sat on the editorial board or was a reviewer, rather than an actual editor. Unlike complaint counsel's inaccurate paraphrase, Dr. Stampfer's report correctly describes his specific role, and should be used instead: Technical Reviewer, New England Journal of Medicine; Associate Editor, American Journal of Epidemiology; Editor, American Journal of Epidemiology; Editorial Board, Journal of the American College of Nutrition; Associate Editor, American Journal of Epidemiology; Editorial Board, American Journal of Medicine; Editorial Board, American Journal of Clinical Nutrition; and Editorial Board, Clinical Chemistry. (CX1293 (Stampfer, Report at 0001-0002)).

Complaint counsel cites no evidentiary support whatsoever for its proposed finding that "In connection with his positions on these journals, he has had the opportunity to evaluate articles involving the design and conduct of clinical trials, and articles relating to the relationship between nutrition and CVD or cancer." That proposed finding is not supported by the record, and should not be made, because it is gratuitous and contested lawyer's argument, rather than a finding of fact.

699. Based on his training, experience, and expertise, the Court recognized Dr. Stampfer as an expert on: 1) epidemiology; 2) nutrition, including its relation to the prevention and treatment of CVD and prostate cancer; and 3) clinical testing related to the prevention of prostate cancer and CVD. (Stampfer, Tr. 704-05 (noting no objection by Respondents to Dr. Stampfer's qualifications); *see also* CX1293 (Stampfer, Report at 0005)).

Response to Finding No. 699:

The proposed statement is erroneous insofar as Dr. Stampfer was permitted to testify as an expert regarding "the clinical testing relating to the *progression* of cardiovascular

disease and prostate cancer" (Stampfer, Tr. 704-705) (emphasis added), not clinical testing relating to the "*prevention* of prostate cancer and CVD" as complaint counsel now proposes. The trial record on this point should be followed, rather than complaint counsel's proposed finding.

700. Dr. Stampfer was asked to determine whether the materials submitted by Respondents were sufficient to support claims that:

- drinking eight ounces of POM Juice, or taking one POMx Pill or one teaspoon of POMx Liquid, daily, treats, prevents, or reduces the risk of heart disease, including by decreasing arterial plaque, lowering blood pressure, and/or improving blood flow to the heart;
- tests prove that drinking eight ounces of POM Juice or taking one POMx Pill or one teaspoon of POMx Liquid, daily, treats, prevents, or reduces the risk of heart disease, including by decreasing arterial plaque, lowering blood pressure, and/or improving blood flow to the heart;
- drinking eight ounces of POM Juice, or taking one POMx Pill or one teaspoon of POMx Liquid, daily, treats, prevents, or reduces the risk of prostate cancer, including by prolonging prostate-specific antigen doubling time ("PSADT"); and
- tests prove that drinking eight ounces of POM Juice, or taking one POMx Pill or one teaspoon of POMx Liquid, daily, treats, prevents, or reduces the risk of prostate cancer, including by prolonging "PSADT."

(CX1293 (Stampfer, Report at 0005-06)).

Response to Finding No. 700:

Complaint counsel's paraphrase misstates its actual request to Dr. Stampfer, eliminating details and interjecting extraneous qualifications (such as the gratuitous new language about "sufficient to support"). The specific language stated in Dr. Stampfer's report should be used instead: "The FTC staff [] requested that [Dr. Stampfer] evaluate, from [his] perspective as an expert in the fields of epidemiology, nutrition, and clinical testing, whether the following claims [were] supported by the materials submitted by the Respondents." (CX1293 (Stampfer, Report at 0005)).

701. To form his opinions, in addition to drawing upon his own expertise in nutrition and CVD and treatment, Dr. Stampfer reviewed materials submitted by Respondents and affiliated researchers, including published and unpublished study reports, protocols, data and data analyses from Respondents' sponsored research, information about ingredients

contained in the POM Products, and deposition transcripts of researchers who conducted studies for Respondents and related deposition exhibits and reports. Dr. Stampfer also reviewed materials he found through his independent literature search. (CX1293 (Stampfer, Report at 0006-07); Stampfer, Tr. 734-36; CX1294).

Response to Finding No. 701:

Dr. Stampfer is not an expert in CVD or its treatment, and complaint counsel proposed finding thus begins with a glaring misstatement. Instead, Dr. Stampfer was recognized as an expert on *nutrition*, including its relation to the prevention and treatment of CVD; and *clinical testing* as it relates to the progression of CVD. (Stampfer, Tr. 704-705). Dr. Stampfer's report likewise states that he relied on his expertise in the fields of epidemiology, nutrition, and clinical testing, *as they relate to CVD* – not that his opinion was based on expertise in CVD or its treatment. (CX1293 (Stampfer, Report at 0007)). Dr. Stampfer is not a cardiologist (Stampfer, Tr. 868), is not even a practicing physician, and has never claimed to be an expert in CVD or its treatment. By deliberately omitting these key qualifications on Dr. Stampfer's expertise, complaint counsel's proposed finding is deeply misleading.

b. Sacks

702. Dr. Frank M. Sacks is a Professor of Cardiovascular Disease Prevention, Department of Nutrition, Harvard School of Public Health, and Professor of Medicine, Harvard Medical School. (Sacks, Tr. 1411-12; CX1291 (Sacks, Report at 0001)). He has taught pharmacology, epidemiology, and nutrition courses related to human disease, CVD, biochemistry, or preventative medicine. (Sacks, Tr. 1412-13; CX1291 (Sacks, Report at 0002)).

Response to Finding No. 702:

Dr. Sacks only spends 10 to 20 percent of his time teaching. (PX361 (Sacks, Dep. at 44)). In addition, Dr. Sacks is not a practicing clinician and, at best, has only spent 10 percent of his time between 1978 and 2010 actually treating patients. (PX361 (Sacks, Dep. at 44)).

703. Dr. Sacks has researched CVD and coronary heart disease ("CHD") and their risk factors, including lipid profiles, hypertension, obesity, and diabetes, and the effects of potential

risk-modifying diets, foods, food components, and drugs. (CX1291 (Sacks, Report at 0002); Sacks, Tr. 1415-18). He is the principal investigator of several NIH studies focusing on dietary nutrients and weight loss, carbohydrate amount and type affecting risk of CVD and diabetes, and dietary fat and high-density lipoprotein ("HDL") metabolism in humans. (CX1291 (Sacks, Report at 0005-06)).

Response to Finding No. 703:

Dr. Sacks has never done any studies examining the effects of pomegranates, antioxidants, or nitric oxide on human health. (PX361 (Sacks, Dep. at 57)). In addition, Dr. Sacks has never researched whether a single fruit, such as the pomegranate, has health benefits, but instead has only studied "fruits and vegetables as a category." (PX0361 (Sacks, Dep. at 54-56)) (emphasis added).

704. Dr. Sacks has published more than 160 articles in peer-reviewed scientific journals relating to CVD, CHD, and the relationship between nutrition and these diseases. (Sacks, Tr. 1412-13, 1424-25; CX1291 (Sacks, Report at 0002-04)). Dr. Sacks has also written over 60 reviews, reports, editorials, and book chapters, addressing CVD, CHD, and the relationship between nutrition and these diseases or their risk factors. (CX1291 (Sacks, Report at 0004)).

Response to Finding No. 704:

Respondents have no specific response.

705. Through his professional memberships and activities, Dr. Sacks keeps current on new developments and research in the areas of nutrition, CVD, cholesterol disorders, and hypertension. (Sacks, Tr. 1424). He served as an editor for the *American Journal of Clinical Nutrition*, *Journal of Clinical Lipidology*, a *Nutrition Journal (BioMed Central),* and *The Journal of Lipid Research.* (CX1291 (Sacks, Report at 0006)). In these positions, he reviewed the adequacy of the design, the conduct of clinical research, and the appropriateness and accuracy of the statistical methodology in hundreds of papers submitted for publication. (Sacks, Tr. 1424-25; CX1291 (Sacks, Report at 0006)).

Response to Finding No. 705:

At trial, Dr. Sacks testified that he was only the associate editor of the *American Journal of Clinical Nutrition*, in which Respondents have published at least one of their cardiovascular studies (PX0004), and where he had the responsibility for evaluating manuscripts and deciding whether they should be published. (Sacks, Tr. 1424-25). Dr.

Sacks' trial testimony does not establish that he performed the same function for the other journals cited by Complaint Counsel, *Journal of Clinical Lipidology*, a *Nutrition Journal (BioMed Central),* and *The Journal of Lipid Research.* (Sacks, Tr. 1424-25). Although Dr. Sacks' expert report does list him as an associate editor with the *Journal of Clinical Lipidology*, he did not serve in this capacity for the other two journals, a *Nutrition Journal (BioMed Central),* and *The Journal of Lipid Research.* (CX1291_0006).

706. Dr. Sacks serves as a chair of the Nutrition Committee of the American Heart Association (AHA), which advises the AHA on matters of science and public policy and devises guidelines and advisory statements to the government, health professionals, and the public on nutrition. (Sacks, Tr. 1426; CX1291 (Sacks, Report at 0006-07)). Dr. Sacks is also a member of the National Cholesterol Education Program of the National Heart, Lung and Blood Institute of NIH, which revises national guidelines on prevention and treatment of CVD. (CX1291 (Sacks, Report at 0007); Sacks, Tr. 1426).

Response to Finding No. 706:

Respondents have no specific response.

707. Based on his training, experience, and expertise, the Court recognized Dr. Sacks as qualified to provide expert opinions on the areas of nutrition, CVD, CHD, cholesterol disorders, hypertension, and analysis of clinical studies. (Sacks, Tr. 1429-30 (noting no objection by Respondents to Dr. Sack's qualifications); CX1291 (Sacks, Report at 0008)).

Response to Finding No. 707:

Respondents have no specific response, subject to Dr. Sacks' limitations identified in their response to Complaint Counsel's proposed Finding No. 707 and to note that the Court ruled that "[a]ny [of his] opinions that meet the proper legal standards will be considered." (Sacks, Tr. 1429-30).

708. Dr. Sacks was asked to determine whether the materials he reviewed were sufficient to support claims that: 1) drinking eight ounces of POM Juice, or taking one POMx Pill, or one teaspoon of POMx Liquid, daily, treats, prevents, or reduces the risk of heart disease, including by decreasing arterial plaque, lowering blood pressure, and/or improving blood flow to the heart; and 2) clinical studies, trials, and/or tests prove that drinking eight ounces of POM Juice, or taking one POMx Pill, or one teaspoon of POMx Liquid, daily, treats, prevents, or reduces the risk of heart disease. (CX1291 (Sacks, Report 0008-09)).

Response to Finding No. 708:

Although he was asked to provide his expert testimony as stated in his expert report, Dr. Sacks' opinions are limited: he cannot offer any expert opinion regarding the safety of the Challenged Products, or any alleged differences of POM Juice compared to POMx or POM Liquid. Dr. Sacks is not offering any expert opinion regarding any differences between pomegranates and POM juice. (RFF 1267; Sacks, Tr. 1547-48; PX0361 (Sacks, Dep. at 77)). Dr. Sacks testified that he is not offering any opinion in this case about the physical properties of pomegranates or pomegranate juice. (RFF 1268; Sacks, Tr. 1548). In his report, Dr. Sacks did not offer any expert opinion on the issues of safety or bioequivalency and these subjects were not within the scope of his assignment in this case. (RFF 1269; PX0361 (Sacks, Dep. at 76)). Importantly, Dr. Sacks does not know the distinction between POMx Liquid and POM Juice. (RFF 1270; PX0361 (Sacks, Dep. at 75)). Dr. Sacks has no idea how POM Juice or POMx are made. (RFF 1271; Sacks, Tr. 1570; PX 0361 (Sacks, Dep. at 143-145)). Dr. Sacks does not know that pomegranates have been eaten safely for centuries. (RFF 1272; Sacks, Tr. 1570). Dr. Sacks does not know if anybody has been harmed by eating pomegranates. (RFF 1273; Sacks, Tr. 1570-71).

709. To form his opinions, in addition to drawing upon his own expertise in nutrition and CVD treatment, Dr. Sacks reviewed materials submitted by Respondents and affiliated researchers, including published and unpublished study reports, protocols, data, and data analysis from Respondents' sponsored research, information about ingredients contained in the POM Products, and deposition transcripts of researchers who conducted studies for Respondents and related deposition exhibits. Dr. Sacks also reviewed materials he found through an independent literature search. (Sacks, Tr. 1447-49 (identifying materials he reviewed); CX1291 (Sacks, Report at 0008-09); CX1292, Apps. 2, 3, 4).

Response to Finding No. 709:

In preparing his expert report, Dr. Sacks does not know if he has reviewed all of Respondents' research studies on cardiovascular health. (RFF 1266; PX0361 (Sacks, Dep. at 78)).

c. Eastham

710. Dr. James A. Eastham is the Chief of Urology in the Department of Surgery at Memorial Sloan-Kettering Cancer Center in New York. He serves as the Director of Clinical Research, Urology and chairs the protocol review committee for clinical trials in the Department of Surgery. (CX1287 (Eastham, Report at 0001); Eastham, Tr. 1207-08)). He is a board-certified urological surgeon who has treated more than 2,000 patients with prostate cancer, including some who experienced a rise in prostate-specific antigen ("PSA") after receiving initial therapy. (CX1287 (Eastham, Report at 0002); Eastham, Tr. 1206, 1225-28, 1233).

Response to Finding No. 710:

Respondents have no specific response.

711. Dr. Eastham has extensive experience, including as an investigator, in the design and conduct of clinical trials studying prostate cancer. (Eastham, Tr. 1215-17). As a member of the Data Safety Monitoring Board for the Selenium and Vitamin E Cancer Prevention Trial, he is familiar with the design and performance of the largest prevention trials studying antioxidants and prostate cancer. (CX1287 (Eastham, Report at 0002-03); Eastham, Tr. 1210-11)).

Response to Finding No. 711:

Respondents have no specific response other than to object to the extent his participation necessarily makes him an expert in all aspects of antioxidant or prostate cancer study or research.

712. Dr. Eastham is a member of professional associations, including the American Urological Association, the Society of Urologic Oncology, and the National Comprehensive Cancer Network ("NCCN") Prostate Cancer Guidelines Committee. He regularly attends and speaks at national and international meetings of professional societies that specialize in urology and prostate cancer. (CX1287 (Eastham, Report at 0003); Eastham, Tr. 1211-13).

Response to Finding No. 712:

Respondents have no specific response.

713. Dr. Eastham has peer-reviewed numerous papers involving randomized, double-blinded, controlled human clinical studies ("RCTs") that were submitted to medical journals, such as *Urology*, *Journal of Urology*, and *Journal of Clinical Oncology*. (CX1287 (Eastham, Report at 0003); Eastham, Tr. 1224-25). Dr. Eastham has published over 200 peer-reviewed articles in scientific journals, as well as dozens of book chapters or reviews pertaining to urology and the treatment of prostate cancer. (CX1287 (Eastham, Report at 0003-04); CX1288, Ex. A; Eastham, Tr. 1214-15).

Response to Finding No. 713:

Respondents have no specific response.

714. Based upon his education, training, and experience, the Court recognized Dr. Eastham as an expert in: 1) urology specializing in prostate cancer, including the prevention and treatment of prostate cancer; and 2) clinical testing related to the prevention and treatment of prostate cancer. (Eastham, Tr. 1234 (noting no objection by Respondents to Dr. Eastham's qualifications); CX1287 (Eastham, Report at 0004)).

Response to Finding No. 714:

Respondents have no specific response.

715. Dr. Eastham was asked to determine whether the materials he reviewed were sufficient to support claims that: (1) drinking eight ounces of POM Juice, or taking one POMx Pill, or one teaspoon of POMx Liquid, daily treats, prevents, or reduces the risk of prostate cancer, including by prolonging prostate-specific antigen doubling time ("PSADT"); and (2) tests prove that drinking eight ounces of POM Juice, or taking one POMx Pill, or one teaspoon of POMx Liquid, daily, treats, prevents, or reduces the risk of prostate cancer, including by prolonging PSADT. (CX1287 (Eastham, Report at 0004-06)).

Response to Finding No. 715:

Respondents have no specific response.

716. To form his opinion, in addition to drawing upon his own expertise in the field of urology, specializing in prostate cancer, including the prevention and treatment of prostate cancer, and clinical testing relating to the treatment and prevention of prostate cancer, Dr. Eastham reviewed the materials submitted by Respondents and affiliated researchers, including published and unpublished study reports, protocols, data and data analysis from Respondents' sponsored research, and information about ingredients contained in the POM Products. Dr. Eastham also reviewed materials he found through an independent literature search. (CX1287 (Eastham, Report at 005); Eastham, Tr. 1287-88; CX1288, Ex. B).

Response to Finding No. 716:

Respondents have no specific response.

d. Melman

717. Dr. Melman is a Professor and Chairman of the Department of Urology at Albert Einstein College of Medicine and Montefiore Medical Center. (Melman, Tr. 1072-73). Dr. Melman is a board-certified, practicing clinical urologist at Montefiore Medical

Center and has treated thousands of patients with erectile dysfunction. (Melman, Tr. 1071-73).

Response to Finding No. 717:

Respondents have no specific response.

718. Dr. Melman has extensive experience in designing and reviewing protocols for well-designed clinical trials. As an editor of *Sexuality and Disability,* the *Journal of Urology,* and the *International Journal of Impotence Research*, Dr. Melman reviewed hundreds of articles involving erectile dysfunction by evaluating, among other factors, the design, data collection and reporting, and statistical analysis of clinical studies. (Melman, Tr. 1075-77; CX1289 (Melman, Report at 0002)). Furthermore, Dr. Melman was a principal investigator on two National Institutes of Health research grants relating to erectile dysfunction. (Melman, Tr. 1079-80; CX1289 (Melman, Report at 0002-03)).

Response to Finding No. 718:

Despite Dr. Melman's "extensive experience in designing and reviewing protocols," he did not know the meaning of the term "RCT," which is commonly used by researchers to indicate a randomized double-blind, placebo-based trial. (RFF 2174; Melman, Tr. 1134-35). Dr. Melman further testified that he had never heard of the GAQ and had no experience with it prior to his involvement in this case, even though the GAQ is widely used and commonly accepted as a standardized instrument among those conducting erectile dysfunction research —including in virtually every published study of Viagra, Cialis, and Levitra. (RFF 1996-2001, 2167-71; 2167; Melman, Tr. 1180; Goldstein, Tr. 2602, 2603; Burnett, Tr. 2304). Dr. Melman also has taken the extreme position that "pomegranate juice is a drug," and therefore the FDA standard for pharmaceutical drugs should apply. (RFF 2161; PX0360 (Melman, Dep. at 17-19); Melman, Tr. 1141).

Dr. Melman also conceded that he has never conducted any clinical work on a food product, including pomegranates, and has not written about the oral treatment of erectile dysfunction. (RFF 2177, 2178, 2179; Melman, Tr. 1164-65). In fact, most of Dr. Melman's current research is on gene transfer therapy and overactive bladder condition. (RFF 2180; Melman, Tr. 1164-65).

Additionally, Dr. Melman does not agree with the United States Supreme Court's recent opinion in Matrixx Initiatives, Inc. v. Siracusano, 131 S.Ct. 1309, 1320 (2011) that "medical professionals and researchers do not limit the data they consider to statistically significant evidence." (Melman, Tr. 1178-80).

719. Dr. Melman was chairman of the U.S. Food and Drug Administration's Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee, and was a member of the National Institutes of Health's Urology Special Emphasis Panel. (Melman, Tr. 1077-78; CX1289 (Melman, Report at 0001-02)). Dr. Melman is a member of several professional organizations, including the American Federation for Clinical Research, Society of University Urologists, American Urological Association, American Association of Clinical Urologists, International Society of Urology, and International Academy of Sex Research; and has spoken at national and international meetings of professional societies that specialize in urology and erectile dysfunction. (Melman, Tr. 1077-79; CX1289 (Melman, Report at 0001-02)). Dr. Melman has published more than 200 peer-reviewed articles relating to urology in scientific journals. Many of these published articles relate to erectile dysfunction. (Melman, Tr. 1076-77; CX1289 (Melman, Report at 0002)).

Response to Finding No. 719:

Respondents have no specific response.

720. Based upon his education, training, and experience, the Court recognized Dr. Melman as an expert in: (1) urology as it relates to the treatment, prevention, and reduction of risk of erectile dysfunction; and (2) clinical testing involving erectile dysfunction. (Melman, Tr. 1080-81 (noting no objection by Respondents to Dr. Melman's qualifications)).

Response to Finding No. 720:

Dr. Melman's report and testimony only "pertains to POM Wonderful pomegranate juice." (PX0360 (Melman, Dep. at 33, 59)).

721. Dr. Melman was asked to determine whether the materials he reviewed were sufficient to support claims that: 1) drinking eight ounces of POM Juice, daily, prevents, reduces the risk of, or treats erectile dysfunction; and 2) clinical studies, research, and /or trials prove that drinking eight ounces of POM Juice, daily, prevents, reduces the risk of, or treats erectile dysfunction. (CX1289 (Melman, Report at 0003)).

Response to Finding No. 721:

Respondents have no specific response.

722. To form his opinions, in addition to relying on his expertise in urology as it relates to the treatment, prevention, and reduction of risk of erectile dysfunction, and clinical testing involving erectile dysfunction, Dr. Melman reviewed materials submitted by Respondents and affiliated researchers, including included published and unpublished study reports, protocols, and data and data analyses from Respondents' sponsored research. (CX1289 (Melman, Report at 0003); Melman, Tr. 1083). Dr. Melman also reviewed articles he found through his independent research of peer-reviewed journals. (Melman, Tr. 1083; CX1289 (Melman, Report at 0003)).

Response to Finding No. 722:

Respondents have no specific response.

2. Respondents' Experts

a. Heber

723. Dr. David Heber, a Professor of Medicine and Public Health, directs the University of California Center for Human Nutrition. Since 2001, he has directed the UCLA Risk Factor Obesity Program, which focuses on obesity treatment. He has published over 200 peer-reviewed articles and two books, *What Color Is Your Diet* (2001) and *The L.A. Shape Diet* (2004). His areas of research interest encompass obesity, clinical nutrition, inflammation, phytonutrients, and cancer. (PX0192 (Heber, Report at 0005-06, 0092)).

Response to Finding No. 723:

The factual statements are individually correct, but are an incomplete recitation of Dr. Heber's relevant qualifications. That recitation should include the following additional points: Dr. Heber is a treating physician. (Heber, Tr. 1937). He is the founding director of the UCLA Center for Human Nutrition, which is a center for clinical research, education, and public health endeavors. (Heber, Tr. 1937). Dr. Heber was the editor-in-chief of the leading text on nutritional oncology, and has written a book on the importance of diet in maintaining health and resisting diseases. (Heber, Tr. 1939). Dr. Heber received his Ph.D. in Physiology from UCLA, a MD from Harvard Medical School (top 10 percent of his class, Alpha Omega Alpha), and a B.S. (summa cum laude in Chemistry and Phi Beta Kappa) from UCLA. (PX0192-0005).

724. Since approximately 2002, Dr. Heber has worked as Respondents' scientific advisor. (Heber, Tr. 1941, 2013; S. Resnick, Tr. 1637). Dr. Heber testified that he was not paid for his work as an expert in this case. (Heber, Tr. 1942). However, Mr. Resnick and POM's scientific director, Dr. Gillespie, testified that Dr. Heber is on "retainer."

(CX1376 (S. Resnick, OS Dep. at 312); CX1349 (Gillespie, Dep. at 268-69)). Rather than compensating Dr. Heber directly, Respondents have paid UCLA for his services. (*See* Heber, Tr. 2016). Respondents provide some of this funding as "gifts." However, to obtain these gifts, Dr. Heber submitted proposed budgets describing his proposed work for the coming year. (Heber, Tr. 2016; CX873_0001-03; CX1006_0001-07; *see* CX897_0001; CX1150_0001). Between 2004 and 2010, Respondents gave UCLA $1.58 million in "gifts" for Dr. Heber's work. (Heber, Tr. 2023-27). Between 2005 and 2010, Respondents also paid UCLA $489,000 in contract awards pursuant to Dr. Heber's work for POM. (Heber, Tr. 2024-25; CX1132_0002-04). Respondents have also paid $670,000 to the University Medical Research Foundation, which Dr. Heber uses to cover shortfalls in the Center for Human Nutrition's operating costs. (Heber, Tr. 2030; CX1027_0001-02). Dr. Heber has named a laboratory at the Center for Human Nutrition after the Resnicks. (S. Resnick, Tr. 1640-41).

Response to Finding No. 724:

Dr. Heber testified that he is not paid any fee for his work as a consultant. (Heber, Tr. 1941). Dr. Heber testified that UCLA, not himself, has received both research grants and unrestricted gifts from Roll entities. (Heber, Tr. 1941, 2016). Contrary to complaint counsel's contentions, the university uses those funds in an unrestricted way for the research and education missions of the center. (Heber, Tr. 1941). Those gifts went into a general fund, along with other unrestricted funds, which generally support the Center for Human Nutrition. (Heber, Tr. 1941-42).

In erroneously implying that POM's gifts were restricted, Complaint counsel conflates Roll's funding of specific research studies with unrestricted gifts, falsely asserting that "to obtain these gifts, Dr. Heber submitted proposed budgets describing his proposed work for the coming year." Correcting complaint counsel's misstatement, in referring to his research budgets, Dr. Heber testified that he provided those budgets "because there were multiple studies going on[]." (Heber, Tr. 2016-17). Dr. Heber did not testify that the budgets were submitted in exchange for unrestricted gifts, as opposed to research studies.

Citing testimony from Mr. Resnick and Dr. Gillespie, complaint counsel contends that Dr. Heber is on "retainer," implying that he is paid for his testimony in this matter,

contrary to his testimony. But Mr. Resnick's deposition testimony explicitly stated that we he called a "retainer" was just for research funding, funding that long preceded this litigation. (S. Resnick, OS Depo. at 312). Likewise, Dr. Gillespie testified that Dr. Heber did not receive money directly, but rather that what Dr. Gillespie called "retainer" money was paid to the Regents of the University of California, in connection with Dr. Heber's research activities. (Gillespie, Dep. at 268-69). Accordingly, complaint counsel's implication that there is a hidden agreement to pay Dr. Heber for his expert testimony is fallacious, and fails to controvert his explicit testimony to the contrary.

It is correct that Roll entities gave UCLA $1.58 million in unrestricted gifts between 2004 and 2010, but complaint counsel again cites no support for its erroneous contention that these unrestricted gifts were "for Dr. Heber's work." (Heber, Tr. 2023-27). Dr. Heber carefully distinguished between research funding for his work, and unrestricted gifts which go into a general fund. (Heber, Tr. 1941-42). Complaint counsel repeatedly contradicts the record by asserted that unrestricted gifts, accepted and processed in accordance with UCLA policies, are payments "for" Dr. Heber's work.

It is correct that between 2005 and 2010, various Roll entities paid UCLA $489,000 in research grants related to Dr. Heber's work on pomegranates, but not that such grants were for "work for POM," which is complaint counsel's argumentative phrasing. (Heber, Tr. 2024-25; CX1132_0002-04).

Dr. Heber testified that respondents made a $150,000 gift to the University Medical Research Foundation, which is a nonprofit foundation. (Heber, Tr. 2030). But no evidence supports complaint counsel's contention that Respondents paid a total of $670,000 to the University Medical Research Foundation. In the cited trial testimony, Dr. Heber answered counsel's question by only testifying that it's possible an additional $520,000 payment was made, but that he does not recall: "That's possible. I don't

recall." (Heber, Tr. 2030-31). Complaint Counsel cite no other testimony or documentary evidence to support their contention about such an additional $520,000 payment.

725. Dr. Heber has conducted numerous *in vitro* and animal studies on Respondents' pomegranate products, investigated the superiority of Respondents' juices to competitors' products, and researched whether POM Juice or extracts modified various biomarkers in overweight adults or diabetics. (Heber, Tr. 2015-16; CX0859_0001-03 (overweight adults); CX1109_0002 (diabetes study)). Dr. Heber has also done research for Roll on pistachios and triglycerides, and on Fiji Water and bone health. (Heber, Tr. 2015, 2028-30).

Response to Finding No. 725:

Dr. Heber did not testify that he "investigated the superiority of Respondents' juices to competitors' products." Instead, Dr. Heber testified that he has conducted one study in which he looked at the antioxidant potency of various available refrigerated juices. (Heber, Tr. 2015-16.) Complaint counsel argumentatively mischaracterizes that study as investigating "the superiority of Respondent's juices to competitors' products."

Complaint counsel's first sentence is also compound, incorrectly implying that Dr. Heber's research on antioxidant potency and the biomarker research was done in addition to the studies on Respondent's pomegranate products (as opposed to being a subset of those studies).

726. Dr. Heber has coordinated POM's research with other scientists, developed manuscripts and abstracts, presented research agendas, and presented at most POM Research Summits. (Heber, Tr. 2019; CX1006; CX1376 (S. Resnick, OS Dep. at 312-13)). He co-edited a book about POM research. (CX1352 (Heber, Dep. at 397)). Dr. Heber also has provided statements for use in POM's marketing materials. (L. Resnick, Tr. 236-37; CX1426_00041; CCFF ¶¶ 475-476, 557). He communicated frequently with Mr. Resnick and Respondents' employees. (Dreher, Tr. 557, 569; Heber, Tr. 2018-19; S. Resnick, Tr. 1638).

Response to Finding No. 726:

Complaint counsel's proposed first sentence is compound, rendering it ambiguous. Furthermore, Dr. Heber did not testify that he coordinated POM's research with other scientists.

Complaint counsel cites only one statement attributed to Dr. Heber in POM's marketing materials. (CX1426_00041). In her cited testimony, Ms. Resnick testified that she "believes" that Dr. Heber provided such statements, but did not testify that she knows that he did.

For the last sentence, which is compound, the record does not show that Dr. Heber "communicated frequently" with Mr. Resnick. Rather Dr. Dreher's testimony was that Dr. Heber "regularly" attended meetings at POM when research plans were discussed. (Dreher, Tr. 557). Mr. Resnick testified the same on that point. (S. Resnick, Tr. 1638).

For the separate issue of "communications with Respondents' employees," the only supporting testimony is Dr. Dreher's testimony that, during the specific period of his employment, he had frequent meetings with Dr. Heber. (Dreher, Tr. 559). No other Respondent employees are named in the cited testimony, and it is misleading for complaint counsel to phrase the statement as though Dr. Heber was frequently speaking with a variety of different employees.

727. Dr. Heber also has provided expert testimony for Respondents in four federal court cases, including three where he purportedly appeared "pro bono." PX0192 (Heber, Report at 0007-08; PX0045-0007 (*POM Wonderful LLC v. Tropicana Products, Inc.*); PX0046-0007 (*POM Wonderful LLC v. Welch Foods, Inc.*); PX0047-005 (*POM Wonderful LLC v. Ocean Spray Cranberries, Inc.*); PX0353 (Heber Dep. at 189) (noting that Dr. Heber testified in *POM Wonderful LLC v. Purely Juice*)).

Response to Finding No. 727:

Not disputed that Dr. Heber provided expert testimony in these cases on POM's behalf. Dr. Heber testified pro bono in those three cases, however, as the cited reports state, rather than "purportedly" testifying *pro bono*, as complaint counsel implies without any contrary evidence.

728. Respondents offered Dr. Heber as an expert on the relationship between nutrition and various diseases, including coronary heart disease and prostate cancer, as well as other diseases. (Heber, Tr. 1940-41). Dr. Heber does not hold himself out to be an expert in CVD, is not an expert in CVD treatment, and does not know what kind of evidence experts in the field would require to support a claim that a product could lower blood pressure. (Heber, Tr. 2041; PX0353 (Heber, Dep. at 12, 172); PX0353 (Heber, Dep. at 11-12, 172) (his "expertise would be determined by legal folks")). He admits that he is not an expert in prostate cancer treatment or erectile function treatment. (Heber, Tr. 2034-36, 2038-39; PX0353 (Heber, Dep. at 10-11)).

Response to Finding No. 728:

Dr. Heber is an expert in the relationship between nutrition and various diseases. Dr. Heber testified that he is an expert in the biology and mechanisms of heart disease. (Heber, Tr. at 2037). Dr. Heber testified that he is expert in the basic mechanisms related to erectile dysfunction (Heber, Tr. at 2039). Dr. Heber testified that he is an expert in the mechanisms related to prostate cancer, and an expert in prevention of prostate cancer as it relates to nutrition. (Heber, Tr. at 2036-37).

Dr. Heber does not consider that he is an expert in the specific field of treating these specific diseases, however, because he is not a practicing physician in those specific fields. Respondents submitted Dr. Heber's testimony to rebut the testimony of complaint counsel' epidemiologist, Dr. Meir Stampfer, who likewise (being an epidemiologist, and who is not even a practicing physician) is not an expert at treating any of these specific diseases.

In failing to address the full context and nature of Dr. Heber's expert testimony, complaint counsel's proposed finding of fact is inaccurate, biased, and incomplete.

729. Dr. Heber was asked to comment on Dr. Stampfer's expert report and provide opinions on issues related to pomegranate juice and extract, including: (1) antioxidants found in pomegranates, their potency, and how they act in the body (their mechanisms of action); (2) the health and safety effects; and (3) nutritional research methodology relating to the evaluation of scientific research on health benefits. (PX0192 (Heber, Report at 0004)).

Response to Finding No. 729:

Not disputed, except to the extent it is implied that this finding encompasses the entirety of what Dr. Heber was asked to give his opinion on in this action.

730. Dr. Heber was *not* asked to opine on whether the heart benefit claims challenged in the complaint were true or substantiated. When asked at his deposition whether competent and reliable scientific evidence supports the conclusion that drinking eight ounces of POM Juice, or taking one POMx Pill, or one teaspoon of POMx Liquid daily, *prevents or reduces the risk of* heart disease including by decreasing arterial plaque, lowering blood pressure, or improving blood flow, Dr. Heber repeatedly stated that "the body of research on pomegranate juice and extract revealing how it acts on the body provides support for *potential* health benefits for heart disease." (PX0353 (Heber, Dep. at 76-79 (emphasis added)); *see also* PX0192 (Heber, Report at 0019) ("the body of research on pomegranate juice and extract provides support for "potential health benefits for heart disease, and prostate cancer")). When asked whether competent and reliable scientific evidence supports the conclusion that drinking POM Juice or taking POMx Pills or Liquid *treats* heart disease including by decreasing arterial plaque, lowering blood pressure, or improving blood flow to the heart, Dr. Heber states that "nutrition is not a treatment for disease. . . since you characterized it with the word 'treatment' I'm not agreeing with your statement." (PX0353 (Heber, Dep. at 81-83)).

Response to Finding No. 730:

Dr. Heber gave extensive expert testimony that supports Respondents' position on the benefits of pomegranate juice and/or extracts for cardiovascular health, focusing on the basic mechanisms of disease and how they relate to compounds within pomegranate juice. (Heber, Tr. 1957-1986). For example, Dr. Heber opined that Dr. Davidson's constitutes competent and reliable evidence that the consumption of POM Juice is beneficial to cardiovascular health by, among other things, reducing arterial plaque. (PX0014; Heber Tr. 1979-86).

In trying to downplay that testimony, complaint counsel presents a defective semantic argument, proposing a finding that Dr. Heber was not asked to opine on "the heart benefit claims challenged in the complaint." Dr. Heber opined at length on what the science shows about the relationship between consumption of pomegranate juice/pomegranate extract and heart health. (Heber, Tr. 1957-1986). Dr. Heber's testimony thus directly supports the conclusions stated in POM's proposed findings of fact.

Being a scientist rather than a lawyer or advertising expert, Dr. Heber's deposition testimony did not couch his scientific opinion in the argumentative legal language that complaint counsel advocates – for example, complaint counsel contends that pomegranate juice is a "drug" used for "treating" disease – which complaint counsel has borrowed from FDA pharmaceutical regulations. In criticizing Dr. Heber's preference for stating his position about the benefits of nutrition in scientific language, complaint counsel underscores its effort to substitute borrowed regulatory terminology for science.

731. Similarly, when asked whether clinical studies, research, and/or trials prove that drinking POM Juice, or taking POMx Pills or one teaspoon of POMx Liquid daily, prevents or reduces the risk of heart disease including by decreasing arterial plaque, lowering blood pressure, or increasing blood flow to the heart, Dr. Heber repeated that "my professional opinion is that the body of research including clinical studies on pomegranate juice and extract revealing how they act in the body provides support for *potential* benefits for heart disease" including blood flow. (PX0353 (Heber, Dep. at 87-89) (emphasis added)). Asked whether clinical studies, research, and/or trials prove that POM Juice, POMx Pills, and POMx Liquid *treats* heart disease, including by lowering blood pressure, or improving blood flow to the heart, he repeated that the "body of research . . . provides support for *potential* health benefits for heart disease including blood flow." (PX0353 (Heber, Dep. at 89-90) (emphasis added)).

Response to Finding No. 731:

Dr. Heber gave extensive expert testimony that supports Respondents' position on the benefits of pomegranate juice and/or extracts for cardiovascular health, focusing on the basic mechanisms of disease and how they relate to compounds within pomegranate juice. (Heber, Tr. 1957-1986). For example, Dr. Heber opined that Dr. Davidson's constitutes competent and reliable evidence that the consumption of POM Juice is

beneficial to cardiovascular health by, among other things, reducing arterial plaque. (PX0014; Heber Tr. 1979-86). Dr. Heber's testimony thus directly supports the conclusions stated in POM's proposed findings of fact.

Through italicized emphasis of the "potential" word in his deposition testimony, this proposed finding of fact attempts to contrast Dr. Heber's deposition testimony with the previous proposed finding of fact's recitation of "the heart benefit claims challenged in the complaint." Dr. Heber expressed his opinion in scientific language that, through the use of the word 'potential,' accepts the possibility of future changes in research. At trial, Dr. Heber elaborated in detail on his opinion regarding the benefits of pomegranate juice/extract for cardiovascular health, as shown by the current state of scientific research. (Heber, Tr. 1957-1986). That trial testimony is completely consistent with his deposition testimony.

732. Dr. Heber was not asked to opine on whether the prostate benefit claims challenged in the complaint were true and substantiated. Asked whether competent and reliable scientific evidence supports the conclusion that POM Juice, POMx Pills, or POMx Liquid prevents or reduces the risk of prostate cancer including by prolonging prostate specific antigen doubling time, he stated that "my professional opinion is the body of research on pomegranate juice and extract revealing how they act in the body provides support for *potential* health benefits for prostate cancer including prolongation of PSA doubling time." (PX0353 (Heber Dep. at 84-85)(emphasis added)). Asked whether the challenged prostate *treatment* claims were supported by competent and reliable scientific evidence, he stated that "I would disagree with the term 'treatment' for a nutritional product and say that my professional opinion is that the body of research on pomegranate juice and extract provides support for *potential* health benefits for prostate cancer." (PX0353 (Heber, Dep. at 85-86)) (emphasis added). When asked whether clinical studies, research, and/or trials prove that POM Juice, POMx Pills, or POM Liquid prevents, reduces the risk of, or treats prostate cancer, including by prolonging PSADT, he stated only that "the body of research . . . provides support for *potential* benefits for prostate cancer including" prolongation of PSADT. (PX0353 (Heber, Dep. at 90-92) (emphasis added)).

Response to Finding No. 732:

Dr. Heber gave extensive expert testimony that supports Respondents' position on the benefits of pomegranate juice and/or extracts for cardiovascular health, focusing on the basic mechanisms of disease and how they relate to compounds within pomegranate

juice. (Heber, Tr. 1992-1993, 1996-1997, 2012-2013, 2151, 2156; Heber, Dep. 84-91, 155-156, 257-258, 268, 314-317). For example, Dr. Heber opined that "PSA doubling time is an accepted variable by the vast majority of the urological community, including members of the American Urological Association and all the leading experts in prostate cancer research in the United States. This is not in dispute." (Heber, Tr. 2151). Likewise, Dr. Heber opined that competent and reliable science showed that POM and POMx lengthens the PSA doubling time for men who have had prostate cancer. (Heber, Tr. 2012).

In trying to downplay that testimony, complaint counsel presents a defective semantic argument, proposing a finding that Dr. Heber was not asked to opine on "whether the prostate benefit claims challenged in the complaint were true and substantiated." Dr. Heber opined at length on what the science shows about the relationship between consumption of pomegranate juice/pomegranate extract and prostate disease health. (Heber, Tr. 1992-1993, 1996-1997, 2012-2013, 2151, 2156). Dr. Heber's testimony thus directly supports the conclusions stated in POM's proposed findings of fact.

Being a scientist rather than a lawyer or advertising expert, Dr. Heber's deposition testimony did not couch his scientific opinion in the argumentative legal language that complaint counsel advocates – for example, complaint counsel contends that pomegranate juice is a "drug" used for "treating" disease – which complaint counsel has borrowed from FDA pharmaceutical regulations. In criticizing Dr. Heber's preference for stating his position about the benefits of nutrition in scientific language, complaint counsel underscores its effort to substitute borrowed regulatory terminology for science.

b. Ornish

733. Dr. Dean Ornish is the Founder and President of the Preventative Medicine Research Institute ("PMRI") in Sausalito, CA. (PX0025 (Ornish, Report at 0001)).

Response to Finding No. 733:

Respondents have no specific response, but to note that Dr. Ornish's full credentials and qualifications are set forth in Respondents' proposed Findings of Fact Nos. 1147-1182. (*See also* PX0025 containing Dr. Ornish's expert report and curriculum vitae).

734. Dr. Ornish's career has focused on testing the theory that comprehensive, intensive lifestyle changes can improve medical risk factors in people with disease, including heart disease. For example, his Lifestyle Intervention Program asked patients to eat a very low-fat, plant based diet, exercise at certain levels, engage in stress management, and attend group support sessions. (Ornish, Tr. 2466). He believes that a comprehensive lifestyle program can treat CVD. (Ornish, Tr. 2467). Dr. Ornish is the author of six books, including Dr. Dean Ornish's Program for Reversing Heart Disease; Eat More, Weigh Less; and The Spectrum. (PX0025 (Ornish, Report at 0003-04)).

Response to Finding No. 734:

Respondents have no specific response, but to note that Dr. Ornish's full credentials and qualifications are set forth in Respondents' proposed Findings of Fact Nos. 1147-1182. (*See also* PX0025 containing Dr. Ornish's expert report and curriculum vitae).

735. Dr. Ornish conducted two pomegranate juice studies, sponsored by Respondents; one was published, and one was not. (See CCFF ¶¶ C.2.b.822, C.2.b(1)(a)824-74). Other than these two pomegranate juice studies for Respondents, Dr. Ornish has never studied whether a single food product is beneficial in maintaining cardiovascular health or for any other endpoint. (Ornish, Tr. 2464). Nor does his curriculum vitae identify any studies conducted by him to determine whether an individual drug intervention provides cardiovascular or other benefits. (See PX0025 (Ornish, Report at 0053-56)). Prior to the time that PMRI conducted the two pomegranate juice studies for Respondents, the Resnicks had provided Dr. Ornish with a "generous" grant to study whether comprehensive lifestyle changes could halt progression of early prostate cancer. (CX1339 (Ornish, Dep. at 215)).

Response to Finding No. 735:

Complaint Counsel's suggestion that Dr. Ornish lacks expertise to offer his expert opinions because he has purportedly "never studied whether a single food product is beneficial in maintaining cardiovascular health" is irrelevant and misplaced. Complaint Counsel's own expert, Dr. Sacks, has never researched whether a single fruit, such as the pomegranate, has health benefits, but instead has only studied "fruits and vegetables as a

category." (PX0361 (Sacks, Dep. at 54-56)) (emphasis added). Dr. Ornish's curriculum vitae, cited by Complaint Counsel, only lists a "Selected Bibliography" of his scientific research, so no definitive conclusions can be drawn from the document. (PX0025-0053-0056)).

Complaint Counsel's implication that Dr. Ornish is somehow biased because he previously received a grant to conduct prostate cancer research lacks merit given that: (1) the Resnicks are not presently sponsoring any of Dr. Ornish's current research; (2) Dr. Ornish is only being compensated one dollar an hour as an expert witness; (3) although he has been asked to serve as an expert witness all of the time, this is the first time Dr. Ornish has agreed to do so; and (4) Dr. Ornish is serving as an expert witness in this case because he believes this is a historic case and that liberties of the American public are at stake. (RFF 1176-1179; Ornish, Tr. 2323-24; 2374).

736. Respondents offered Dr. Ornish as an expert in "the relationship between the heart and nutrition and in cardiovascular disease and its relationship to nutrition, nutrients, and such things." (Ornish, Tr. 2321-22).

Response to Finding No. 736:

In addition, Dr. Ornish also stated in his expert report that he is "an expert in the evaluation of whether a food or product is beneficial in maintaining cardiovascular health and lessening the risk of cardiovascular disease, and also the analysis of clinical studies." (PX0025-0004).

737. Dr. Ornish was not, according to his expert report, asked to opine on whether the heart benefit prevention, reduction of risk, or treatment claims alleged in the complaint were substantiated, or whether the heart benefit "establishment claims" (that is, the claims that "clinical studies, research, and/or trials prove heart benefits in terms of prevention, reduction of risk, or treatment) were true. (See PX0025 (Ornish, Report at 0004-05)). Instead, he was asked to evaluate Dr. Sacks' expert report and provide an opinion on: (1) whether drinking eight ounces of POM Juice, or taking one POMx Pill, or one teaspoon of POMx Liquid "may be beneficial in maintaining cardiovascular health and lessening the risk of CVD;" and (2) whether "basic science, clinical studies, research, and/or trials show that the consumption of POM Juice, POMx Pill, or POMx Liquid may be beneficial in maintaining cardiovascular health and lessening the risk of CVD." (PX0025 (Ornish, Report at 0004-05); PX0355 (Ornish, Dep. at 20) (emphasis added)).

Response to Finding No. 737:

The record is replete with Dr. Ornish's expert testimony concerning the health benefits of pomegranate juice and/or its derivatives and Respondents' scientific research regarding the same.

In the record, Dr. Ornish made the following expert opinions:

- Taken as a whole, the preponderance of the scientific evidence from basic scientific studies, animal research, and clinical trials in humans reveals that the pomegranate in its various forms (including POM Wonderful 100% Pomegranate Juice, POMx Pills, or POMx Liquid) is likely to be beneficial in maintaining cardiovascular health and is likely to help reduce the risk of cardiovascular disease. (RFF 1206; PX0025-0005).

- The universe of existing science provides significant evidence that pomegranate juice is likely to, among other things, reduce arterial plaque, improve blood flow, and reduce blood pressure. (RFF 1207; PX0025-0005; PX0355 (Ornish, Dep. at 42); Ornish, Tr. 2374-75).

- The consumption of pomegranate juice or its derivatives is not a "silver bullet" or a substitute for conventional treatments for heart disease, and Respondents do not suggest otherwise. (RFF 1208; PX0025-0005).

- Drinking eight ounces of POM Juice, or taking one POMx Pill or one teaspoon of POMx Liquid, daily, is likely to help prevent or reduce the risk of heart disease by decreasing arterial plaque; (2) lowering blood pressure, and/or (3) improving blood flow to the heart. (RFF 1210; PX0025-0005; Ornish, Tr. 2374-75; PX0355 (Ornish, Dep. at 42)).

- Drinking eight ounces of POM Juice, or taking one POMx Pill or one teaspoon of POMx Liquid, daily, is likely to treat heart disease by reversing the progression of heart disease in people who already have severe heart disease. (RFF 1211; Ornish, Tr. 2354-55)

Contrary to Complaint Counsel's assertion, Dr. Ornish did provide expert testimony regarding the so-called establishment claims when explicitly stated in deposition and trial that "it is my expert opinion that clinical studies, research and trials, provide significant evidence that pomegranate juice is likely to *reduce blood pressure, improve blood flow, and reduce arterial plaque, period*." (RFF 1210; PX0025-0005; Ornish, Tr. 2374-75; PX0355 (Ornish, Dep. at 42)) (emphasis added).

738. At trial, Dr. Ornish testified only with regard to the two studies that he had conducted, and opined that they constitute credible and reliable scientific evidence that pomegranate juice lessens the risk of cardiovascular problems by improving blood flow in people who already had heart disease. (Ornish, Tr. 2354). He previously testified, however, that he did not consider his own CIMT study (*see* CCFF ¶ 872) to be a "part of the evidence" relating to whether or not pomegranate juice has beneficial effects on heart disease, and that he did not include those results in reaching his opinions. (PX0355 (Ornish, Dep. at 191-93).

Response to Finding No. 738:

At trial, with respect to the studies he conducted and the benefits of pomegranate juice, Dr. Ornish further testified that "So, we're not just talking about risk of heart disease in terms of preventing it in otherwise healthy people. We're talking about reversing the progression of heart disease in people who already have severe heart disease. Clearly, if you can reverse a disease that's -- or begin to reverse a disease, it would only make sense that it would work even better to help prevent it in the first place." (Ornish, Tr. 2354-55).

Complaint Counsel misstates Dr. Ornish's testimony with regard to the Ornish CIMT Study. Dr. Ornish merely testified that it was an indeterminate study that cannot be relied upon: "It neither proves or disproves. It would be, again, as wrong to say that it proves as it would be for Dr. Sacks to assert that it disproves it." (PX0355 (Ornish, Dep. at 192-93)).

c. deKernion

739. Dr. Jean B. deKernion is the former Chairman of the Department of Urology and Senior Associate Dean for Clinical Operations at the UCLA School of Medicine in Los Angeles, California. (deKernion, Tr. 3039). Dr. deKernion is board certified by the American Board of Surgery and the American Board of Urology and maintains an active urologic oncology practice treating patients for prostate, kidney, and bladder cancer. (deKernion, Tr. 3039-40, 3111-12).

Response to Finding No. 739:

Respondents have no specific response.

740. Dr. deKernion's major research contributions early in his career were in the field of kidney cancer, focusing on immunomodulation and immunotherapy. (deKernion, Tr.

3111). For the last 30 years, Dr. deKernion has been more of a research administrator and facilitator than a hands-on researcher. (deKernion, Tr. 3110-11).

Response to Finding No. 740:

Complaint Counsel mischaracterizes Dr. deKernion's testimony, taking his isolated statements out of context in an attempt to paint a picture that Dr. deKernion was somehow not heavily involved in prostate research or clinical practice or that he served an administrator function only for most of his career. Neither could be further from the truth, and even a cursory glance at his CV demonstrates this point. (PX0161). To the contrary, much of his medical practice over the years (particularly in the last 10-15 years) was based specifically on prostate cancer and many of the over 200 papers and 133 book chapters he authored focused on prostate cancer. (PX0161; deKernion, Tr. 3110-13). Similarly, and as testified to Dr. deKernion, in his administrative and facilitator role, he did not stop participating in research, it just meant that he did not do the hands on lab work like he used to—but he was very involved. (PX0161; deKernion, Tr. 3110-13).

741. Dr. deKernion has several personal and professional connections to Respondents and the Pantuck Phase II Prostate Cancer Study (2006). (deKernion, Tr. 3112-17). Dr. Pantuck and Dr. Arie Belldegrun conducted the Pantuck Phase II Prostate Cancer Study (2006) and reported to Dr. deKernion, Chairman of the Urology Department at the UCLA School of Medicine. (deKernion, Tr. 3114). He encouraged Dr. Pantuck and the other investigators to conduct the Pantuck Phase II Prostate Cancer Study (2006) and even sought an exemption from UCLA rules to allow Dr. Pantuck to serve as the primary investigator for the Pantuck Phase II Prostate Cancer Study (2006). (deKernion, Tr. 3113, 3115; CX0570_0001).

Response to Finding No. 741:

Respondents object to the extent Complaint Counsel insinuate that Dr. deKernion's familiarity with the Pantuck Study or its investigators or Respondents somehow suggests he is biased or that the study is not a well done, peer-reviewed and published study. In fact, Dr. Eastham admitted during his testimony that the Pantuck study was a well-designed, good study. (Eastham, Tr. 1339). Moreover, to the extent Complaint Counsel suggests the application for the exemption from tenure-only research rule for Dr.

Pantuck—meaning only tenure-bound track professors are allowed to serve as principal investigators with grant money—shows bias or is otherwise unusual, it is not. Dr. deKernion specifically testified that he often sought exemption from that rule for all sorts of visiting professors or non-tenure tracked professors if he felt the research was worthwhile. (deKernion, Tr. 3113-15).

742. Dr. deKernion was listed as an investigator on the original protocol for the Pantuck Phase II Prostate Cancer Study (2006) because he helped identify patients under his medical care for the study. (CX0666_0001; deKernion, Tr. 3112-13). Dr. deKernion's department directly benefitted from Respondents' funding of the Pantuck Phase II Prostate Cancer Study (2006). (deKernion, Tr. 3115).

Response to Finding No. 742:

Respondents have no response other than to object to the extent Complaint Counsel insinuate that Dr. deKernion was somehow motivated by money to his department to either allow the Pantuck study to go forward at UCLA or is otherwise biased in favor of the study. As testified to by Dr deKernion, the funding for this study was nothing compared to the budget of the UCLA urology department. (PX0351 (deKernion, Dep. at 118)).

743. Dr. deKernion was a founding member and board member of Agensys until 2007. (PX0351 (deKernion, Dep. at 116-17); deKernion, Tr. 3115). Respondents paid Agensys $1.8 million in 2000 and 2001 for its *in vitro* and animal research on POM Juice. (CX1263_0003). The Pantuck Phase II Prostate Cancer Study (2006) protocol cited the Agensys *in vitro* and animal research on the effect of POM Juice on prostate cancer to support its hypothesis that POM Juice may affect PSA. (CX0666_0008).

Response to Finding No. 743:

Respondents have no response other than to object to the extent Complaint Counsel insinuate that Dr. deKernion was somehow motivated by money in providing testimony or that the research done by Agensys or Pantuck is suspect or not good science because it was funded by Respondents.

744. Dr. deKernion operated on Respondent Stewart Resnick for his prostate cancer. (CX1376 (S. Resnick, Dep. at 152); deKernion, Tr. 3117).

Response to Finding No. 744:

Respondents have no specific response other than to object to extent Complaint Counsel suggests this has biased Dr. deKernion.

745. Respondents offered Dr. deKernion as an expert to discuss "the experiments, the studies that have been done on the prostate . . . about pomegranate juice and POM products." (deKernion, Tr. 3043-44). Respondents asked Dr. deKernion to rebut the opinions in Dr. Eastham's expert report. (deKernion, Tr. 3108-09).

Response to Finding No. 745:

Respondents have no specific response other than to note those were not the only opinions Dr. deKernion was asked to provide. (PX0161).

746. Respondents did not ask Dr. deKernion to determine whether Respondents' evidence, considered as a whole, was sufficient to support the claims that: (1) drinking eight ounces of POM Juice, or taking one POMx Pill, or one teaspoon of POMx Liquid, daily, treats, prevents, or reduces the risk of prostate cancer, including by prolonging PSADT; and (2) clinical studies, research, or trials prove that drinking eight ounces of POM Juice, or taking one POMx Pill, or one teaspoon of POMx Liquid, daily, treats, prevents or reduces the risk of prostate cancer, including by prolonging PSADT. (*See* PX0161 (deKernion, Report at 0003-04); deKernion, Tr. 3061; *see also* PX0351 (deKernion, Dep. at 30) (Respondents did not ask Dr. deKernion to opine on the claims alleged in the Complaint)).

Response to Finding No. 746:

Respondents have no specific response other than to note that Dr. deKernion was not asked to opine on the exact statements as posed by the FTC. He was, however, asked, and as noted in his expert report: "I agreed to give expert opinion on the research done in our Department, and the research on pomegranate as it relates to the prostate, and the validity of PSA doubling time in assessing response to POM products. I will address the issues raised by Dr. Eastham in his report with respect to the data regarding POM products for patients with prostate cancer, and provide my own opinion regarding the strength of the science supporting the role of POM in prostate health and prostate cancer." (PX0161—0003).

747. To form his opinion, Dr. deKernion reviewed the expert reports of Dr. Eastham and Dr. Miller, the FTC depositions of Dr. Pantuck and Dr. Carducci, protocols for the Pantuck Phase II Prostate Cancer Study (2006), the Carducci Dose Study, and the Pantuck Phase III Study (*see* CCFF ¶ D.3.1026), articles cited in Dr. Eastham's report, scientific articles found by conducting a literature search, and marketing materials. (PX0351 (deKernion, Dep. at 6-8, 27-29); PX0351a4; PX0351a5). Dr. deKernion did not review the Complaint in this matter. (deKernion, Tr. 3109; PX0351 (deKernion, Dep. at 28)).

Response to Finding No. 747:

Respondents have no specific response other than to note he also relied on his years of practice and research.

d. Burnett

748. Dr. Burnett is a Professor of Urology at Johns Hopkins Medical School, Director of the Basic Science Laboratory in Neurology at the James Buchanan Brady Urological Institute, and Director of the Male Consultation Clinic of the Sexual Medicine Division of Johns Hopkins' Department of Urology. (Burnett, Tr. 2241; PX0149a01-0001). Dr. Burnett has held editor positions on the *Journal of Urology*, *Journal of Sexual Medicine*, *Journal of Andrology*, and *Practical Reviews in Urology*. (Burnett, Tr. 2242). Dr. Burnett has published over 180 peer-reviewed articles and written 40 book chapters. (Burnett, Tr. 2243).

Response to Finding No. 748:

Dr. Burnett is the Patrick C. Walsh Professor of Urology serving on the faculty of the Department of Urology at the Johns Hopkins University School of Medicine/Johns Hopkins Hospital. (PX149-001; Burnett, Tr. 2241). Dr. Burnett obtained his medical degree from the Johns Hopkins University School of Medicine in Baltimore, Maryland and completed his internship, residency and fellowship at the Johns Hopkins Hospital. (PX149-0001; Burnett, Tr. 2240-41). Dr. Burnett holds a faculty appointment in the Cellular and Molecular Medicine Training Program of the Johns Hopkins University School of Medicine and is the Director of the Basic Science Laboratory in Neuro-urology of the James Buchanan Brady Urological Institute and Director of the Male Consultation Clinic/Sexual Medicine Division of the Department of Urology at Johns Hopkins. (PX149-0001; Burnett, Tr. 2241). Dr. Burnett has authored and published over 180

original peer-reviewed articles and 40 book chapters. (PX149-0003). Dr. Burnett has treated between 10,000 and 15,000 patients for erectile dysfunction. (Burnett, Tr. 2244).

Moreover, Dr. Burnett's research on nitric oxide ("NO") is world renowned. (PX149-003). Dr. Burnett's work on nitric oxide and erectile function has continuously been funded by the National Institutes of Health. (PX149-003; Burnett, Tr. 2243). Dr. Burnett's lab was instrumental in describing NO as a physiologic mediator of penile erection and the mechanism of NO-dependent penile erection. (PX149-0005). Their research work established neuronal NO as the physiologic initiator of penile erection and further clarified the molecular mechanisms involved in neurogenic stimulation of the erectile response. (PX149-0005). Dr. Burnett's lab further described blood flow endothelial NO-dependent forces in the penis, which promote and sustain the erectile response, and described the new science of penile erections involving combined roles of neuronal and endothelial NO mechanisms. (PX149-0005). Dr. Burnett's lab also refined the understanding of PDE5 function in the penis, which varies with different medical conditions (diabetes, cardiovascular diseases, aging, cigarette smoking, sickle cell disease) and accordingly accounts in varying ways for erectile dysfunction problems. (PX149-0005). Dr. Burnett's lab also contributed research work that has clarified the interaction between NO and other major opposing regulatory mediators of penile erection including agents that cause penile vasoconstriction (anti-erectile mediators) and oxidative stress factors (reactive oxygen species/molecules that cause tissue damage). (PX149-0005). Complaint Counsel's purported erectile health expert, Arnold Melman, recognizes "[t]hat Dr. Burnett of Johns Hopkins is a man highly respected in his field." (Melman, Tr. 1166).

749. Respondents proffered Dr. Burnett as expert in nitric oxide and erectile function. (PX0149 (Burnett, Report at 0004)).

Response to Finding No. 749:

Based upon his education, training, scientific work, and practice and knowledge in the fields of urology and sexual medicine, including the promotion of erectile health and treatment of erectile dysfunction, Respondents proffered Dr. Burnett as an expert in: (1) the science of nitric oxide biology; (2) the mechanisms by which nitric oxide is formed and acts in penile erection and in the promotion of erectile health, erectile function and treatment of erectile dysfunction; (3) the impact of pomegranate juice and antioxidants and nitric oxide on erectile health, erectile function and erectile dysfunction; and (4) scientific studies involving erectile function and dysfunction. (PX0149-0001-0007; Burnett, Tr. 2243-44, 2249-51, 2255-56, 2270-74; PX0349 (Burnett, Dep. at 23-25, 103, 112, 116-118, 137)).

750. Dr. Burnett was asked to provide opinions regarding pomegranate juice, nitric oxide, and erectile health. (PX0149 (Burnett, Report at 0004-0006)). Dr. Burnett offered no opinions on POMx Pills or Liquid. (PX0349 (Burnett, Dep. at 172)).

Response to Finding No. 750:

Dr. Burnett was asked to provide expert testimony regarding POM's basic science and clinical study, as well as pomegranate juice's effect on the nitric oxide regulatory mechanism, the vascular system/function, and on erectile health, erectile function and erectile dysfunction. (PX0149-0004-0007; PX0349 (Burnett, Dep. at 103, 112, 116-118); Burnett, Tr. 2243-44, 2255-56, 2270-74)

Moreover, Complaint Counsel is incorrect about Dr. Burnett not offering opinions on POMx Pills or POM Liquid. In fact, Dr. Burnett testified that his testimony and opinions regarding pomegranate juice also apply to POMx and POM Liquid. (PX0349 (Burnett, Dep. at 103, 173-174)).

751. To form his opinion, Dr. Burnett reviewed studies on erectile function and nitric oxide, including POM-sponsored studies such as the Forest Erectile Dysfunction Study (2007) and a few *in vitro* and animal studies. (PX0149 (Burnett, Report at 0004)). Burnett

relied upon his "education, experience, and knowledge of developments in the fields of urology and sexual medicine, including the promotion of erectile health and treatment of erectile dysfunction." (PX0149 (Burnett, Report at 0004)).

Response to Finding No. 751:

Respondents have no specific response.

e. Goldstein

752. Dr. Irwin Goldstein is the Director of Sexual Medicine at Alvarado Hospital and a Clinical Professor of Surgery at University of California at San Diego. (Goldstein, Tr. 2590). Dr. Goldstein was a member of the Nutraceutical Committee for the Sexual Medicine Society of North America. The Nutraceutical Committee included physicians from various universities. Through this committee, Dr. Goldstein was an author of two articles: *Prevention and Treatment of Erectile Dysfunction Using Lifestyle Changes and Dietary Supplements: What Works and What Is Worthless, Part I* and *Prevention and Treatment of Erectile Dysfunction Using Lifestyle Changes and Dietary Supplements: What Works and What Is Worthless, Part II*, which were published in 2004 in *Urologic Clinics of North America*. (Goldstein, Tr. 2612-15). Dr. Goldstein was also an author of *Erectile Dysfunction*, which was published in *Clinical Evidence* in 2011. (Goldstein, Tr. 2627).

Response to Finding No. 752:

Dr. Goldstein is a urology sexual medicine physician who has been practicing medicine since 1976 and has been involved in sexual medicine clinical practice, clinical research and basic science research since 1980. (PX0189-0001, 4; PX0352 (Goldstein, Dep. at 14)). "Sexual medicine is a subsection or specialty within the field of medicine that specializes in the study, diagnosis and treatment of men and women with sexual health problems. PX0352 (Goldstein, Dep. at 13-15)). Dr. Goldstein has been certified by the American Board of Urology since 1982. (PX0189-0001). Dr. Goldstein obtained his medical degree in 1975 from McGill University in Montreal, Quebec, Canada, and from 1975-1976, completed an internship at the Royal Victoria Hospital in Montreal, Canada. (PX0149-0001). Dr. Goldstein completed his first year surgical residency and urology residency at the Boston University School of Medicine at University Hospital in Boston. (PX0149-0001). He was Professor of Urology and Professor of Gynecology at the Boston University School of Medicine from 1990-2005 and 2002-2005, respectively.

(PX0149-0001). Dr. Goldstein was Director of the Institute for Sexual Medicine at the Boston University School of Medicine from 2002-2005. (PX0189-0001). He is currently Director of San Diego Sexual Medicine, APC; Director, Sexual Medicine, Alvarado Hospital, San Diego, California; and Clinical Professor of Surgery, University of California, San Diego. (PX0189-001; PX0352 (Goldstein, Dep. at 11)). Dr. Goldstein has published over 250 original peer-reviewed manuscripts in male and female sexual medicine. (PX0189-0002). Dr. Goldstein is currently a member of, and has been involved in, numerous sexual medicine societies including serving as Board Member and Editor-in-Chief of The Journal of Sexual Medicine since 2004, and serving as Editor-in-Chief of The International Journal of Impotence Research from 2002-2003. (PX0189-0002). For 25 consecutive years, Dr. Goldstein has received funding from the NIH to study physiology of erectile function and pathophysiology of erectile dysfunction. (Goldstein, Tr. 2591-92).

Dr. Goldstein also established the first sexual medicine clinic in a Veterans Administration Hospital in the United States. (Goldstein, Tr. 2591). Dr. Goldstein was part of the original advisory board to Pfizer that engaged in a very extensive drug development plan that developed sildenafil (Viagra), and was also on the advisory boards of Bayer and Eli Lilly for the development of vardenafil (Levitra) and tadalafil (Cialis), respectively. (Goldstein, Tr. 2590-91). Complaint Counsel's designated erectile-health expert, Dr. Melman, also recognizes Dr. Goldstein as "highly regarded" in the field. (Melman, Tr. 1166-67).

753. Respondents offered Dr. Goldstein as expert in sexual medicine and the impact of pomegranate juice, antioxidants, and nitric oxide on erectile function and dysfunction. (Goldstein, Tr. 2592.)

Response to Finding No. 753:

Based upon his education, training, scientific work, and practice and knowledge in the fields of urology and sexual medicine, including the promotion of erectile health and treatment of erectile dysfunction, Respondents offered Dr. Goldstein as an expert in: (1) sexual medicine; (2) the study, design, and treatment of men with sexual health problem; (3) the studies that have been done on sexual medicine particularly regarding the promotion of erectile health and treatment of erectile dysfunction; (4) the mechanisms by which nitric oxide is formed and acts in penile erection and in the promotion of erectile health and treatment of erectile dysfunction; (5) urology as it relates to the treatment, prevention, and reduction of risk of erectile dysfunction; (6) the impact of pomegranate juice and antioxidants and nitric oxide on erectile health, erectile function and erectile dysfunction; and (7) scientific testing involving erectile health, erectile function and erectile dysfunction. (PX0352 (Goldstein, Dep. at 19-22, 37-42; PX0189-0003-00015; Goldstein, Tr. 2592, 2600-05, 2611, 2620).

Moreover, Dr. Goldstein's opinions regarding pomegranate juice also apply to POMx and POM Liquid. (PX0352 (Goldstein, Dep. at 19-20)).

754. Dr. Goldstein was asked to "determine whether clinicians who regularly treat men with sexual health concerns would conclude that competent and reliable scientific evidence exists to suggest that the consumption of pomegranate juice promotes erectile health." (PX0189 (Goldstein, Report at 0010); *see also* PX0352 (Goldstein, Dep. at 19)). Dr. Goldstein did not evaluate any pomegranate extract product and did not know whether pomegranate pills were safe for human consumption. (PX0352 (Goldstein, Dep. at 169-70, 173)). Dr. Goldstein assumed that any pomegranate extract or pill were equivalent to POM Juice. (PX0352 (Goldstein, Dep. at 169-70, 173)).

Response to Finding No. 754:

Respondents have no specific response.

755. To form his opinion, Dr. Goldstein reviewed studies on erectile function, nitric oxide, and the Mediterranean diet, including POM-sponsored studies such as the Forest Erectile Dysfunction Study (2007) and several *in vitro* and animal studies. (PX0189 (Goldstein, Report at 0005); PX0352 (Goldstein, Dep. at 125)). Dr. Goldstein relied upon his

"education, experience, and knowledge of developments in the fields of urology and sexual medicine, including the promotion of erectile health and treatment of erectile dysfunction." (PX0189 (Goldstein, Report at 0005)).

Response to Finding No. 755:

Respondents add that Dr. Goldstein also reviewed an article entitled *Recreational Use of Phsphodiesterase Type 5 Inhibitors by Healthy Young Men* (2010) (PX0191) which suggests that 22% of healthy men between the ages of 22 and 30 have used PDE5 inhibitors (such as Viagra, Cialis and Levitra) as a recreational drug to be more sexual confident, have better erection quality and better sexual performance. Dr. Goldstein opined that "such data shows to the medical community who actually treat patients that there is an unmet need for a product, with no known risk factors and suggested scientific evidence, to help the man without erectile dysfunction promote his erectile health." (PX0189-0004-0005). Dr. Goldstein further opined that the "available data suggest that pomegranate juice may meet this need." (PX0189-0004).

f. Miller

756. Dr. Denis Miller is a clinical professor at Robert Wood Johnson School of Medicine. (Miller, Tr. 2189).

Response to Finding No. 756:

Respondents have no specific response.

757. Dr. Miller is an oncologist. He is not a nutritionist or an expert on the role of foods in the prevention and treatment of disease. (Miller, Tr. 2215). Dr. Miller is not an expert in CVD, has never treated patients specifically for CVD, and has never performed a clinical trial specifically on CVD. (Miller, Tr. 2229). Dr. Miller also is not an expert in erectile dysfunction and has never been involved in clinical trials related to erectile dysfunction. (Miller, Tr. 2230).

Response to Finding No. 757:

The proposed factual finding contains several errors. First, as directly stated in the cited testimony, Dr. Miller is a practicing oncologist and hematologist. (Miller, Tr. 2189).

Complaint Counsel deliberately and misleadingly omits Dr. Miller's expertise in hematology, presumably because hematology is so closely related to CVD. Second, Dr. Miller directly testified that he has performed a clinical trial on thalassemia, which is an inherited blood disorder with a cardiac function component. (Miller, Tr. 2229). Dr. Miller further testified that he has been involved in clinical trials looking at the effects of chemotherapy agents on cardiac function. (Miller, Tr. 2229). The remaining statements are not disputed.

758. Dr. Miller states he is an expert in the Food and Drug Administration's ("FDA") post-approval regulatory requirements for drug treatments, and it is part of what qualifies him to offer an opinion on the standard for substantiating claims for POM's products. (Miller, Tr. 2217). However, he is not an expert in the FDA's regulations for dietary supplements, and is not aware of the FDA's regulations governing the standard for making health benefit claims for a food. (Miller, Tr. 2217-18).

Response to Finding No. 758:

Complaint Counsel strangely omits to mention that Dr. Miller testified he is an expert in FDA regulatory approval and in FDA post-approval regulatory requirements for drug treatments. (Miller, Tr. 2216). The proposed finding just states the second, more specialized, category of his regulatory expertise. Apart from that point, Respondents do not dispute the proposed finding.

759. Respondents proffered Dr. Miller to testify about the applicable standards for substantiating evidence for fruit, fruit juice, and food products in general as opposed to the standard that is applicable for drugs. He was asked to testify about the *standard* only, not about the specific scientific studies on POM or whether Respondents' evidence was sufficient to support POM's claims. (Miller, Tr. 2192).

Response to Finding No. 759:

Respondents have no specific response.

760. Dr. Miller stated that he was not testifying about the substantiation standard related to foods and CVD, or foods and erectile dysfunction. (Miller, Tr. 2219). Dr. Miller has not published any articles on diet or foods in the prevention or treatment of cancer. (Miller, Tr. 2215). He has not been involved in the design of clinical trials to prevent cancer in healthy people, and has not done any clinical trials for foods. Rather he has only participated in trials involving drugs or biotechnology products. (Miller, Tr. 2218, 2220).

Response to Finding No. 760:

The proposed finding misleadingly omits to state that Dr. Miller testified that he was testifying about the substantiation standard related to foods and prostate cancer, as well as the general substantiation standard for health claims made in connection with food. (Miller, Tr. 2219). Without that background to explain the significance of distinguishing the other categories it mentions, the proposed finding is biased to the point of incoherence. At a general level, the proposed finding is also unduly fragmentary and partial regarding Dr. Miller's expertise. For example, Dr. Miller has authored or co-authored over 300 book chapters, peer-reviewed articles, and abstracts mostly on cancer and blood disorders. RFF 114. Dr. Miller has designed, managed, and directed many different research studies calculated to develop new anti-cancer agents RFF 113. Because of his expertise, Complaint Counsel have retained Dr. Miller on several matters, and he testified for Complaint Counsel previously in *Daniel Chapter One*. RFF 115.

761. Dr. Miller was fired by the FTC due to his simultaneous work on a nonpublic, FTC matter and his work for Respondents. (Miller, Tr. 2224-26).

Response to Finding No. 761:

Not supported by the cited testimony, which nowhere says why he was fired. (Miller, Tr. 2224-26). Complaint Counsel's questioning implied that a conflict of interest was the reason, but Complaint Counsel presented no testimony or evidence about what the reason actually was. Indeed, Complaint Counsel have retained Dr. Miller on several matters, and he testified for Complaint Counsel previously in *Daniel Chapter One*. RFF 115. The most likely inference from the record is that Complaint Counsel were upset that Dr. Miller's testimony in this action has seriously damaged and undercut the credibility of their position, and terminated him in retaliation. The record presented at the hearing, however, is simply not sufficient to determine the actual reason.

B. Study Designs for Examining the Relationship between Foods and Nutrients

and Disease Outcomes

1. Types of Studies

762. There are four study types for examining the relation between a food or nutrient and a disease outcome: (a) *in vitro* studies; (b) animal studies; (c) human observational studies; and (d) human clinical studies. (CX1293 (Stampfer, Report at 0008)).

Response to Finding No. 762:

While there may be four types of studies, Respondents' experts and Complaint Counsel's experts agree that RCTs are not required, nor even preferred to substantiate the health benefits of 100% natural, safe and healthy foods such as the Challenged Products. (RFF 569-744, 1184-1205, 1784-92, 2122, 2123; PX0149-0006-0007; Burnett, Tr. 2272-74, 2303 (testifying that RCTs are not necessary to deal with studies of drinking pomegranate juice); PX0189-0003, 0014; PX0352 (Goldstein, Dep. at 50-52, 61) (testifying that pharmaceutical type trials should not be applied to nutraceuticals—"a natural food product [from a plant] with health benefits"); Goldstein, Tr. 2600-02, 2611, 2620; deKernion, Tr. 3060 (in the case of fruit juice such as POM Juice, that has low or no toxicity, it is not necessary to have a RCT, placebo-controlled test); Miller, Tr. 2194, 2201; PX0206-0010-0015; Heber, Tr. at 1948-50, 2056, 2166; PX0149-0006-0007; PX0025-0007; Sacks, Tr. 1545-46; PX0361 (Sacks, Dep. at 134-135); Stampfer, Tr. 830; CX1293_0029-0030; RX5007 to RPTB; PX0362 (Stampfer, Dep. at 73-79, 98)).

Complaint Counsel's designated expert on this matter, Professor Stampfer, testified that RCTs are not required to conclude a causal link regarding a nutrient and disease. (RFF 624-644; Stampfer, Tr. 830; PX0362 (Stampfer, Dep. at 73-79, 98)). Professor Stampfer further testified that in a nutritional context, a hypothesis about disease causation can, rarely, if ever, be directly tested in humans using the RCT design. (RFF 640; Stampfer, Tr. 832-33; PX0362 (Stampfer, Dep. at 73, 98); RX5007 to RPTB).

In his expert report, Professor Stampfer also admitted that he "believe[s] that it may be appropriate to use evidence short of randomized clinical trials for crafting public health recommendations regarding nutrient guidelines even when causality cannot be established, because everyone eats and the public should be given advice based on the best evidence available." (RFF 628; CX1293_0029-0030) (emphasis added).

Also, in a recently published article entitled "*Evidence-based criteria in the nutritional context*," Professor Stampfer opined that the general principles of evidence-based nutrition "can provide a sufficient foundation for establishing nutrient requirements and dietary guidelines in the absence of RCTs for every nutrient and food group." (RFF 630; Stampfer, Tr. 831; RX5007 to RPTB) (opining that because RCT study designs may not be "available" (economically or scientifically) for nutrients, "nutrient related decisions could be made at a level of certainty somewhat below that required for drugs.") Professor Stampfer also noted that some of the intellectual fathers of evidence based medicine "stressed" that evidence based medicine was "'not restricted to randomized trials and meta-analyses.'" (RFF 643; RX5007 to RPTB). In the article, Professor Stampfer stated that "certain features of [evidence-based medicine] seem ill-suited to the nutrition context." (RFF 631; RX5007 to RPTB). He also opined that "to fail to act in the absence of conclusive RCT evidence increases the risk of forgoing benefits that might have been achieved with little risk and at low cost." (RFF 644; RX5007 to RPTB).

Professor Stampfer noted that some of the differences between the evaluation of drugs and nutrients are:

> "(i) medical interventions are designed to cure a disease not produced by their absence, while nutrients prevent dysfunction that would result from their inadequate intake; (ii) it is usually not plausible to summon clinical equipoise for basic nutrient effects, thus creating ethical impediments to many trials; (iii) drug effects are generally intended to be large with limited scope of action, while nutrient effects are

> typically polyvalent in scope and, in effect size, are typically within the "noise" range of biological variability; (iv) drug effects are tend to be monotonic, with response varying in proportion to dose, while nutrient effects are often of a sigmoid character, with useful response occurring only across a portion of the intake range; (v) drug effects can be tested against a non-exposed (placebo) contrast group, whereas it is impossible and/or unethical to attempt a zero intake group for nutrients; and (vi) therapeutic drugs are intended to be efficacious within a relatively short term while the impact of nutrients on the reduction of risk of chronic disease may require decades to demonstrate – a difference with significant implications for the feasibility of conducting pertinent RCTs."

(RFF 634; RX5007 to RPTB; PX0362 (Stampfer, Dep. at 78)) (emphasis added).

Additionally, Complaint Counsel's expert, Dr. Sacks, concedes that a causal influence can be demonstrated between an agent and its effect on humans without the use of RCTs. (RFF 647; PX0361 (Sacks, Dep. at 134-135)). Dr. Sacks testified that you do not need RCT trials to test the benefit of food categories that are included in a diet already tested, like the DASH diet, which includes pomegranates. (RFF 648; Sacks, Tr. 1545-46). Dr. Ornish noted that most of Dr. Sacks' published studies have been epidemiological and observational in nature, rather than RCTs, and include relatively small numbers of patients. (RFF 1186; PX0025-0007).

Respondents' expert, Dr. Miller, confirms that when a food product is safe, and where the claim or advertisement does not suggest that the product be used as a substitute for conventional medical care or treatment, then it is appropriate to look at the totality of the science (and in some cases, only basic science), and not require only RCTs, to substantiate health benefit claims. (RFF 657-744; Miller, Tr. 2194, 2201; PX0206-0010-0015; Heber, Tr. at 1948-50, 2056, 2166; PX0149-0006-0007; Burnett, Tr. 2272-74, 2303; PX0189-0003; Goldstein, Tr. 2600-02, 2611, 2620); deKernion, Tr. 3060; PX0025-0007). Dr. Miller testified that if a fruit juice were claiming to prevent prostate cancer

and there was reliable scientific data to support that you could make that claim without a RCT. (RFF 1878; Miller, Tr. 2201).

Similarly, Dr. Heber testified that most experts in the field of nutrition consider competent and reliable science to support health benefit claims for pomegranate juice based upon the totality of evidence, which does not necessarily include RCTs. (RFF 652; Heber, Tr. 1948-49, 2166, 2182).

Moreover, Respondents' prostate expert, Dr. deKernion, testified that in the case of fruit juice such as POM Juice, that has low or no toxicity, it is not necessary to have a RCT, placebo-controlled test. (RFF 1784; deKernion, Tr. 3060).

Respondents' erectile and nitric oxide experts, Drs. Goldstein and Burnett, also testified that urologist who treat men with erectile health concerns would not require that pomegranate juice be subjected to RCTs before concluding that pomegranate juice has a beneficial effect on preserving erectile function and erectile dysfunction. (RFF 650-651; 2122, 2123, 2164; PX0149-0006-0007; Burnett, Tr. 2272-74, 2303 (testifying that RCTs are not necessary to deal with studies of drinking pomegranate juice); PX0189-0003, 0014; PX0352 (Goldstein, Dep. at 50-52, 61) (testifying that pharmaceutical type trials should not be applied to nutraceuticals—"a natural food product [from a plant] with health benefits"); Goldstein, Tr. 2600-02, 2611, 2620).

Furthermore, Respondents cardio expert, Dr. Ornish, opined in his expert report that "it is an extreme position to state that the therapeutic efficacy of a fruit juice or extract of pomegranate juice should be held to the same standard of evidence as a new drug." (RFF 1192; PX0025-0008). Dr. Ornish opined that the study of pomegranates or pomegranate juice is different than studying a new drug, in which harmful side-effects, both short-term and long-term, are the rule rather than the exception. (RFF 1195; PX0025-0008). Dr. Ornish opined that he is "not aware of any studies showing any harmful effects of

consuming pomegranates or pomegranate juice." (RFF 1194; PX0025-0008). Dr. Ornish testified that a new drug needs to be held to a higher standard than a juice that has been around for thousands of years. (RFF 1196; Ornish, Tr. 2340). Dr. Ornish noted that RCTs, even when conducted perfectly, do not control for all sources of bias and may inject new ones unique to RCTs. (RFF 1190; PX0025-0008). Rather, Dr. Ornish noted that a more thoughtful way of analyzing therapeutic efficacy is to carefully examine the totality of scientific evidence, including but not limited to RCTs that are perfectly conducted. (RFF 1191; PX0025-0008).

In fact, much of what physicians provide patients in their clinical practices has not been proven to be beneficial in RCTs. (RFF 745-751; PX0025-0007; Sacks, Tr. 1559; PX0361 (Sacks Dep. at 111); CX1341 (Pantuck, Dep. at 276-277)). For example, Complaint Counsel's own expert, Dr. Eastham, admitted he has performed over 200 radical prostatectomies per year for a number of years before there were any RCTs showing that it worked. (RFF 746; Eastham Tr. 1331-32; PX0358 (Eastham, Dep. at 154-155)). Dr. Eastham performed these radical operations without RCTs despite the fact that the side-effects of this operation are significant and include impotence, incontinence, bleeding, embolisms, infection plus risks of general anesthetic. (RFF 747; Eastham, Tr. 1331-32). Also, Dr. Pantuck stated that clinicians remove kidneys without a RCT showing the benefits of nephrectomy. (RFF 748; CX1341 (Pantuck, Dep. at 276-277)).

Dr. Ornish also noted that randomized controlled trials have shown that angioplasties and stents do not prevent heart attacks or prolong life, yet the number of these procedures performed is greater than ever. (RFF 749; PX0025-0007). Dr. Miller indicated that although health professionals, third party insurance carriers, and health related agencies highly recommend that eating 5 portions of fresh fruits and vegetables may prevent cancer, it is accepted without requiring controlled non-clinical or clinical trials. (RFF 750; PX0206-0012-0013).

Further, Complaint Counsel's experts, Professor Stampfer and Dr. Sacks, admitted that they have made public health recommendations that were not supported by RCTs. (RFF 751; Stampfer, Tr. at 810, 813-14; PX0300 (Stampfer, Dep. at 173); PX0361 (Sacks, Dep. at 35-38, 130-131)).

b. *In vitro* Studies

763. *In vitro* studies are those where blood elements or cells are removed from the body and tested in a controlled laboratory environment, such as a test tube. (CX1293 (Stampfer, Report at 0008); CX1291 (Sacks, Report at 0015-16); *see* Melman, Tr. 1112)). They are used to identify potential biologic mechanisms and generate hypotheses for studies in humans. (CX1293 (Stampfer, Report at 0008); CX1291 (Sacks, Report at 0015-16)). Human metabolism and disease processes are very complicated and cannot be replicated in a petri dish, and therefore, many *in vitro* studies produce results cannot be replicated in humans. (CX1291 (Sacks, Report at 0015); Sacks, Tr. 1450; *see also* Stampfer, Tr. 725-26 (cannot assume *in vitro* results will be repeated in humans); deKernion, Tr. 3063-64 (even strong *in vitro* evidence does not prove an agent works in humans)).

Response to Finding No. 763:

Complaint Counsel's proposed finding is conclusory. While Complaint Counsel's expert, Professor Stampfer, is correct in opining that "it is possible that the results of [*in vitro*] studies do not correspond to what would occur in humans," (CX1293_0008), in some instances, however, basic science is enough to provide sufficient substantiation for a beneficial effect in humans. (RFF 569-582, 618-656, 1784-1792, 2122, 2123; PX0206-0010-0011, 0013; Miller Tr. 2194; Heber, Tr. 2086, 2149, 2182; CX1352 (Heber, Dep. at 243); PX192-0011,0037,0038,0047-0055; Burnett, Tr. 2255; PX0349 (Burnett, Dep. at 103, 116-118); PX0149-0006-0007).

Dr. Burnett, Respondents erectile and nitric oxide expert, testified, for example, that POM's basic science alone "support[s] the potential benefit at the human level to improve the physiology of erectile tissue preserving erect tissue health." (RFF 2103-06; PX0149-0003,0005; PX0349 (Burnett, Dep. at 103, 112, 116-118)). Dr Burnett also opined in his expert report that "basic scientific evidence exists that establishes that pomegranate juice possesses potent anti-oxidative molecular effects and these effects

operate by activating endothelial NO mechanisms in vasculature [structures involved in human penile erection]." (RFF 2093; PX0149-0005-0006). Dr. Burnett also testified that POM's basic science alone:

> "provide powerful support for pomegranate juice. . . as antioxidants; that they work with very potent effects on the nitric oxide regulatory mechanism; that there's evidence that they do demonstrate antioxidant effects on genes that have to do with the oxidative stress mechanisms and the nitric oxide release mechanisms; that there is evidence that these agents do reduce some of the pathophysiologic effects at the tissue level including structural changes on the tissue in terms of atherosclerosis, that is, hardening of vessels that leads to the functional changes where the tissue is not able to properly relax and is consistent with how the blood vessels have to dilate and allow blood flow to occur within target organs."

(PX0349 (Burnett, Dep. at 116)).

Dr. Burnett further testified that he believes pomegranate juice has a "potential benefit on the basis of animal studies or *in vitro* studies to likely improve one's erection physiology," not just maintain it. (Burnett, Tr., 2262-63) (emphasis added). To that end, Dr. Burnett testified that which helps erectile function may also help improve one's erectile dysfunction. (Burnett, Tr., 2303).

Similarly, Dr. Goldstein also testified that "pomegranate juice has excellent basic science both in animal tissue and human tissue and excellent animal model data." (PX0352 (Goldstein, Dep. at 51)). Dr. Goldstein opined that POM's "strong *in vitro* and *in vivo* studies . . . suggest a probable benefit of pomegranate juice on erectile health," and that "in and of itself has shown huge pieces of information that will be helpful in understanding how it works in humans . . . ." (PX0189-0013; Goldstein, Tr. 2642 ("[I]n general, in the field of erectile function and dysfunction, preclinical studies have managed to mimic how agents work in a human being.") Moreover, Dr. Goldstein

opined that the large body of basic science supports the mechanism by which consuming pomegranate juice promotes erectile health—*i.e.*, "through the data that pomegranate juice possesses antioxidant properties, antioxidants help maintain endothelial health, endothelial health is strongly associated with erectile health, and therefore, pomegranate juice helps to maintain erectile health." (PX0189-0003, 0008-0009; PX0190-0006).

Additionally, Dr. Heber testified "that the scientific community believes that the research done by Dr. Ornish and Dr. Aviram and Dr. Davidson on the basis of the basic science does provide a significant scientific agreement" that pomegranate helps to reduce the risk of heart disease. (RFF 582; Heber, Tr. 2081).

Moreover, Complaint Counsel's cardio expert, Dr. Sacks, testified that *in vitro* studies can be competent and reliable evidence of an agent's effect on a particular mechanism. (RFF 576; Sacks, Tr. 1578; PX0361 (Sacks, Dep. at 123-124)).

Furthermore, Respondents' cardio expert, Dr. Ornish, opined that it is an extreme position to state that evidence from *in vitro* and animal studies should not be considered in determining the therapeutic value of an intervention. (RFF 574; PX0025-0007). He further opined that while there are limitations to extrapolating from *in vitro* and animal studies to human studies, it is false to say this research has no value in determining therapeutic efficacy. (RFF 575; PX0025-0007).

c. Animal Studies

764. Animal studies are tools for identifying potential treatments, mechanisms, and side effects. (CX1291 (Sacks, Report at 0016)). Animals are not the same as humans, either biologically or psychologically, and therefore, many findings of dietary or drug effects in animals are not confirmed in human testing. (CX1291 (Sacks, Report at 0016); Sacks, Tr. 1451; Melman, Tr. 1112-13; CX1289 (Melman, Report at 0011); *see* PX0355 (Ornish, Dep. at 66) (animal physiology is similar but not identical to humans)). Thus, animal studies alone are not sufficient to show that a tested product will prevent or treat human disease. (Sacks, Tr. 1451-52; Melman, Tr. 1112-13; CX1289 (Melman, Report at 0011); PX0352 (Goldstein, Dep. at 124) ("you have to study humans to make statements about humans"); Goldstein, Tr. at 2644; PX0349 (Burnett, Dep. at 57, 112-13) (stating that he would have concerns with animal studies being the sole basis to establish a product as a treatment for erectile dysfunction)).

Response to Finding No. 764:

Respondents object to any suggestion that scientific animal studies involving nutraceuticals (a naturally occurring botanical product (from a plant) with health-promoting characteristics) are not compelling or do not demonstrate a probable benefit in humans. (RFF 569-582, 618-656, 1184-1205, 1784-1792, 2122, 2123; PX0206-0010-0011, 0013; Miller Tr. 2194; Heber, Tr. 2086, 2149, 2182; CX1352 (Heber, Dep. at 243); PX192-0011,0037,0038,0047-0055; Burnett, Tr. 2255; PX0349 (Burnett, Dep. at 103, 116-118); PX0149-0006-0007).

Rather, animal studies are very informative as it can characterize what's going on at the human level, and provide for some clinical insights. (RFF 570; PX0349 (Burnett, Dep. at 111); PX0352 (Goldstein, Dep. at 122-124); Goldstein, Tr. 2644; Heber, Tr. 2086, 2149; CX1352 (Heber, Dep. at 243); Heber, Tr. 2086; 2149, 2182; CX1352 (Heber, Dep. at 243); PX192-0011,0037,0038,0047-0055). In an animal study, researchers can isolate mechanisms of action and accomplish toxicity or safety testing, as well as examine specific mechanisms by taking out their organs and cells, which you cannot do in humans. (RFF 577-578; PX0361 (Sacks, Dep. at 89-91). Results from such animal studies have potential for benefit of therapy at the human level. (RFF 571-572; PX0206-0010-0011, 0013; Miller Tr. 2194; PX0349 (Burnett, Dep. at 112); Burnett, Tr. 2262-63; Heber, Tr. 2086, 2149; CX1352 (Heber, Dep. at 243); Heber, Tr. 2086; 2149, 2182; CX1352 (Heber, Dep. at 243); PX192-0011,0037,0038,0047-0055).

Respondents' cardio expert, Dr. Ornish, opined that it is an extreme position to state that evidence from *in vitro* and animal studies should not be considered in determining the therapeutic value of an intervention. (RFF 574; PX0025-0007). He further opined that while there are limitations to extrapolating from *in vitro* and animal studies to human

studies, it is false to say this research has no value in determining therapeutic efficacy. (RFF 575; PX0025-0007).

Respondents' expert, Dr. Burnett testified for example that "there are interventions that [he would] think have some potential benefit on the basis of animal studies. . . ." (Burnett, Tr. 2262-63). In fact, Dr. Burnett testified that POM's basic science alone "support[s] the potential benefit at the human level to improve the physiology of erectile tissue preserving erect tissue health." (RFF 2103-06; PX0149-0003,0005; PX0349 (Burnett, Dep. at 103, 112, 116-118)). Dr Burnett also opined in his expert report that "basic scientific evidence exists that establishes that pomegranate juice possesses potent anti-oxidative molecular effects and these effects operate by activating endothelial NO mechanisms in vasculature [structures involved in human penile erection]." (RFF 2093; PX0149-0005-0006). Moreover, Dr. Burnett testified that "animal studies are very informative to the extent that some of the basic physiology is there . . . [and it] can characterize what's going on at the human level." (PX0349 (Burnett, Dep. at 111)). Dr. Burnett also testified that POM's basic science alone:

> "provide powerful support for pomegranate juice. . . as antioxidants; that they work with very potent effects on the nitric oxide regulatory mechanism; that there's evidence that they do demonstrate antioxidant effects on genes that have to do with the oxidative stress mechanisms and the nitric oxide release mechanisms; that there is evidence that these agents do reduce some of the pathophysiologic effects at the tissue level including structural changes on the tissue in terms of atherosclerosis, that is, hardening of vessels that leads to the functional changes where the tissue is not able to properly relax and is consistent with how the blood vessels have to dilate and allow blood flow to occur within target organs."

(PX0349 (Burnett, Dep. at 116)).

Dr. Burnett further testified that he believes pomegranate juice has a "potential benefit on the basis of animal studies to likely improve one's erection physiology," not just maintain it. (Burnett, Tr., 2262-63) (emphasis added). To that end, Dr. Burnett testified that which helps erectile function may also help improve one's erectile dysfunction. (Burnett, Tr., 2303).

Similarly, Dr. Goldstein opined that POM's "strong *in vitro* and *in vivo* studies . . . suggest a probable benefit of pomegranate juice on erectile health," and that "in and of itself has shown huge pieces of information that will be helpful in understanding how it works in humans . . . ." (PX0189-0013; Goldstein, Tr. 2642 ("[I]n general, in the field of erectile function and dysfunction, preclinical studies have managed to mimic how agents work in a human being.") Moreover, Dr. Goldstein opined that the large body of basic science supports the mechanism by which consuming pomegranate juice promotes erectile health—*i.e.*, "through the data that pomegranate juice possesses antioxidant properties, antioxidants help maintain endothelial health, endothelial health is strongly associated with erectile health, and therefore, pomegranate juice helps to maintain erectile health." (PX0189-0003, 0008-0009; PX0190-0006).

Additionally, Respondents prostate expert, Dr. deKernion, testified that the *in vitro* and animal studies alone showed that pomegranate juice inhibited the growth of prostate cancer cells and actually killed them. (RFF 580; deKernion, Tr. 3044-45, 3120). Dr. Heber testified "that the scientific community believes that the research done by Dr. Ornish and Dr. Aviram and Dr. Davidson on the basis of the basic science does provide a significant scientific agreement" that pomegranate helps to reduce the risk of heart disease. (RFF 582; Heber, Tr. 2081).

Moreover, Complaint Counsel's experts agree with this position. with this position. Dr. Sacks, Complaint Counsel's cardio expert, testified that he considers all levels of science

in issuing national guidelines for the prevention or treatment of cardiovascular disease. (PX0361 (Sacks Dep. at 71)). Similarly, Complaint Counsel's erectile expert, Dr. Melman, testified that based on the results of his gene therapy erectile dysfunction product in an animal model, he was "personally satisfied" that it would also work in humans. (PX0360 (Melman, Dep. at 56-57)).

d. Human Observational Studies

765. Human observational studies are large human studies that compare intake of various levels of nutrients (for example, low vitamin C versus high vitamin C) with various endpoints, such as disease outcomes, over time. (CX1293 (Stampfer Report at 0008); Stampfer, Tr. 719; *see* Heber, Tr. 2168 (observational studies are population studies that compare intake of different nutrients and endpoints over time)). They can support a conclusion that there is an association between a nutrient and a disease of interest, but generally do not prove causation, due to the potential, even in well-designed studies, for unidentified biases or inadequately controlled confounding factors. (CX1293 (Stampfer, Report at 0008-09); Stampfer, Tr. 720-21; *see* Sacks, Tr. 1418-19 (cannot prove a causal effect between an intervention and reduction of heart disease from observational research)).

Response to Finding No. 765:

Respondents have no specific response.

766. In any event, there is no observational study evidence on pomegranates, pomegranate juice, or pomegranate extract. (Heber, Tr. 2168; Stampfer, Tr. 722).

Response to Finding No. 766:

Respondents have no specific response.

e. Human Clinical Studies

767. Human clinical studies are those in which investigators assign the exposure level to participants -- meaning that the investigators tell the subjects how much of a particular nutrient to consume, in contrast to observational studies, where the investigators study existing exposure levels within a particular population. (CX1293 (Stampfer, Report at 0009)).

Response to Finding No. 767:

Respondents have no specific response.

768. There is a typical progression in human clinical studies, from exploratory research to RCTs (randomized clinical trials). (PX0025 (Ornish, Report at 0010, 0024) ("Science usually progresses when someone publishes a study of a series of patients with a nonrandomized control group that shows an unprecedented finding which is then replicated by one or more subsequent randomized controlled trials[;]" "[t]here is a logical progression in science which often begins with a pilot study that has no control group")).

Response to Finding No. 768:

Respondents dispute that safe and healthy 100% pure and natural fruit juices need to be subjected to the standards of safety and efficacy traditionally required by the FDA for approval of a pharmaceutical drug (*i.e.*, RCTs) before concluding that it has a beneficial effect in humans. (RFF 569-582, 618-656, 1184-1205, 1784-1792, 2122, 2123; PX0149-0006-0007; Burnett, Tr. 2272-74, 2303 (testifying that RCTs are not necessary to deal with studies of drinking pomegranate juice); PX0189-0003, 0014; PX0352 (Goldstein, Dep. at 50-52, 61) (testifying that pharmaceutical type trials should not be applied to nutraceuticals—"a natural food product [from a plant] with health benefits"); Goldstein, Tr. 2600-02, 2611, 2620; deKernion, Tr. 3060 (in the case of fruit juice such as POM Juice, that has low or no toxicity, it is not necessary to have a RCT, placebo-controlled test); Miller, Tr. 2194, 2201; PX0206-0010-0015; Heber, Tr. at 1948-50, 2056, 2166; PX0149-0006-0007; PX0025-0007). In fact, a RCT is almost unheard of in the food industry. (RFF 621; CX1338 (Padma-Nathan, Dep. at 196); Goldstein, Tr. 2601-02, 2613-14). Complaint Counsel have also admitted in discovery responses that scientific research undertaken without the purpose or goal of obtaining drug approval from the FDA can be used to substantiate health benefit claims. (RFF 623; PX0268-0016).

Indeed, Complaint Counsel's own expert, Professor Stampfer, testified that RCTS are not required to conclude a causal link regarding a nutrient and disease. (RFF 624-627; Stampfer, Tr. 830; PX0362 (Stampfer, Dep. at 73-79, 98)). Professor Stampfer further testified that in a nutritional context, a hypothesis about disease causation can, rarely, if

ever, be directly tested in humans using the RCT design. (RFF 640; Stampfer, Tr. 832-33; PX0362 (Stampfer, Dep. at 73, 98); RX5007 to RPTB).

Moreover, in his expert report, Professor Stampfer admitted that he "believe[s] that it may be appropriate to use evidence short of randomized clinical trials for crafting public health recommendations regarding nutrient guidelines even when causality cannot be established, because everyone eats and the public should be given advice based on the best evidence available." (RFF 628; CX1293_0029-0030).

Also, in a recently published article entitled "*Evidence-based criteria in the nutritional context*," Professor Stampfer opined that the general principles of evidence-based nutrition "can provide a sufficient foundation for establishing nutrient requirements and dietary guidelines in the absence of RCTs for every nutrient and food group." (RFF 630; Stampfer, Tr. 831; RX5007 to RPTB) (He opined that because RCT study designs may not be "available" (economically or scientifically) for nutrients, "nutrient related decisions could be made at a level of certainty somewhat below that required for drugs.") Professor Stampfer also noted that some of the intellectual fathers of evidence based medicine "stressed" that evidence based medicine was "'not restricted to randomized trials and meta-analyses.'" (RFF 643 RX5007 to RPTB). In the article, Professor Stampfer stated that "certain features of [evidence-based medicine] seem ill-suited to the nutrition context." (RFF 63; RX5007 to RPTB).

Professor Stampfer noted that some of the differences between the evaluation of drugs and nutrients are:

> "(i) medical interventions are designed to cure a disease not produced by their absence, while nutrients prevent dysfunction that would result from their inadequate intake; (ii) it is usually not plausible to summon clinical equipoise for basic nutrient effects, thus creating ethical impediments to many trials; (iii) drug effects are generally intended to be

> large with limited scope of action, while nutrient effects are typically polyvalent in scope and, in effect size, are typically within the "noise" range of biological variability; (iv) drug effects are tend to be monotonic, with response varying in proportion to dose, while nutrient effects are often of a sigmoid character, with useful response occurring only across a portion of the intake range; (v) drug effects can be tested against a non-exposed (placebo) contrast group, whereas it is impossible and/or unethical to attempt a zero intake group for nutrients; and (vi) therapeutic drugs are intended to be efficacious within a relatively short term while the impact of nutrients on the reduction of risk of chronic disease may require decades to demonstrate – a difference with significant implications for the feasibility of conducting pertinent RCTs."

(RFF 6345; RX5007 to RPTB; PX0362 (Stampfer, Dep. at 78)). Moreover, in the article, Professor Stampfer stated that "to fail to act in the absence of conclusive RCT evidence increases the risk of forgoing benefits that might have been achieved with little risk and at low cost." (RFF 644; RX5007 to RPTB).

Dr. Heber agrees with Professor Stampfer, that in dealing with nutrients, RCTs are often infeasible and too expensive and that the drug standard should not be applied. (RFF 646; Heber, Tr. 1950; RX5007 to RPTB). Dr. Heber also testified that most experts in the field of nutrition believe that RCTs have some significant drawbacks when it comes to the study of nutrient substances like pomegranates. (RFF 653; Heber, Tr. 1948-49).

Additionally, Complaint Counsel's expert, Dr. Sacks, concedes that a causal influence can be demonstrated between an agent and its effect on humans without the use of RCTs. (RFF 647; PX0361 (Sacks, Dep. at 134-135)). Dr. Sacks testified that you don't need RCT trials to test the benefit of food categories that are included in a diet already tested, like the DASH diet, which includes pomegranates. (RFF 648; Sacks, Tr. 1545-46).

Moreover, urologists who treat men with erectile health concerns would not require that pomegranate juice be subjected to RCTs before concluding that pomegranate juice has a

beneficial effect on preserving erectile function and erectile dysfunction. (RFF 650-651; PX0149-0006-0007; Burnett, Tr. 2272-74, 2303; PX0189-0003; Goldstein, Tr. 2600-02, 2611, 2620).

Respondents' expert, Dr. Miller, confirms that when a food product is safe, and where the claim or advertisement does not suggest that the product be used as a substitute for conventional medical care or treatment, then it is appropriate to look at the totality of the science (and in some cases, only basic science), and not require only RCTs, to substantiate health benefit claims. (RFF 657-744; Miller, Tr. 2194, 2201; PX0206-0010-0015; Heber, Tr. at 1948-50, 2056, 2166; PX0149-0006-0007; Burnett, Tr. 2272-74, 2303; PX0189-0003; Goldstein, Tr. 2600-02, 2611, 2620); deKernion, Tr. 3060; PX0025-0007).

769. Some researchers describe the progression of research in terms of "phases," where a: Phase I trial tests a treatments in a small number of patients to find a safe dose (CX1287 (Eastham, Report at 0009); Phase II trial tests the intervention in a larger number of people to identify specific effects (CX1341 (Pantuck, Dep. at 28-29)); Phase III trials test the treatment in a larger number of people, to compare it to "standard treatment;" and Phase IV trial tests a treatment in several hundred to thousands of people to assess long-term safety and effectiveness. (CX1287 (Eastham, Report at 0009); *see also* Burnett, Tr. 2262 (equating RCTs with Phase III trials)).

Response to Finding No. 769:

While there may be "phases" for pharmaceutical drugs, Respondents dispute that nutraceuticals, such as a safe and healthy fruit juice, need to be subjected to the standards of safety and efficacy traditionally required by the FDA for approval of a pharmaceutical drug (*i.e.*, RCTs) before concluding that it has a beneficial effect in humans. (RFF 569-744, 1184-1205, 1784-92, 2122, 2123; PX0149-0006-0007; Burnett, Tr. 2272-74, 2303 (testifying that RCTs are not necessary to deal with studies of drinking pomegranate juice); PX0189-0003, 0014; PX0352 (Goldstein, Dep. at 50-52, 61) (testifying that pharmaceutical type trials should not be applied to nutraceuticals—"a natural food product [from a plant] with health benefits"); Goldstein, Tr. 2600-02, 2611, 2620;

deKernion, Tr. 3060 (in the case of fruit juice such as POM Juice, that has low or no toxicity, it is not necessary to have a RCT, placebo-controlled test); Miller, Tr. 2194, 2201; PX0206-0010-0015; Heber, Tr. at 1948-50, 2056, 2166; PX0149-0006-0007; PX0025-0007; Sacks, Tr. 1545-46; PX0361 (Sacks, Dep. at 134-135); Stampfer, Tr. 830; CX1293_0029-0030; RX5007 to RPTB; PX0362 (Stampfer, Dep. at 73-79, 98)).

Complaint Counsel's designated expert on this matter, Professor Stampfer, testified that RCTs are not required to conclude a causal link regarding a nutrient and disease. (RFF 624-644; Stampfer, Tr. 830; PX0362 (Stampfer, Dep. at 73-79, 98)). Professor Stampfer further testified that in a nutritional context, a hypothesis about disease causation can, rarely, if ever, be directly tested in humans using the RCT design. (RFF 640; Stampfer, Tr. 832-33; PX0362 (Stampfer, Dep. at 73, 98); RX5007 to RPTB).

In his expert report, Professor Stampfer also admitted that he "believe[s] that it may be appropriate to use evidence short of randomized clinical trials for crafting public health recommendations regarding nutrient guidelines even when causality cannot be established, <u>because everyone eats and the public should be given advice based on the best evidence available</u>." (RFF 628; CX1293_0029-0030) (emphasis added).

Also, in a recently published article entitled "*Evidence-based criteria in the nutritional context*," Professor Stampfer opined that the general principles of evidence-based nutrition "can provide a sufficient foundation for establishing nutrient requirements and dietary guidelines in the absence of RCTs for every nutrient and food group." (RFF 630; Stampfer, Tr. 831; RX5007 to RPTB) (opining that because RCT study designs may not be "available" (economically or scientifically) for nutrients, "nutrient related decisions could be made at a level of certainty somewhat below that required for drugs.") Professor Stampfer also noted that some of the intellectual fathers of evidence based medicine "stressed" that evidence based medicine was "'not restricted to randomized

trials and meta-analyses.'" (RFF 643; RX5007 to RPTB). In the article, Professor Stampfer stated that "certain features of [evidence-based medicine] seem ill-suited to the nutrition context." (RFF 631; RX5007 to RPTB). He also opined that "to fail to act in the absence of conclusive RCT evidence increases the risk of forgoing benefits that might have been achieved with little risk and at low cost." (RFF 644; RX5007 to RPTB).

Professor Stampfer noted that some of the differences between the evaluation of drugs and nutrients are:

> "(i) medical interventions are designed to cure a disease not produced by their absence, while nutrients prevent dysfunction that would result from their inadequate intake; (ii) it is usually not plausible to summon clinical equipoise for basic nutrient effects, thus creating ethical impediments to many trials; (iii) drug effects are generally intended to be large with limited scope of action, while nutrient effects are typically polyvalent in scope and, in effect size, are typically within the "noise" range of biological variability; (iv) drug effects are tend to be monotonic, with response varying in proportion to dose, while nutrient effects are often of a sigmoid character, with useful response occurring only across a portion of the intake range; (v) drug effects can be tested against a non-exposed (placebo) contrast group, whereas it is impossible and/or unethical to attempt a zero intake group for nutrients; and (vi) therapeutic drugs are intended to be efficacious within a relatively short term while the impact of nutrients on the reduction of risk of chronic disease may require decades to demonstrate – a difference with significant implications for the feasibility of conducting pertinent RCTs."

(RFF 634; RX5007 to RPTB; PX0362 (Stampfer, Dep. at 78)) (emphasis added).

Additionally, Complaint Counsel's expert, Dr. Sacks, concedes that a causal influence can be demonstrated between an agent and its effect on humans without the use of RCTs. (RFF 647; PX0361 (Sacks, Dep. at 134-135)). Dr. Sacks testified that you do not need RCT trials to test the benefit of food categories that are included in a diet already tested,

like the DASH diet, which includes pomegranates. (RFF 648; Sacks, Tr. 1545-46). Dr. Ornish noted that most of Dr. Sacks' published studies have been epidemiological and observational in nature, rather than RCTs, and include relatively small numbers of patients. (RFF 1186; PX0025-0007).

Respondents' expert, Dr. Miller, confirms that when a food product is safe, and where the claim or advertisement does not suggest that the product be used as a substitute for conventional medical care or treatment, then it is appropriate to look at the totality of the science (and in some cases, only basic science), and not require only RCTs, to substantiate health benefit claims. (RFF 657-744; Miller, Tr. 2194, 2201; PX0206-0010-0015; Heber, Tr. at 1948-50, 2056, 2166; PX0149-0006-0007; Burnett, Tr. 2272-74, 2303; PX0189-0003; Goldstein, Tr. 2600-02, 2611, 2620); deKernion, Tr. 3060; PX0025-0007). Dr. Miller testified that if a fruit juice were claiming to prevent prostate cancer and there was reliable scientific data to support that you could make that claim without a RCT. (RFF 1878; Miller, Tr. 2201).

Similarly, Dr. Heber testified that most experts in the field of nutrition consider competent and reliable science to support health benefit claims for pomegranate juice based upon the totality of evidence, which does not necessarily include RCTs. (RFF 652; Heber, Tr. 1948-49, 2166, 2182). Dr. Heber further testified that in dealing with nutrients, RCTs are often infeasible and too expensive and that the drug standard should not be applied. (RFF 646; Heber, Tr. 1950; RX5007 to RPTB).

Moreover, Respondents' prostate expert, Dr. deKernion, testified that in the case of fruit juice such as POM Juice, that has low or no toxicity, it is not necessary to have a RCT, placebo-controlled test. (RFF 1784; deKernion, Tr. 3060).

Respondents' erectile and nitric oxide experts, Drs. Goldstein and Burnett, also testified that urologist who treat men with erectile health concerns would not require that

pomegranate juice be subjected to RCTs before concluding that pomegranate juice has a beneficial effect on preserving erectile function and erectile dysfunction. (RFF 650-651; 2122, 2123, 2164; PX0149-0006-0007; Burnett, Tr. 2272-74, 2303 (testifying that RCTs are not necessary to deal with studies of drinking pomegranate juice); PX0189-0003, 0014; PX0352 (Goldstein, Dep. at 50-52, 61) (testifying that pharmaceutical type trials should not be applied to nutraceuticals—"a natural food product [from a plant] with health benefits"); Goldstein, Tr. 2600-02, 2611, 2620).

Furthermore, Respondents cardio expert, Dr. Ornish, opined in his expert report that "it is an extreme position to state that the therapeutic efficacy of a fruit juice or extract of pomegranate juice should be held to the same standard of evidence as a new drug." (RFF 1192; PX0025-0008). Dr. Ornish opined that the study of pomegranates or pomegranate juice is different than studying a new drug, in which harmful side-effects, both short-term and long-term, are the rule rather than the exception. (RFF 1195; PX0025-0008). Dr. Ornish opined that he is "not aware of any studies showing any harmful effects of consuming pomegranates or pomegranate juice." (RFF 1194; PX0025-0008). Dr. Ornish testified that a new drug needs to be held to a higher standard than a juice that has been around for thousands of years. (RFF 1196; Ornish, Tr. 2340). Dr. Ornish noted that RCTs, even when conducted perfectly, do not control for all sources of bias and may inject new ones unique to RCTs. (RFF 1190; PX0025-0008). Rather, Dr. Ornish noted that a more thoughtful way of analyzing therapeutic efficacy is to carefully examine the totality of scientific evidence, including but not limited to RCTs that are perfectly conducted. (RFF 1191; PX0025-0008).

In fact, much of what physicians provide patients in their clinical practices has not been proven to be beneficial in RCTs. (RFF 745-751; PX0025-0007; Sacks, Tr. 1559; PX0361 (Sacks Dep. at 111); CX1341 (Pantuck, Dep. at 276-277)). For example, Complaint Counsel's own expert, Dr. Eastham, admitted he has performed over 200 radical

prostatectomies per year for a number of years before there were any RCTs showing that it worked. (RFF 746; Eastham Tr. 1331-32; PX0358 (Eastham, Dep. at 154-155)). Dr. Eastham performed these radical operations without RCTs despite the fact that the side-effects of this operation are significant and include impotence, incontinence, bleeding, embolisms, infection plus risks of general anesthetic. (RFF 747; Eastham, Tr. 1331-32). Also, Dr. Pantuck stated that clinicians remove kidneys without a RCT showing the benefits of nephrectomy. (RFF 748; CX1341 (Pantuck, Dep. at 276-277)).

Dr. Ornish also noted that randomized controlled trials have shown that angioplasties and stents do not prevent heart attacks or prolong life, yet the number of these procedures performed is greater than ever. (RFF 749; PX0025-0007). Dr. Miller indicated that although health professionals, third party insurance carriers, and health related agencies highly recommend that eating 5 portions of fresh fruits and vegetables may prevent cancer, it is accepted without requiring controlled non-clinical or clinical trials. (RFF 750; PX0206-0012-0013).

Further, Complaint Counsel's experts, Professor Stampfer and Dr. Sacks, admitted that they have made public health recommendations that were not supported by RCTs. (RFF 751; Stampfer, Tr. at 810, 813-14; PX0300 (Stampfer, Dep. at 173); PX0361 (Sacks, Dep. at 35-38, 130-131)).

770. Typically, researchers conduct pilot or exploratory studies to demonstrate the feasibility of larger studies. Such research can reveal potential changes from an intervention, allows the researchers to see if people can tolerate the intervention or if it causes unexpected side effects, and paves the way for more definitive research. (Stampfer, Tr. 747-48; CX1342 (Hill, Dep. at 45-48 (uncontrolled pilot study allows you to determine how to design a good placebo-controlled trial)).

Response to Finding No. 770:

Complaint Counsel's proposed finding contradicts its proposed finding no. 1064 below, which, correctly states that the purpose of a pilot study is "to investigate whether there is

any evidence of a treatment effect." (CC's Finding No. 1064; *see also* CX1193_0001; Melman, Tr. 1116 (a pilot study is a small or exploratory study)).

Pilot studies are generally considered by other scientists and clinicians in the scientific community to be perfectly valid, accurate, and reliable studies. (RFF 583-598; CX1336 (Davidson, Dep. at 232-233); CX1342 (Hill, Dep. at 48, 49, 53); CX1339 (Ornish, Dep. at 23)). Dr. Aviram considers pilot studies to be positive and disputes that a pilot study cannot be good enough to substantiate a claim. (RFF 1284; CX1348 (Aviram, Dep. at 17)).

A "pilot" study does not mean that it is not as scientifically valid as a larger study. (RFF 1532; PX1339 (Ornish, Dep. at 23; 119-20). A small number of participants do not weaken the importance of the results, especially if they are in agreement with *in vitro*, mechanistical studies and in animal models. (RFF 585; CX1358 (Aviram, Dep. at 18)). In fact, Dr. Heber testified that "sometimes small studies can be more informative than large studies." (RFF 586; Heber, Tr. 1963).

The reason a researcher conducts a "pilot" study is because he or she is not certain how many subjects it will take to adequately power the study. (RFF 1526; CX1342 (Hill, Dep. at 48)). If it turns out that a researcher has adequately powered his or her study, then statistics confirm that it does not matter if it was a "pilot" study. (RFF 1527; CX1342 (Hill, Dep. at 48)). If there is no effect shown, then this allows the investigators to address any concerns regarding the study. (RFF 1528; CX1342 (Hill, Dep. at 46-47)). In short, there is no difference between a pilot study and regular study if there is statistical significance. (RFF 1529; CX1342 (Hill, Dep. at 49)). For example, although the NAD noted "the small size of the test population utilized" in a POM pilot study conducted by Dr. Aviram, it found that it "was satisfied that the study was sufficiently

powered and did not find that the number of participants here rendered the results unreliable." (RFF 584; CX0037_0007).

771. Data from RCTs provide the best evidence of a causal relationship between a nutrient and a disease outcome in humans. (CX1293 (Stampfer, Report at 0009); Stampfer Tr. 716; Goldstein, Tr. 2612-13). A causal link means a cause-and-effect relation, *i.e.*, that the intervention would reliably result in a change and that but for the relationship, the result would not have occurred. (Stampfer, Tr. 716; *see also* RX5007 at 479, 480 (RCTs, if well designed and well executed, provide a high level of certainty that a specific intervention can reliably be counted on to produce a specific effect in a selected population)). For a drug, juice, or lifestyle intervention, when you are trying to determine whether an intervention is *causing* effects, or whether the effects are a coincidence, RCTs are the most rigorous design, because they control for known and unknown sources of bias. (CX1339 (Ornish, Dep. at 19-20)). The elements of RCTs are further discussed below.

Response to Finding No. 771:

While data from RCTs may provide the best evidence of a causal relationship between a treatment and a disease outcome in a pharmaceutical drug, Respondents' experts and Complaint Counsel's experts agree that RCTs are not required, nor even preferred to substantiate the health benefits of 100% natural, safe and healthy foods such as the Challenged Products. (RFF 569-744, 1184-1205, 1784-92, 2122, 2123; PX0149-0006-0007; Burnett, Tr. 2272-74, 2303 (testifying that RCTs are not necessary to deal with studies of drinking pomegranate juice); PX0189-0003, 0014; PX0352 (Goldstein, Dep. at 50-52, 61) (testifying that pharmaceutical type trials should not be applied to nutraceuticals—"a natural food product [from a plant] with health benefits"); Goldstein, Tr. 2600-02, 2611, 2620; deKernion, Tr. 3060 (in the case of fruit juice such as POM Juice, that has low or no toxicity, it is not necessary to have a RCT, placebo-controlled test); Miller, Tr. 2194, 2201; PX0206-0010-0015; Heber, Tr. at 1948-50, 2056, 2166; PX0149-0006-0007; PX0025-0007; Sacks, Tr. 1545-46; PX0361 (Sacks, Dep. at 134-135); Stampfer, Tr. 830; CX1293_0029-0030; RX5007 to RPTB; PX0362 (Stampfer, Dep. at 73-79, 98)).

2. Randomized Clinical Trials ("RCTs")

772. It is standard practice, in human research, to begin with a *protocol*. (Stampfer, Tr. 760; Sacks, Tr. 1436-37; Heber, Tr. 2044-45 (every study he conducts has a protocol)). A protocol describes the key features of a study, such as objectives, methodology, statistical analysis plan, the definition of the *p* value, and primary outcome variables (endpoints). (Sacks, Tr. 1436-37; Stampfer, Tr. 760; *see* Ornish, Tr. 2367 (agreeing that a researcher should determine in advance how many patients will be needed, what the procedures will be, and what kind of analysis to apply and that "you can't just make it up as you go along")). The purpose of identifying the primary outcomes in advance is to prevent a researcher from using positive results and ignoring negative ones, resulting in bias. (Sacks, Tr. 1475; CX1291 (Sacks, Report at 0021)).

Response to Finding No. 772:

Respondents object to this proposed finding to the extent it insinuates that RCTs are required to substantiate the health benefits of 100% natural, safe and healthy foods such as the Challenged Products. (RFF 569-744, 1184-1205, 1784-92, 2122, 2123; RRFF 771; PX0149-0006-0007; Burnett, Tr. 2272-74, 2303 (testifying that RCTs are not necessary to deal with studies of drinking pomegranate juice); PX0189-0003, 0014; PX0352 (Goldstein, Dep. at 50-52, 61) (testifying that pharmaceutical type trials should not be applied to nutraceuticals—"a natural food product [from a plant] with health benefits"); Goldstein, Tr. 2600-02, 2611, 2620; deKernion, Tr. 3060 (in the case of fruit juice such as POM Juice, that has low or no toxicity, it is not necessary to have a RCT, placebo-controlled test); Miller, Tr. 2194, 2201; PX0206-0010-0015; Heber, Tr. at 1948-50, 2056, 2166; PX0149-0006-0007; PX0025-0007; Sacks, Tr. 1545-46; PX0361 (Sacks, Dep. at 134-135); Stampfer, Tr. 830; CX1293_0029-0030; RX5007 to RPTB; PX0362 (Stampfer, Dep. at 73-79, 98)).

773. A *controlled* study is one that includes a group of patients receiving the purported treatment ("treatment" or "active" group) and a control group ("placebo" or "control" group). (CX1291 (Sacks, Report at 0011)). A control group provides a standard by which results observed in the treatment group can be evaluated. (CX1287 (Eastham, Report at 0013)). A control group allows investigators to distinguish between real effects from the intervention, and other changes, including those due to the mere act of being treated ("placebo effect"), the passage of time, change in seasons, other environmental changes, and equipment changes (such as calibration changes). (CX1291 (Sacks, Report at 0011); Burnett, Tr. 2265; Eastham, Tr. 1268 (a placebo arm balances factors that may influence an endpoint); *see* CX1293 (Stampfer, Report at 0009); Ornish, Tr. 2367 (agreeing that you need to control for the power of belief, because that can affect people's

reaction to an intervention)). The control group should be approximately the same size as and meet the same criteria as the treatment group. (Eastham, Tr. 1268-69; CX1287 (Eastham, Report at 0013); CX1291 (Sacks, Report at 0011); Melman, Tr. 1095; CX1289 (Melman, Report at 0009)). It also should receive the same measurements and attention from the researchers as the treatment group. (CX1291 (Sacks, Report at 0011)).

Response to Finding No. 773:

Respondents object to this proposed finding to the extent it insinuates that RCTs are required to substantiate the health benefits of 100% natural, safe and healthy foods such as the Challenged Products. (RFF 569-744, 1184-1205, 1784-92, 2122, 2123; RRFF 771; PX0149-0006-0007; Burnett, Tr. 2272-74, 2303 (testifying that RCTs are not necessary to deal with studies of drinking pomegranate juice); PX0189-0003, 0014; PX0352 (Goldstein, Dep. at 50-52, 61) (testifying that pharmaceutical type trials should not be applied to nutraceuticals—"a natural food product [from a plant] with health benefits"); Goldstein, Tr. 2600-02, 2611, 2620; deKernion, Tr. 3060 (in the case of fruit juice such as POM Juice, that has low or no toxicity, it is not necessary to have a RCT, placebo-controlled test); Miller, Tr. 2194, 2201; PX0206-0010-0015; Heber, Tr. at 1948-50, 2056, 2166; PX0149-0006-0007; PX0025-0007; Sacks, Tr. 1545-46; PX0361 (Sacks, Dep. at 134-135); Stampfer, Tr. 830; CX1293_0029-0030; RX5007 to RPTB; PX0362 (Stampfer, Dep. at 73-79, 98)).

Moreover, Respondents object to this proposed finding to the extent it suggests a "control group" (also known as a "placebo group") is required. (RFF 654, 1540; PX0361 (Sacks, Dep. at 137); CX1342 (Hill, Dep. at 131); PX0025-0024).

According to Dr. Hill, there are two ways to test an intervention. First, in what is called a "pre/post design," the effect of an intervention is measured on a person before and after he/she receives the intervention. In a second design, a control group design, one group would receive the intervention while another group would receive a placebo. The results of both groups would then be compared. (RFF 655, 1533, 1534; CX1342 (Hill, Dep. at

45)). The two approaches are apples and oranges: each provides different information, but both are very fair and reasonable designs, and some questions lend themselves more to a between group analysis, while some lend themselves to a within group analysis. (RFF 1536; CX1342 (Hill, Dep. at 100-101, 133)).

However, no one design is better than the other. (RFF 655, 1533, 1534; CX1342 (Hill, Dep. at 45)). A placebo-controlled trial is more costly and requires a lot more effort to conduct. (RFF 1537; CX1342 (Hill, Dep. at 45)). While there are some advantages to a placebo controlled trial, a pre/post design can be very powerful when you are convinced that you are assessing a steady-state at baseline, and that the differences are attributed to your intervention. (RFF 1539; CX 1342 (Hill, Dep. at 131)).

Dr. Sacks agrees that some studies cannot be conducted with a placebo, *i.e.*, foods and nutrients. (RFF 1248; PX0361 (Sacks, Dep. at 111, 137)). In studying a pharmaceutical drug, RCTs are possible because placebos can be used and subjects, therefore, do not know if they are getting a drug or not. (RFF 1243; Ornish, Tr. 2328; RFF 758; PX0206-0008) (Dr. Miller opined, however, that many cancer agents now used in clinical practice in the US and around the world were approved in open-label randomized controlled trials without a placebo control arm). In studying a fruit or a food, however, it is very hard to do a RCT because the subjects know what they are consuming. (RFF 1244; Ornish, Tr. 2328). In addition, in RCTs involving a food or juice, because the control group often knows the intervention, the subjects could begin taking the food or beverage thereby contaminating the study, such is what occurred with diets during the Women's Health Initiative Study. (RFF 1245; Ornish, Tr. 2328-29).

Dr. Sacks admits that a control group taking nothing can serve as a control. (RFF 1298; Sacks, Tr. 1585-86). Similarly, Dr. Aviram testified that the use of each patient as his or her own control and without a placebo represents another method to conduct an animal or

human study, and is not a less appropriate method. (RFF 1282; CX1348 (Aviram, Dep. at 12-13)).

774. *Randomization* means assigning subjects to the active product group or the control group in a random fashion, whether using a computer program, random number table, or coin toss. (Burnett, Tr. 2264-65; CX1291 (Sacks, Report at 0011); CX1339 (Ornish, Dep. at 20); Eastham, Tr. 1266; Melman, Tr. 1096). It is another way to control for bias. (Eastham, Tr. 1266). It increases the likelihood that the treatment and control groups are similar in relevant characteristics, so that any difference in the outcome between the two groups can be attributed to the treatment. (CX1291 (Sacks, Report at 0011-12); CX1293 (Stampfer, Report at 0009); CX1287 (Eastham, Report at 0012-13); CX1339 (Ornish, Dep. at 20) ("By randomizing people, if there were some unknown factor that was biasing your outcomes, it would be likely to be distributed across both groups")). It also prevents the investigator from deciding who gets which treatment, which can introduce bias into the study. (CX1345 (deGroof, Dep. at 62); Melman, Tr. 1096.

Response to Finding No. 774:

Respondents object to this proposed finding to the extent it insinuates that RCTs are required to substantiate the health benefits of 100% natural, safe and healthy foods such as the Challenged Products. (RFF 569-744, 1184-1205, 1784-92, 2122, 2123; RRFF 771; PX0149-0006-0007; Burnett, Tr. 2272-74, 2303 (testifying that RCTs are not necessary to deal with studies of drinking pomegranate juice); PX0189-0003, 0014; PX0352 (Goldstein, Dep. at 50-52, 61) (testifying that pharmaceutical type trials should not be applied to nutraceuticals—"a natural food product [from a plant] with health benefits"); Goldstein, Tr. 2600-02, 2611, 2620; deKernion, Tr. 3060 (in the case of fruit juice such as POM Juice, that has low or no toxicity, it is not necessary to have a RCT, placebo-controlled test); Miller, Tr. 2194, 2201; PX0206-0010-0015; Heber, Tr. at 1948-50, 2056, 2166; PX0149-0006-0007; PX0025-0007; Sacks, Tr. 1545-46; PX0361 (Sacks, Dep. at 134-135); Stampfer, Tr. 830; CX1293_0029-0030; RX5007 to RPTB; PX0362 (Stampfer, Dep. at 73-79, 98)).

Moreover, Respondents object to this proposed finding to the extent it suggests a control group/placebo group is required. (*See* RRFF 773).

775. A *placebo* is an inactive product or treatment given to the control group, in lieu of the intervention being tested. (Stampfer, Tr. 708; Eastham, Tr. 1267-68 (a placebo is a nonactive product); Melman, Tr. 1094-95 (product that does not contain the drug is given to the control group)). For example, in a study of a pill, the placebo would be a pill that looks like the intervention, but does not contain the active ingredient. (Stampfer, Tr. 708). A placebo should be identical, in all ways possible, to the active treatment. (CX1291 (Sacks, Report at 0011); Melman, Tr. 1095). A double blind study, *see* CCFF ¶ 777, blinds participants and investigators as to whether study participants are in the active or placebo group. (CX1293 (Stampfer, Report at 0009); Melman, Tr. 1095-96).

Response to Finding No. 775:

Respondents object to this proposed finding to the extent it insinuates that RCTs are required to substantiate the health benefits of 100% natural, safe and healthy foods such as the Challenged Products. (RFF 569-744, 1184-1205, 1784-92, 2122, 2123; RRFF 771; PX0149-0006-0007; Burnett, Tr. 2272-74, 2303 (testifying that RCTs are not necessary to deal with studies of drinking pomegranate juice); PX0189-0003, 0014; PX0352 (Goldstein, Dep. at 50-52, 61) (testifying that pharmaceutical type trials should not be applied to nutraceuticals—"a natural food product [from a plant] with health benefits"); Goldstein, Tr. 2600-02, 2611, 2620; deKernion, Tr. 3060 (in the case of fruit juice such as POM Juice, that has low or no toxicity, it is not necessary to have a RCT, placebo-controlled test); Miller, Tr. 2194, 2201; PX0206-0010-0015; Heber, Tr. at 1948-50, 2056, 2166; PX0149-0006-0007; PX0025-0007; Sacks, Tr. 1545-46; PX0361 (Sacks, Dep. at 134-135); Stampfer, Tr. 830; CX1293_0029-0030; RX5007 to RPTB; PX0362 (Stampfer, Dep. at 73-79, 98)).

Moreover, Respondents object to this proposed finding to the extent it suggests a placebo is required. (RFF 654, 1540; RRFF 773; PX0361 (Sacks, Dep. at 137); CX1342 (Hill, Dep. at 131); PX0025-0024). Complaint Counsel's own expert, Dr. Sacks, agrees that some studies cannot be conducted with a placebo, *i.e.*, foods and nutrients, and a study is not thrown out because it does not have a placebo. (RFF 1248; PX0361 (Sacks, Dep. at 111, 137)). In studying a pharmaceutical drug, RCTs are possible because placebos can be used and subjects, therefore, do not know if they are getting a drug or not. (RFF 1243;

Ornish, Tr. 2328; RFF 758; PX0206-0008) (Dr. Miller opined, however, that many cancer agents now used in clinical practice in the US and around the world were approved in open-label randomized controlled trials without a placebo control arm). In studying a fruit or a food, however, it is very hard to do a RCT because the subjects know what they are consuming. (RFF 1244; Ornish, Tr. 2328). In addition, in RCTs involving a food or juice, because the control group often knows the intervention, the subjects could begin taking the food or beverage thereby contaminating the study, such is what occurred with diets during the Women's Health Initiative Study. (RFF 1245; Ornish, Tr. 2328-29).

According to Dr. Hill, there are two ways to test an intervention. First, in what is called a "pre/post design," the effect of an intervention is measured on a person before and after he/she receives the intervention. In a second design, a control group design, one group would receive the intervention while another group would receive a placebo. The results of both groups would then be compared. (RFF 655, 1533, 1534; CX1342 (Hill, Dep. at 45)). The two approaches are apples and oranges: each provides different information, but both are very fair and reasonable designs, and some questions lend themselves more to a between group analysis, while some lend themselves to a within group analysis. (RFF 1536; CX1342 (Hill, Dep. at 100-101, 133)).

However, no one design is better than the other. (RFF 655, 1533, 1534; CX1342 (Hill, Dep. at 45)). A placebo-controlled trial is more costly and requires a lot more effort to conduct. (RFF 1537; CX1342 (Hill, Dep. at 45)). While there are some advantages to a placebo controlled trial, a pre/post design can be very powerful when you are convinced that you are assessing a steady-state at baseline, and that the differences are attributed to your intervention. (RFF 1539; CX 1342 (Hill, Dep. at 131)).

Dr. Sacks admits that a control group taking nothing can serve as a control. (RFF 1298; Sacks, Tr. 1585-86). Similarly, Dr. Aviram testified that the use of each patient as his or

her own control and without a placebo represents another method to conduct an animal or human study, and is not a less appropriate method. (RFF 1282; CX1348 (Aviram, Dep. at 12-13)).

776. It should be noted that, when dealing with diseases for which there is an accepted "standard of care" – that is, a routine medical practice for addressing that disease – and a researcher wants to know whether a new product (or treatment) will produce a *better* result than the standard of care, patients can be given the standard of care product (or treatment), rather than a placebo, to test against the new product or treatment being studied. (Eastham, Tr. 1326, 1350-51).

Response to Finding No. 776:

Respondents object to this proposed finding to the extent it insinuates that RCTs are required to substantiate the health benefits of 100% natural, safe and healthy foods such as the Challenged Products. (RFF 569-744, 1184-1205, 1784-92, 2122, 2123; RRFF 771; PX0149-0006-0007; Burnett, Tr. 2272-74, 2303 (testifying that RCTs are not necessary to deal with studies of drinking pomegranate juice); PX0189-0003, 0014; PX0352 (Goldstein, Dep. at 50-52, 61) (testifying that pharmaceutical type trials should not be applied to nutraceuticals—"a natural food product [from a plant] with health benefits"); Goldstein, Tr. 2600-02, 2611, 2620; deKernion, Tr. 3060 (in the case of fruit juice such as POM Juice, that has low or no toxicity, it is not necessary to have a RCT, placebo-controlled test); Miller, Tr. 2194, 2201; PX0206-0010-0015; Heber, Tr. at 1948-50, 2056, 2166; PX0149-0006-0007; PX0025-0007; Sacks, Tr. 1545-46; PX0361 (Sacks, Dep. at 134-135); Stampfer, Tr. 830; CX1293_0029-0030; RX5007 to RPTB; PX0362 (Stampfer, Dep. at 73-79, 98)).

777. *Blinding* refers to steps taken to ensure that neither the study participants nor the researchers conducting the outcome measurements are aware of whether a patient is in the active group or the control group. (CX1291 (Sacks, Report at 0012); Melman, Tr. 1097). *Double-blinding*, that is, blinding of both the patients and investigators, is optimal to prevent bias arising from actions of the patients or investigators. (CX1293 (Stampfer, Report at 0009); Stampfer Tr. 708-09 (patients aware of group assignment may change their behavior in a way that modifies risk; researchers aware of patient group assignment may introduce subtle biases in terms of interpreting endpoints); Eastham, Tr. 1267 (patients who learn they are on placebo can try other treatments or otherwise alter behavior in a way that may impact study results; physicians aware of patient group

assignment may be influenced in their interpretation of the outcome); Melman, Tr. 1098; CX1287 (Eastham, Report at 0013); *see also* Heber, Tr. 2044 (investigator bias can affect trial results)).

Response to Finding No. 777:

Respondents object to this proposed finding to the extent it insinuates that RCTs are required to substantiate the health benefits of 100% natural, safe and healthy foods such as the Challenged Products. (RFF 569-744, 1184-1205, 1784-92, 2122, 2123; RRFF 771; PX0149-0006-0007; Burnett, Tr. 2272-74, 2303 (testifying that RCTs are not necessary to deal with studies of drinking pomegranate juice); PX0189-0003, 0014; PX0352 (Goldstein, Dep. at 50-52, 61) (testifying that pharmaceutical type trials should not be applied to nutraceuticals—"a natural food product [from a plant] with health benefits"); Goldstein, Tr. 2600-02, 2611, 2620; deKernion, Tr. 3060 (in the case of fruit juice such as POM Juice, that has low or no toxicity, it is not necessary to have a RCT, placebo-controlled test); Miller, Tr. 2194, 2201; PX0206-0010-0015; Heber, Tr. at 1948-50, 2056, 2166; PX0149-0006-0007; PX0025-0007; Sacks, Tr. 1545-46; PX0361 (Sacks, Dep. at 134-135); Stampfer, Tr. 830; CX1293_0029-0030; RX5007 to RPTB; PX0362 (Stampfer, Dep. at 73-79, 98)).

Moreover, while blinding is one component of a good study design, both Respondents' and Complaint Counsel's expert agree that in some instances, the blinding of patients is not possible and if a study becomes unblinded, it can still have value. (RFF 1247; Sacks, Tr. 1435; PX0 361 (Sacks, Dep. at 104-105); RFF 1392; RFF 1390-98; Ornish, Tr. 2345 (Dr. Ornish agrees with Dr. Sacks that the fact that a few participants became unblinded is a "demerit," but this does not affect the outcome of the study); RFF 1828; Eastham, Tr. 1327, 1339 (Dr. Eastham agreed that the Pantuck study as a Phase II study could not be blinded; he also agreed that blinding is not important in such a study).

778. Once a randomized controlled trial is completed and all data collected, data for the control and active treatment groups must be compared through use of appropriate *statistical analyses*. (Eastham, Tr. 1272; CX1287 (Eastham, Report at 0014); CX1291

(Sacks, Report at 0012-13)). Only if the results of the treatment group are *statistically significant* from those of the control group at the end of the trial can it be concluded that the tested product is effective. (CX1291 (Sacks, Report at 0012); Burnett, Tr. 2269). This analysis is called a *between-group analysis*. (CX1291 (Sacks, Report at 0012-13)). A *within-group* analysis, where a researcher compares the treatment group participants' "before" data to their "after" data has much less scientific value, because it relies on the assumption that without the intervention there would have been no change in the study participants' condition; this is not a reasonable assumption because "we know that things change over time all the time." (Stampfer, Tr. 714).

Response to Finding No. 778:

Respondents object to this proposed finding to the extent it insinuates that RCTs are required to substantiate the health benefits of 100% natural, safe and healthy foods such as the Challenged Products. (RFF 569-744, 1184-1205, 1784-92, 2122, 2123; RRFF 771; PX0149-0006-0007; Burnett, Tr. 2272-74, 2303 (testifying that RCTs are not necessary to deal with studies of drinking pomegranate juice); PX0189-0003, 0014; PX0352 (Goldstein, Dep. at 50-52, 61) (testifying that pharmaceutical type trials should not be applied to nutraceuticals—"a natural food product [from a plant] with health benefits"); Goldstein, Tr. 2600-02, 2611, 2620; deKernion, Tr. 3060 (in the case of fruit juice such as POM Juice, that has low or no toxicity, it is not necessary to have a RCT, placebo-controlled test); Miller, Tr. 2194, 2201; PX0206-0010-0015; Heber, Tr. at 1948-50, 2056, 2166; PX0149-0006-0007; PX0025-0007; Sacks, Tr. 1545-46; PX0361 (Sacks, Dep. at 134-135); Stampfer, Tr. 830; CX1293_0029-0030; RX5007 to RPTB; PX0362 (Stampfer, Dep. at 73-79, 98)).

Respondents further dispute this finding as contrary to the evidence in the record. Statistical significance, which is defined as a p-value of 0.05, is an arbitrary convention in the context of studying a whole food, like pomegranate juice. (RFF 599-614, 1252-56, 1984; Ornish, Tr. 2340; Goldstein, Tr. 2598-99) (Dr. Goldstein testified that choosing a significance level is technically an arbitrary task, and "in specific situations a different value could be utilized.") Thus, there is nothing magical about the five percent threshold. (RFF 1254; Ornish, Tr. 2368).

Furthermore, a lack of statistical significance for a positive result is not proof of the opposite. (RFF 604, 611, 614; Sacks, Tr. 1608-09; CX1352 (Heber, Dep. at 218); PX0361 (Sacks, Dep. at 223-224, 230, 238, 243); Goldstein, Tr. 2598-99)). While there is no evidence or argument suggesting that a p-value significantly greater than .05 can show a benefit, there is ample evidence presented that slight variations of this number can still evidence a clinically meaningful benefit that is scientifically supportable. (RFF 435, 606, 2108, 2129-32; PX0352 (Goldstein, Dep. at 108-109); Goldstein, Tr. at 2599; PX0189-0013; PX0349 (Burnett, Dep. at 67, 138-139) ("[a] product could be potentially clinically significant and not meet statistical significance and it still be informative and really valuable to know and worth communicating and potentially having a role for patients out there."); Burnett, Tr. 2270-71; CX1350 (Liker, Dep. at 190-191); PX0361 (Sacks, Dep. at 109); Sacks, Tr. at 1608-09).

For example, although the *Forest/Padma-Nathan RCT Study* achieved a probability value ("p-value") of 0.058 which was a hair above a statistical significance measure of 0.050, Respondents' experts testified there were "significant clinical findings in this study." (RFF 1982, 1986; RRFF 1074; PX0189-0012-0013; PX0149-0006; CX0908; Heber, Tr. 1978-79, 2001; Goldstein, Tr. 2598-99; PX0352 (Goldstein, Dep. at 105-109, 116); Burnett, Tr. 2256; PX0349 (Burnett, Dep. at 138-139); CX1350 (Liker, Dep. at 190-191)).

779. Evaluating data from a clinical trial for *statistical significance* is the standard practice to demonstrate that a study's hypothesis has been proven. (Burnett, Tr. 2269; CX1287 (Eastham, Report at 0014)). *Statistical significance* is recognized as being attained if the statistical test for probability, referred to as the "*p*" value, is less than or equal to 0.05 ($p \leq 0.05$), which means that there is only a 5 percent or less chance that the difference between the treatment and placebo groups is due to chance. (CX1291 (Sacks, Report at 0012); Eastham, Tr. 1273; Ornish, Tr. 2368 (by convention, most people have arbitrarily accepted the 5 percent cut-off as being statistically significant); Melman, Tr. 1102-03; CX1289 (Melman, Report at 0010)). It means that the results demonstrated would occur no more than 1 time out of 20, and therefore, other causes of the result, such as chance, are less likely as an explanation. (Stampfer, Tr. 710-11).

Response to Finding No. 779:

Respondents object to this proposed finding to the extent it insinuates that RCTs are required to substantiate the health benefits of 100% natural, safe and healthy foods such as the Challenged Products. (RFF 569-744, 1184-1205, 1784-92, 2122, 2123; RRFF 771; PX0149-0006-0007; Burnett, Tr. 2272-74, 2303 (testifying that RCTs are not necessary to deal with studies of drinking pomegranate juice); PX0189-0003, 0014; PX0352 (Goldstein, Dep. at 50-52, 61) (testifying that pharmaceutical type trials should not be applied to nutraceuticals—"a natural food product [from a plant] with health benefits"); Goldstein, Tr. 2600-02, 2611, 2620; deKernion, Tr. 3060 (in the case of fruit juice such as POM Juice, that has low or no toxicity, it is not necessary to have a RCT, placebo-controlled test); Miller, Tr. 2194, 2201; PX0206-0010-0015; Heber, Tr. at 1948-50, 2056, 2166; PX0149-0006-0007; PX0025-0007; Sacks, Tr. 1545-46; PX0361 (Sacks, Dep. at 134-135); Stampfer, Tr. 830; CX1293_0029-0030; RX5007 to RPTB; PX0362 (Stampfer, Dep. at 73-79, 98)).

Respondents further dispute this finding as contrary to the evidence in the record. Statistical significance, which is defined as a p-value of 0.05, is an arbitrary convention in the context of studying a whole food, like pomegranate juice. (RFF 599-614, 1252-56, 1984; Ornish, Tr. 2340; Goldstein, Tr. 2598-99) (Dr. Goldstein testified that choosing a significance level is technically an arbitrary task, and "in specific situations a different value could be utilized.") Thus, there is nothing magical about the five percent threshold. (RFF 1254; Ornish, Tr. 2368).

Furthermore, a lack of statistical significance for a positive result is not proof of the opposite. (RFF 604, 611, 614; Sacks, Tr. 1608-09; CX1352 (Heber, Dep. at 218); PX0361 (Sacks, Dep. at 223-224, 230, 238, 243); Goldstein, Tr. 2598-99)). While there is no evidence or argument suggesting that a p-value significantly greater than .05 can

show a benefit, there is ample evidence presented that slight variations of this number can still evidence a clinically meaningful benefit that is scientifically supportable. (RFF 435, 606, 2108, 2129-32; PX0352 (Goldstein, Dep. at 108-109); Goldstein, Tr. at 2599; PX0189-0013; PX0349 (Burnett, Dep. at 67, 138-139) ("[a] product could be potentially clinically significant and not meet statistical significance and it still be informative and really valuable to know and worth communicating and potentially having a role for patients out there."); Burnett, Tr. 2270-71; CX1350 (Liker, Dep. at 190-191); PX0361 (Sacks, Dep. at 109); Sacks, Tr. at 1608-09).

For example, although the *Forest/Padma-Nathan RCT Study* achieved a probability value ("p-value") of 0.058 which was a hair above a statistical significance measure of 0.050, Respondents' experts testified there were "significant clinical findings in this study." (RFF 1982, 1986; RRFF 1074; PX0189-0012-0013; PX0149-0006; CX0908; Heber, Tr. 1978-79, 2001; Goldstein, Tr. 2598-99; PX0352 (Goldstein, Dep. at 105-109, 116); Burnett, Tr. 2256; PX0349 (Burnett, Dep. at 138-139); CX1350 (Liker, Dep. at 190-191)).

780. *Endpoints*, *outcomes*, *or variables* are the outcomes being measured in a study. (CX1287 (Eastham, Report at 0009); Eastham, Tr. 1273)).

Response to Finding No. 780:

Complaint Counsel's proposed finding is vague, ambiguous and unintelligible, and impossible to object to in the abstract.

781. *Validated* endpoints or surrogate markers are those outcomes that, while not direct endpoints, have been shown to be so closely linked to a direct endpoint that a change in the surrogate marker is confidently predictive of a change in the disease. (*See* CX1291 (Sacks, Report at 0013); *see* CX1287 (Eastham, Report at 0010) ("changes in a surrogate are expected to reflect changes in a clinically meaningful endpoint")). *Validated* measures or assessment tools are those that have been established as reliable through rigorous assessments involving a large number of individuals. (Burnett Tr. 2266-67; Melman, Tr. 1100).

Response to Finding No. 781:

Respondents object to this proposed finding to the extent it insinuates that RCTs are required to substantiate the health benefits of 100% natural, safe and healthy foods such as the Challenged Products. (RFF 569-744, 1184-1205, 1784-92, 2122, 2123; RRFF 771; PX0149-0006-0007; Burnett, Tr. 2272-74, 2303 (testifying that RCTs are not necessary to deal with studies of drinking pomegranate juice); PX0189-0003, 0014; PX0352 (Goldstein, Dep. at 50-52, 61) (testifying that pharmaceutical type trials should not be applied to nutraceuticals—"a natural food product [from a plant] with health benefits"); Goldstein, Tr. 2600-02, 2611, 2620; deKernion, Tr. 3060 (in the case of fruit juice such as POM Juice, that has low or no toxicity, it is not necessary to have a RCT, placebo-controlled test); Miller, Tr. 2194, 2201; PX0206-0010-0015; Heber, Tr. at 1948-50, 2056, 2166; PX0149-0006-0007; PX0025-0007; Sacks, Tr. 1545-46; PX0361 (Sacks, Dep. at 134-135); Stampfer, Tr. 830; CX1293_0029-0030; RX5007 to RPTB; PX0362 (Stampfer, Dep. at 73-79, 98)).

Respondents add that certain validated measures, like the International Index of Erectile Function ("IIEF"), were originally intended for pharmaceutical products and "not necessarily designed for a nutraceutical." (RFF 2005; PX0352 (Goldstein, Dep. at 67-69); Goldstein, Tr. 2604, 2633).

Respondents further object to the extent that Complaint Counsel insinuates that validated endpoints are only those endpoints approved by the FDA. For instance, as Complaint Counsel's expert Dr. Eastham notes, PSA doubling time can be used as a surrogate marker for prostate cancer specific death although not accepted by the FDA. (RFF 1838; PX0178-0001). Dr. Heber testified that there is a lot of support from the urological community to get the FDA to accept PSA as a surrogate endpoint. (RFF 1753; CX1352 (Heber, Dep. at 316)). Dr. Heber testified that there is, "a lot of feeling in the urological

community and scientific agreement that [the] rate of rise of PSA is an important biomarker." (RFF 1754; CX1352 (Heber, Dep. at 316-317)). Dr. Heber also opined that, "PSA doubling time is an accepted variable by the vast majority of the urological community, including members of the American Urological Association and all the leading experts in prostate cancer research in the United States. This is not in dispute." (RFF 1755; Heber, Tr. 2151).

Respondents further add that certain non-validated measures are very "informative and . . . valuable to use in clinical studies." (RFF 1997; Burnett, Tr. 2294). For example, Respondents' erectile experts testified that the GAQ, a non-validated measure, is commonly accepted as a standardized instrument among those conducting erectile dysfunction research, and was used in every sildenafil (Viagra), vardenafil (Levitra) and tadalafil (Cialis) trial. (RFF 1997-2002; Goldstein, Tr. 2602-03; PX0352 (Goldstein, Dep. at 57, 73, 76); Burnett, Tr. 2304; CX1337 (Forest, Dep. at 79)). Indeed, Dr. Goldstein testified that "in the development of pharmaceutical products for sexual medicine the [FDA] widely approves of non-validated PROs [patient-reported outcomes, such as the GAQ]." (PX0352 (Goldstein, Dep. at 57)). To that end, Dr. Goldstein testified "it has to be strongly suspicious that an unvalidated questionnaire constantly gets repeated." (PX0352 (Goldstein, Dep. at 90)).

782. *Clinical significance* means that the treatment makes a real difference in a patient's life. (Melman, Tr. 1103; Eastham, Tr. 1274). A result may be statistically significant, but not clinically significant. (Melman, Tr. 1104; Eastham, Tr. 1274).

Response to Finding No. 782:

Complaint Counsel's proposed finding is vague, ambiguous and unintelligible, and impossible to object to in the abstract. "To the extent that [a study] has any impact [or potential benefit] on the human level suggests clinical significance." (PX0349 (Burnett, Dep. at 62-63)). Moreover, a result may be clinically significant even if did not reach

statistical significance. (RFF 435, 606, 2108, 2129-32; PX0352 (Goldstein, Dep. at 108-109); Goldstein, Tr. at 2599; PX0189-0013; PX0349 (Burnett, Dep. at 67, 138-139) ("[a] product could be potentially clinically significant and not meet statistical significance and it still be informative and really valuable to know and worth communicating and potentially having a role for patients out there."); Burnett, Tr. 2270-71; CX1350 (Liker, Dep. at 190-191); PX0361 (Sacks, Dep. at 109).

783. *Replication* ensures that the results obtained in one study are not due to chance. (Sacks, Tr. 1446; CX1291 (Sacks, Report at 0014-15)). Even with the safeguards contained in an RCT, the results contained in any one study may be due to chance or may not be generalizable due to uniqueness of the study sample. Most scientists believe that at least two well-designed RCTs, conducted by independent researchers, and each showing strong results, are needed to constitute reliable evidence that an intervention causes a result. (Sacks, Tr. 1446; CX1291 (Sacks, Report at 0014-15); Melman, Tr. 1092-93; Burnett, Tr. 2264 (experts would require two to three randomized, controlled human trials to reach a conclusion)).

Response to Finding No. 783:

Respondents object to this proposed finding to the extent it insinuates that RCTs are required to substantiate the health benefits of 100% natural, safe and healthy foods such as the Challenged Products. (RFF 569-744, 1184-1205, 1784-92, 2122, 2123; RRFF 771; PX0149-0006-0007; Burnett, Tr. 2272-74, 2303 (testifying that RCTs are not necessary to deal with studies of drinking pomegranate juice); PX0189-0003, 0014; PX0352 (Goldstein, Dep. at 50-52, 61) (testifying that pharmaceutical type trials should not be applied to nutraceuticals—"a natural food product [from a plant] with health benefits"); Goldstein, Tr. 2600-02, 2611, 2620; deKernion, Tr. 3060 (in the case of fruit juice such as POM Juice, that has low or no toxicity, it is not necessary to have a RCT, placebo-controlled test); Miller, Tr. 2194, 2201; PX0206-0010-0015; Heber, Tr. at 1948-50, 2056, 2166; PX0149-0006-0007; PX0025-0007; Sacks, Tr. 1545-46; PX0361 (Sacks, Dep. at 134-135); Stampfer, Tr. 830; CX1293_0029-0030; RX5007 to RPTB; PX0362 (Stampfer, Dep. at 73-79, 98)).

Complaint Counsel's cited evidence does not support the proposition that RCTs are required to conclude a causal link regarding a nutrient and disease. In fact, Complaint Counsel's citation to Dr. Burnett conveniently failed to include his explanation that "this level of rigor" is in the context of pharmaceutical drug therapies—not nutraceuticals. (Burnett, Tr. 2261-2264). Also, while Complaint Counsel's expert, Dr. Melman, claims that Respondents must have two RCTs before they can publicize the positive effects of pomegranate juice on men with ED, he publicized preliminary results of studies on his gene-transfer therapy based only on the results of an animal study. (RRF 2191; Melman, Tr. 1149-55).

Complaint Counsel's designated expert on this matter, Professor Stampfer, also testified that RCTs are not required to conclude a causal link regarding a nutrient and disease. (RFF 624-644; Stampfer, Tr. 830; PX0362 (Stampfer, Dep. at 73-79, 98)). Professor Stampfer further testified that in a nutritional context, a hypothesis about disease causation can, rarely, if ever, be directly tested in humans using the RCT design. (RFF 640; Stampfer, Tr. 832-33; PX0362 (Stampfer, Dep. at 73, 98); RX5007 to RPTB).

In his expert report, Professor Stampfer also admitted that he "believe[s] that it may be appropriate to use evidence short of randomized clinical trials for crafting public health recommendations regarding nutrient guidelines even when causality cannot be established, because everyone eats and the public should be given advice based on the best evidence available." (RFF 628; CX1293_0029-0030) (emphasis added).

Also, in a recently published article entitled "*Evidence-based criteria in the nutritional context*," Professor Stampfer opined that the general principles of evidence-based nutrition "can provide a sufficient foundation for establishing nutrient requirements and dietary guidelines in the absence of RCTs for every nutrient and food group." (RFF 630; Stampfer, Tr. 831; RX5007 to RPTB) (opining that because RCT study designs may not

be "available" (economically or scientifically) for nutrients, "nutrient related decisions could be made at a level of certainty somewhat below that required for drugs.") Professor Stampfer also noted that some of the intellectual fathers of evidence based medicine "stressed" that evidence based medicine was "'not restricted to randomized trials and meta-analyses.'" (RFF 643; RX5007 to RPTB). In the article, Professor Stampfer stated that "certain features of [evidence-based medicine] seem ill-suited to the nutrition context." (RFF 631; RX5007 to RPTB). He also opined that "to fail to act in the absence of conclusive RCT evidence increases the risk of forgoing benefits that might have been achieved with little risk and at low cost." (RFF 644; RX5007 to RPTB).

Professor Stampfer noted that some of the differences between the evaluation of drugs and nutrients are:

> "(i) medical interventions are designed to cure a disease not produced by their absence, while nutrients prevent dysfunction that would result from their inadequate intake; (ii) it is usually not plausible to summon clinical equipoise for basic nutrient effects, thus creating ethical impediments to many trials; (iii) drug effects are generally intended to be large with limited scope of action, while nutrient effects are typically polyvalent in scope and, in effect size, are typically within the "noise" range of biological variability; (iv) drug effects are tend to be monotonic, with response varying in proportion to dose, while nutrient effects are often of a sigmoid character, with useful response occurring only across a portion of the intake range; (v) drug effects can be tested against a non-exposed (placebo) contrast group, whereas it is impossible and/or unethical to attempt a zero intake group for nutrients; and (vi) therapeutic drugs are intended to be efficacious within a relatively short term while the impact of nutrients on the reduction of risk of chronic disease may require decades to demonstrate – a difference with significant implications for the feasibility of conducting pertinent RCTs."

(RFF 634; RX5007 to RPTB; PX0362 (Stampfer, Dep. at 78)) (emphasis added).

Additionally, Complaint Counsel's expert, Dr. Sacks, concedes that a causal influence can be demonstrated between an agent and its effect on humans without the use of RCTs. (RFF 647; PX0361 (Sacks, Dep. at 134-135)). Dr. Sacks testified that you do not need RCT trials to test the benefit of food categories that are included in a diet already tested, like the DASH diet, which includes pomegranates. (RFF 648; Sacks, Tr. 1545-46). Dr. Ornish noted that most of Dr. Sacks' published studies have been epidemiological and observational in nature, rather than RCTs, and include relatively small numbers of patients. (RFF 1186; PX0025-0007).

Respondents' expert, Dr. Miller, confirms that when a food product is safe, and where the claim or advertisement does not suggest that the product be used as a substitute for conventional medical care or treatment, then it is appropriate to look at the totality of the science (and in some cases, only basic science), and not require only RCTs, to substantiate health benefit claims. (RFF 657-744; Miller, Tr. 2194, 2201; PX0206-0010-0015; Heber, Tr. at 1948-50, 2056, 2166; PX0149-0006-0007; Burnett, Tr. 2272-74, 2303; PX0189-0003; Goldstein, Tr. 2600-02, 2611, 2620); deKernion, Tr. 3060; PX0025-0007). Dr. Miller testified that if a fruit juice were claiming to prevent prostate cancer and there was reliable scientific data to support that you could make that claim without a RCT. (RFF 1878; Miller, Tr. 2201).

Similarly, Dr. Heber testified that most experts in the field of nutrition consider competent and reliable science to support health claims for pomegranate juice based upon the totality of evidence, which does not necessarily include RCTs. (RFF 652; Heber, Tr. 1948-49, 2166, 2182). Dr. Heber further testified that in dealing with nutrients, RCTs are often infeasible and too expensive and that the drug standard should not be applied. (RFF 646; Heber, Tr. 1950; RX5007 to RPTB).

Moreover, Respondents' prostate expert, Dr. deKernion, testified that in the case of fruit juice such as POM Juice, that has low or no toxicity, it is not necessary to have a RCT, placebo-controlled test. (RFF 1784; deKernion, Tr. 3060).

Respondents' erectile and nitric oxide experts, Drs. Goldstein and Burnett, also testified that urologist who treat men with erectile health concerns would not require that pomegranate juice be subjected to RCTs before concluding that pomegranate juice has a beneficial effect on preserving erectile function and erectile dysfunction. (RFF 650-651; 2122, 2123, 2164; PX0149-0006-0007; Burnett, Tr. 2272-74, 2303 (testifying that RCTs are not necessary to deal with studies of drinking pomegranate juice); PX0189-0003, 0014; PX0352 (Goldstein, Dep. at 50-52, 61) (testifying that pharmaceutical type trials should not be applied to nutraceuticals—"a natural food product [from a plant] with health benefits"); Goldstein, Tr. 2600-02, 2611, 2620).

Furthermore, Respondents cardio expert, Dr. Ornish, opined in his expert report that "it is an extreme position to state that the therapeutic efficacy of a fruit juice or extract of pomegranate juice should be held to the same standard of evidence as a new drug." (RFF 1192; PX0025-0008). Dr. Ornish opined that the study of pomegranates or pomegranate juice is different than studying a new drug, in which harmful side-effects, both short-term and long-term, are the rule rather than the exception. (RFF 1195; PX0025-0008). Dr. Ornish opined that he is "not aware of any studies showing any harmful effects of consuming pomegranates or pomegranate juice." (RFF 1194; PX0025-0008). Dr. Ornish testified that a new drug needs to be held to a higher standard than a juice that has been around for thousands of years. (RFF 1196; Ornish, Tr. 2340). Dr. Ornish noted that RCTs, even when conducted perfectly, do not control for all sources of bias and may inject new ones unique to RCTs. (RFF 1190; PX0025-0008). Rather, Dr. Ornish noted that a more thoughtful way of analyzing therapeutic efficacy is to carefully examine the

totality of scientific evidence, including but not limited to RCTs that are perfectly conducted. (RFF 1191; PX0025-0008).

In fact, much of what physicians provide patients in their clinical practices has not been proven to be beneficial in RCTs. (RFF 745-751; PX0025-0007; Sacks, Tr. 1559; PX0361 (Sacks Dep. at 111); CX1341 (Pantuck, Dep. at 276-277)). For example, Complaint Counsel's own expert, Dr. Eastham, admitted he has performed over 200 radical prostatectomies per year for a number of years before there were any RCTs showing that it worked. (RFF 746; Eastham Tr. 1331-32; PX0358 (Eastham, Dep. at 154-155)). Dr. Eastham performed these radical operations without RCTs despite the fact that the side-effects of this operation are significant and include impotence, incontinence, bleeding, embolisms, infection plus risks of general anesthetic. (RFF 747; Eastham, Tr. 1331-32). Also, Dr. Pantuck stated that clinicians remove kidneys without a RCT showing the benefits of nephrectomy. (RFF 748; CX1341 (Pantuck, Dep. at 276-277)).

Dr. Ornish also noted that randomized controlled trials have shown that angioplasties and stents do not prevent heart attacks or prolong life, yet the number of these procedures performed is greater than ever. (RFF 749; PX0025-0007). Dr. Miller indicated that although health professionals, third party insurance carriers, and health related agencies highly recommend that eating 5 portions of fresh fruits and vegetables may prevent cancer, it is accepted without requiring controlled non-clinical or clinical trials. (RFF 750; PX0206-0012-0013).

Further, Complaint Counsel's experts, Professor Stampfer and Dr. Sacks, admitted that they have made public health recommendations that were not supported by RCTs. (RFF 751; Stampfer, Tr. at 810, 813-14; PX0300 (Stampfer, Dep. at 173); PX0361 (Sacks, Dep. at 35-38, 130-131)).

C. Analysis of Respondents' Research Related to Heart Disease

1. Background Information

784. To substantiate a claim that a food or a diet supplement can *treat* heart disease, one needs appropriately analyzed data from well-designed, well-conducted RCTs showing significant changes in valid surrogate markers of cardiovascular health. The study subjects must have established CVD or CHD. (CX1291 (Sacks, Report at 0010_11)). The same evidence is needed to show that such benefits are scientifically proven. *Prevention and risk reduction* claims also require well-conducted RCTs measuring valid surrogate markers, but the study subjects may be persons with *or* without CVD or CHD. (CX1291 (Sacks, Report at 0010-11)). There must be a sufficient number and diversity of subjects tested to conclude that the measured effect can be generalized to a larger population. The study also must be of sufficient duration to show that the effect will last. (CX1291 (Sacks, Report at 0014)).

Response to Finding No. 784:

Contrary to Complaint Counsel's assertions, and those of its experts, Dr. Sacks and Professor Stampfer, RCTs are not required to substantiate the efficacy of a fruit juice or nutrient, *although Respondents certainly do employ the use of RCTs*. First, as a matter of law, "[n]othing in the Federal Trade Commission Act…. requires placebo-controlled, double-blind studies. The Act forbids false and misleading statements, and a statement that is plausible but has not been tested in the most reliable way cannot be condemned out of hand." *F.T.C. v. QT, Inc.*, 512 F.3d 858, 861 (7th Cir. 2008); *see also F.T.C. v. Direct Mktg. Concepts, Inc.*, 624 F.3d 1, 9 (1st Cir. 2010) ("a double-blind study is not necessarily required" to satisfy a reasonable basis claim).

Second, as explained by Respondents' experts, Dr. Miller, Dr. Ornish and Dr. Heber, the totality of scientific evidence should be examined, not just RCTs, given that: (1) pomegranate juice and its extracts are safe; (2) no one suggests that pomegranate juice or its extracts should be offered in lieu of conventional medical treatment or surgery; (3) the expense associated for conducting a FDA drug study for a non-patentable, natural food is exorbitant and prohibitive; and (4) the potential benefit or information to be gained by the public outweighs any plausible harm. (RFF 1184-1205).

As discussed in Respondents' Post-Trial Brief, Dr. Sacks conceded at trial and in deposition that: (1) in evaluating a natural food, RCTs are simply not necessary in all cases; (2) a lesser standard of evidence is appropriate for fruits and fruit juices as evidenced by his own DASH diet; (3) he has recommended (or would recommend) fish oil (Omega-3) or a reduction in sodium to patients with coronary heart disease even though no RCTs have been conducted; (4) RCTs are not feasible because of logistical, financial, and ethical considerations; and (5) he nevertheless concedes that we should weigh the risk that the product will do harm against the potential of keeping information from the public. (RFF 1214; 1221-22; 1227-48). Dr. Sacks' opinion on the appropriate standard of evidence for evaluating cardiovascular science, therefore, should be disregarded.

Similarly, Professor Stampfer undermines Complaint Counsel's assertion that RCTs are required to demonstrate the efficacy of a whole fruit or juice. In his expert report, for instance, Dr. Stampfer agrees that it may be appropriate to communicate health recommendations in the absence of RCTs:

> I believe that it may be appropriate to use evidence short of randomized clinical trials for crafting public health recommendations regarding nutrient guidelines even when causality cannot be established, because everyone eats and the public should be given advice based on *the best evidence available*…*Long term trials of diet and disease outcomes are often unfeasible due to the financial and participant burden required to perform such studies*, but it is indisputable that the randomized clinical trial is the best study design that permits strong causal inference concerning the relationship between an administered agent (whether drug or nutrient) and any specific outcome.

(CX1293_0029-0030)(emphasis added).

Thus, based on these statements alone, Professor Stampfer concedes that the "*best evidence available*" should be considered, not just RCTs as argued by Complaint

Counsel, even when "causality cannot be established" because in his words, "everyone eats." (CX1293_0029-0030). Moreover, Professor Stampfer acknowledges that RCTs "are often infeasible" with respect to diet and disease outcomes. (CX1293_0030). At trial, Professor Stampfer disclosed that he has made public statements or recommendations that food and beverage products lower the risk of certain diseases, in the absence of RCTs and even when the product is not completely safe. (RFF 208-209). Based on the foregoing, neither Professor Stampfer nor Dr. Sacks can faithfully support Complaint Counsel's evidentiary drug standard requiring RCTs to evaluate the effect of a fruit or fruit juice on cardiovascular health.

There is ample evidence in the record refuting Dr. Sacks' expert testimony on the subject of RCTs. While data from RCTs may provide the best evidence of a causal relationship between a treatment and a disease outcome in a pharmaceutical drug, Respondents' experts and Complaint Counsel's experts agree that RCTs are not required, nor even preferred to substantiate the health benefits of 100% natural, safe and healthy foods such as the Challenged Products. (RFF 569-744, 1184-1205, 1784-92, 2122, 2123; PX0149-0006-0007; Burnett, Tr. 2272-74, 2303) (testifying RCTs are not necessary to deal with studies of drinking pomegranate juice); PX0189-0003, 0014; PX0352 (Goldstein, Dep. at 50-52, 61) (testifying that pharmaceutical type trials should not be applied to nutraceuticals); Goldstein, Tr. 2600-02, 2620; deKernion, Tr. 3060) (Dr. deKernion testified that in the case of fruit juice such as POM Juice, that has low or no toxicity, it is not necessary to have a RCT, placebo-controlled test); Miller, Tr. 2194, 2201; PX0206-0010-0015; Heber, Tr. at 1948-50, 2056, 2166; PX0149-0006-0007; PX0025-0007; Sacks, Tr. 1545-46; PX0361 (Sacks, Dep. at 134-135); Stampfer, Tr. 830; CX1293_0029-0030; RX5007 to RTPB; PX0362 (Stampfer, Dep. at 73-79, 98)).

Dr. Heber testified "that the scientific community believes that the research done by Dr. Ornish and Dr. Aviram and Dr. Davidson on the basis of the basic science does provide a

significant scientific agreement" that pomegranate helps to reduce the risk of heart disease. (RFF 582; Heber, Tr. 2081).

Complaint Counsel's cardio expert, Dr. Sacks, similarly testified that *in vitro* studies can be competent and reliable evidence of an agent's effect on a particular mechanism. (RFF 576; Sacks, Tr. 1578; PX0361 (Sacks, Dep. at 123-124)). And Respondents' cardio expert, Dr. Ornish, opined that it is an extreme position to state that evidence from *in vitro* and animal studies should not be considered in determining the therapeutic value of an intervention. (RFF 574; PX0025-0007). He further opined that while there are limitations to extrapolating from *in vitro* and animal studies to human studies, it is false to say this research has no value in determining therapeutic efficacy. (RFF 575; PX0025-0007).

And Complaint Counsel's designated expert on this matter, Professor Stampfer, testified that RCTs are not required to conclude a causal link regarding a nutrient and disease. (RFF 624-644; Stampfer, Tr. 830; PX0362 (Stampfer, Dep. at 73-79, 98)). Professor Stampfer further testified that in a nutritional context, a hypothesis about disease causation can, rarely, if ever, be directly tested in humans using the RCT design. (RFF 640; Stampfer, Tr. 832-33; PX0362 (Stampfer, Dep. at 73, 98); RX5007 to RPTB).

Also, in a recently published article entitled "*Evidence-based criteria in the nutritional context*," Professor Stampfer opined that the general principles of evidence-based nutrition "can provide a sufficient foundation for establishing nutrient requirements and dietary guidelines in the absence of RCTs for every nutrient and food group." (RFF 630; Stampfer, Tr. 831; RX5007 to RPTB) (Opining that because RCT study designs may not be "available" (economically or scientifically) for nutrients, "nutrient related decisions could be made at a level of certainty somewhat below that required for drugs.") Professor Stampfer also noted that some of the intellectual fathers of evidence based medicine

"stressed" that evidence based medicine was "'not restricted to randomized trials and meta-analyses.'" (RFF 643; RX5007 to RPTB). In the article, Professor Stampfer stated that "certain features of [evidence-based medicine] seem ill-suited to the nutrition context." (RFF 631; RX5007 to RPTB). He also opined that "to fail to act in the absence of conclusive RCT evidence increases the risk of forgoing benefits that might have been achieved with little risk and at low cost." (RFF 644; RX5007 to RPTB).

Professor Stampfer noted that some of the differences between the evaluation of drugs and nutrients are:

> "(i) medical interventions are designed to cure a disease not produced by their absence, while nutrients prevent dysfunction that would result from their inadequate intake; (ii) it is usually not plausible to summon clinical equipoise for basic nutrient effects, thus creating ethical impediments to many trials; (iii) drug effects are generally intended to be large with limited scope of action, while nutrient effects are typically polyvalent in scope and, in effect size, are typically within the "noise" range of biological variability; (iv) drug effects are tend to be monotonic, with response varying in proportion to dose, while nutrient effects are often of a sigmoid character, with useful response occurring only across a portion of the intake range; (v) drug effects can be tested against a non-exposed (placebo) contrast group, whereas it is impossible and/or unethical to attempt a zero intake group for nutrients; and (vi) therapeutic drugs are intended to be efficacious within a relatively short term while the impact of nutrients on the reduction of risk of chronic disease may require decades to demonstrate –a difference with significant implications for the feasibility of conducting pertinent RCTs."

(RFF 634; RX5007 to RPTB; PX0362 (Stampfer, Dep. at 78)) (emphasis added).

Respondents' expert, Dr. Miller, confirms that when a food product is safe, and where the claim or advertisement does not suggest that the product be used as a substitute for conventional medical care or treatment, then it is appropriate to look at the totality of the science (and in some cases, only basic science), and not require only RCTs, to substantiate health claims. (RFF 657-744; Miller, Tr. 2194, 2201; PX0206-0010-0015; Heber, Tr. at 1948-50, 2056, 2166; PX0149-0006-0007; Burnett, Tr. 2272-74, 2303; PX0189-0003; Goldstein, Tr. 2600-02, 2611, 2620); deKernion, Tr. 3060; PX0025-

0007). Dr. Miller testified that if a fruit juice were claiming to prevent prostate cancer and there was reliable scientific data to support that you could make that claim without a RCT. (RFF 1878; Miller, Tr. 2201).

Similarly, Dr. Heber testified that most experts in the field of nutrition consider competent and reliable science to support health claims for pomegranate juice based upon the totality of evidence, which does not necessarily include RCTs. (RFF 652; Heber, Tr. 1948-49, 2166, 2182). Dr. Heber further testified that in dealing with nutrients, RCTs are often infeasible and too expensive and that the drug standard should not be applied. (RFF 646; Heber, Tr. 1950; RX5007 to RPTB).

Moreover, Complaint Counsel's experts agree. Dr. Sacks, Complaint Counsel's cardio expert, testified that he considers all levels of science in issuing national guidelines for the prevention or treatment of cardiovascular disease. (PX0361 (Sacks Dep. at 71)). Similarly, Complaint Counsel's erectile expert, Dr. Melman, testified that based on the results of his gene therapy erectile dysfunction product in an animal model, he was "personally satisfied" that it would also work in humans. (PX0360 (Melman, Dep. at 56-57)).

Dr. Sacks also conceded that a causal influence can be demonstrated between an agent and its effect on humans without the use of RCTs. (RFF 647; PX0361 (Sacks, Dep. at 134-135)). Dr. Ornish noted that most of Dr. Sacks' published studies have been epidemiological and observational in nature, rather than RCTs, and include relatively small numbers of patients. (RFF 1186; PX0025-0007).

Dr. Ornish, opined in his expert report that "it is an extreme position to state that the therapeutic efficacy of a fruit juice or extract of pomegranate juice should be held to the same standard of evidence as a new drug." (RFF 1192; PX0025-0008). Dr. Ornish opined that the study of pomegranates or pomegranate juice is different than studying a new

drug, in which harmful side-effects, both short-term and long-term, are the rule rather than the exception. (RFF 1195; PX0025-0008). Dr. Ornish opined that he is "not aware of any studies showing any harmful effects of consuming pomegranates or pomegranate juice." (RFF 1194; PX0025-0008). Dr. Ornish testified that a new drug needs to be held to a higher standard than a juice that has been around for thousands of years. (RFF 1196; Ornish, Tr. 2340). Dr. Ornish noted that RCTs, even when conducted perfectly, do not control for all sources of bias and may inject new ones unique to RCTs. (RFF 1190; PX0025-0008). Rather, Dr. Ornish noted that a more thoughtful way of analyzing therapeutic efficacy is to carefully examine the totality of scientific evidence, including but not limited to RCTs that are perfectly conducted. (RFF 1191; PX0025-0008).

In fact, much of what physicians provide patients in their clinical practices has not been proven to be beneficial in RCTs. (RFF 745-751; PX0025-0007; Sacks, Tr. 1559; PX0361 (Sacks Dep. at 111); CX1341 (Pantuck, Dep. at 276-277)). For example, Complaint Counsel's own expert, Dr. Eastham, admitted he has performed over 200 radical prostatectomies per year for a number of years before there were any RCTs showing that it worked. (RFF 746; Eastham Tr. 1331-32; PX0358 (Eastham, Dep. at 154-155)). Dr. Eastham performed these radical operations without RCTs despite the fact that the side-effects of this operation are significant and include impotence, incontinence, bleeding, embolisms, infection plus risks of general anesthetic. (RFF 747; Eastham, Tr. 1331-32). Also, Dr. Pantuck stated that clinicians remove kidneys without a RCT showing the benefits of nephrectomy. (RFF 748; CX1341 (Pantuck, Dep. at 276-277)).

Dr. Ornish also noted that randomized controlled trials have shown that angioplasties and stents do not prevent heart attacks or prolong life, yet the number of these procedures performed is greater than ever. (RFF 749; PX0025-0007). Dr. Miller indicated that although health professionals, third party insurance carriers, and health related agencies highly recommend that eating 5 portions of fresh fruits and vegetables may prevent

cancer, it is accepted without requiring controlled non-clinical or clinical trials. (RFF 750; PX0206-0012-0013).

In sum, RCTs are not necessary to make health benefit claims for a safe product like food.

785. Direct endpoints of heart disease are heart attack, unstable angina, or the need for coronary artery bypass or angioplasty. (CX1291 (Sacks, Report at 0013)). FDA recognizes blood pressure and LDL cholesterol as validated surrogate markers. Most (but not all) experts also recognize C-reactive protein, HDL cholesterol, and triglycerides as valid surrogate markers. (Sacks, Tr. 1441; CX1291 (Sacks, Report at 0013)).

Response to Finding No. 785:

Complaint Counsel omits an important surrogate marker from its list—blood flow to the heart (myocardial perfusion). As Dr. Ornish stated in his expert report and at trial, blood flow is essential to life, an important measure of heart disease, and *the bottom line in coronary heart disease* (along with how well the heart is pumping blood, called the ejection fraction). (RFF 1305-1306; Ornish, Tr. 2331; PX0025-0012). Blood carries oxygen and nutrients that feed the heart. (RFF 1307; PX0025-0012). If the blood flow to the heart (perfusion) is reduced, then the heart is no longer receiving enough blood flow to maintain itself. (RFF 1308; PX0025-0012). Coronary heart disease, which is the most common form of heart disease, occurs when the heart does not get enough blood to fuel itself and blood carries oxygen, which is the fuel for the heart. (RFF 1309; Ornish, Tr. 2331-32).

Dr. Sacks concedes that if blood flow is reduced, then this is not desirable. (RFF 1310; PX0361 (Sacks, Dep. at 179)). If this is temporary, then the person often experiences angina, or chest pain. (RFF 1311; PX0025-0012). If this reduction in blood to the heart lasts more than a few hours, then that portion of the heart that is underperfused may die and turn in to scar tissue—this is commonly referred to as a "heart attack." (RFF 1312; PX0025-0012). If this scar tissue is small, then the person may live; if this scar tissue is

large or affects a critical part of the heart (e.g., the conduction system), then the person may die. (RFF 1313; PX0025-0012). Any increase in myocardial perfusion would reduce the risk of cardiovascular or coronary problems and improve heart health because, even with a blockage of a minor artery, a patient could have a stent inserted at a hospital or allow him or her to survive the ride in the ambulance, and in the case of a blockage in a major blood vessel, there would be an increased chance of recovery. (RFF 1314; Heber, Tr. at 1972-73).

A surrogate is either a sign or a symptom that is associated along the pathway to a disease. (RFF 1315; Heber, Tr. 1973). The FDA approves of LDL cholesterol as surrogate for cardiovascular disease. (RFF 1316; Ornish, Tr. 2334). Dr. Ornish testified, however, that LDL cholesterol is really a risk factor for heart disease, and because it is not actually heart disease, it cannot be a valid surrogate. (RFF 1317; Ornish, Tr. 2334). While the FDA for the purposes of drug registration and testing only accepts a limited number of surrogate markers, such as LDL cholesterol and blood pressure, the number of indicators that physicians and scientists use are much greater and can be at many points along the pathway of heart disease. (RFF 1318; Heber, Tr. 1973). Clinical decisions are made, the health of the patient assessed and certain procedures are undertaken based on things that are surrogate markers, but may not be officially accepted by the FDA. (RFF 1319; Heber, Tr. 1973). Doctors want a surrogate marker to be something as closely related as possible to the actual disease, so that studying the surrogate may allow us to predict the likelihood of the disease or its progression. (RFF 1320; Heber, Tr. 1973-74).

In comparing myocardial perfusion and LDL cholesterol, myocardial perfusion is more closely connected as a surrogate for cardiovascular disease. (RFF 1321; Ornish, Tr. 2334). When a person has a biomarker like high LDL cholesterol which increases his or her risk, that is very distal or far away from the actual event of a heart attack which may

be affected by many other factors, such as inflammation and oxidation. (RFF 1322; Heber, Tr. 1974). There are a number of people who have low cholesterol levels, but get heart disease. (RFF 1323; Ornish, Tr. 2334-35). About 50 percent of the people who die from a heart attack actually have cholesterol in the normal range. (RFF 1324; Heber, Tr. 1974). There are people who have high cholesterol levels who do not have heart disease, and the same is true blood pressure. (RFF 1325; Ornish, Tr. 2334-35). When measuring myocardial perfusion, researchers are actually measuring what matters most, which is how much blood flow the heart is getting. (RFF 1326; Ornish, Tr. 2334-35).

Dr. Sacks concedes that proper blood flow from the coronary artery and to the heart is fundamental to lowering the risk of cardiovascular disease. (RFF 1327; Sacks, Tr. 1593). Dr. Ornish explains that for many years, it has been recognized that change in myocardial perfusion (blood flow to the heart) is actually a better predictor of cardiac events (thus a better surrogate marker) than coronary angiography. (RFF 1328; PX0025-0012). Coronary angiography measures how much blockage is in the coronary arteries that feed the heart. (RFF 1329; PX0025-0012).

However, the degree of blockage is only one of several mechanisms that affect perfusion, or blood flow to the heart. (RFF 1330; PX0025-0012). These include changes in vasomotor tone (how dilated or constricted the coronary arteries are), platelet aggregation (how sticky the platelets are that can form blood clots which may partially or complete occlude the flow of blood to the heart), and collateral blood flow (the heart can grow new blood vessels that provide additional blood flow around partial or even completely blocked arteries if the blockage occurs slowly overtime). (RFF 1331; PX0025-0012). In addition, conventional coronary angiography (the most commonly performed type in clinical practice) provides only a two-dimensional view of the inside of the lumen of the coronary artery. (RFF 1332; PX0025-0012). In a study a entitled *Compensatory enlargement of human atherosclerotic coronary arteries*, N Engl J Med. 1987 May

28;316(22):1371-5, Dr. Glagov and others demonstrated that the majority of the coronary atherosclerosis (blockage) is inside the vessel wall and cannot be visualized using conventional coronary angiography—somewhat analogous to only being able to view the tipoff an iceberg but not the bulk of it below the surface of the ocean. (RFF 1333; PX0025-0012).

In a major study directly comparing the value of thallium 201-scintigraphy (the test used in Dr. Ornish's study to measure the effects of pomegranate juice on blood flow to the heart) and coronary angiography, the authors found measures of blood flow were more predictive of subsequent clinical events (e.g., heart attacks) than coronary angiography, and both were equivalent in predicting subsequent mortality. (RFF 1334; PX0025-0012 *citing* Gibson RS, Watson DD, Craddock GB, et al., *Prediction of cardiac events after uncomplicated myocardial infarction: a prospective study comparing predischarge exercise thallium-201 scintigraphy and coronary angiography*, Circulation. 1983;68(2):321-336). The authors wrote: "Scintigraphy predicted low-risk status better than exercise testing ($p = .01$) or angiography ($p = .05$). Each predicted mortality with equal accuracy. However, scintigraphy was more sensitive in detecting patients who experienced reinfarction or who developed class III or IV angina….the overall sensitivity of angiography was lower than that of scintigraphy (71% vs. 94%; $p < .01$)." (RFF 1335; PX0025-0012-13). This study was published in Circulation, the American Heart Association's lead scientific journal. (RFF 1336; PX0025-0013).

A more recent study that compared perfusion (blood flow) studies with an extensive variety of other cardiac measures, including coronary angiography, concluded: "Myocardial perfusion abnormalities at rest and after stress are still the best predictors of cardiac event–free survival in patients with known or suspected IHD, even when compared with an extensive diagnostic work-up." (RFF 1337; PX0025-0012-13 *quoting* Gimelli A, Rossi G, Landi P, et al., *Abnormalities by gated SPECT: still the best*

predictor of cardiac events in stable ischemic heart disease, J Nucl Med 2009; 50:546–553). Thus, studies have shown that measures of myocardial perfusion or blood flow to the heart are actually not only as predictive, but are often more predictive of who is going to get a subsequent heart attack or dies than the blockages alone. (RFF 1338; Ornish, Tr. 2333-34).

786. In addition, measures of carotid intima media thickness ("CIMT"), *i.e.*, the combination of the vessel muscle and atherosclerosis (arterial plaque), are usually relevant to cardiovascular health. (Sacks Tr. 1442; CX1291 (Sacks, Report at 0013-14)). However, such measures alone are not conclusive evidence that an intervention treats existing heart disease. (Sacks, Tr. at 1441-44; CX1291 (Sacks, Report at 0014); *see also* Stampfer, Tr. 745). A recent article in a leading cardiology journal analyzed CIMT in relation to cardiovascular events. It found that among a meta-analysis of 41 randomized trials, "there was no significant relationship between IMT regression and CHD . . . events . . . CBV [cerebrovascular] events. . . and for all-cause death." As a result, there is broad consensus that at least two types of imaging studies must be obtained to make inferences on benefit to cardiovascular disease. (CX1291 (Sacks, Report at 0014)).

Response to Finding No. 786:

Respondents incorporate by reference their response to Complaint Counsel's proposed finding No. 786.

787. Respondents' interrogatory responses did not identify the specific studies that they relied on in support of the challenged heart benefit claims. (CX1381_0014 (POM states in its Supplemental Response to First Set of Interrogatories that it relied on the "body of scientific knowledge")). Nonetheless, Respondents' internal documents, and their heart experts, focused primarily on nine human studies – two by Dr. Aviram, two by Dr. Ornish, two by Dr. Davidson, and two conducted on overweight individuals and one on diabetic patients – that looked at heart-related endpoints. (*See* CX1029_0003 (POM Medical Research Portfolio identifying human heart studies by Aviram, Ornish, Davidson, and biomarker studies by Drs. Heber and Hill); PX0192 (Heber, Report at 000038, 0052-54, discussing Aviram, Ornish, Davidson, and "biomarker" studies; and at 0038, discussing Rock diabetes study); PX0025 (Ornish, Report at 0009-25) (discussing Aviram, Ornish, Davidson, and Denver and San Diego overweight studies)). Additionally, at trial Dr. Heber testified as to the negative results of two studies that he and Dr. Hill conducted on diabetics. (*See* CCFF ¶¶ 946-49). As further discussed below, these studies do not substantiate Respondents' heart benefit efficacy claims, or their heart benefit establishment claims.

Response to Finding No. 787:

Respondents have sponsored approximately 15 published studies in cellular and animal models evaluating the effects of pomegranate juice and/or its extracts on cardiovascular health. (PX0002, PX0007, PX0008, PX0009, PX0010, PX0015, CX0543, PX0017, PX0022, PX0055, PX0056, PX0057, PX0058, PX0059, and CX0053).

Respondents' 15 published basic science studies constitute competent and reliable scientific evidence that the Challenged Products are beneficial to cardiovascular health by resulting in, among other things:

- reducing oxidation of LDL cholesterol;
- lessening the uptake of oxidized and native LDL cholesterol by macrophage foam cells;
- diminishing the size of atherosclerotic lesions and foam cells;
- inhibiting macrophage cholesterol biosynthesis;
- decreasing macrophage oxidative stress;
- protecting against cellular lipid peroxidation;
- reducing serum lipids and glucose levels;
- improving PON1;
- lessening of platelet aggregation;
- increasing and preserving levels of nitric oxide and decreasing expression of genes associated with stress and progression of atherosclerosis;
- reducing LDL oxidation, size of atherosclerotic plaques, and formation of foam cells;
- reversing effects of shear stress, which can damage the endothelial cells or thin layer of cells that line the interior of blood vessels;
- decreasing cellular production and release of oxygen radicals in the vascular wall; inhibiting activation of oxidation-sensitive genes; and
- improving biological activity of nitric oxide.

(RFF 1064-1088; PX0025; PX0192; PX0002, PX0007, PX0008, PX0009, PX0010, PX0015, CX0543, PX0017, PX0022, CX0053, PX0055, PX0056, PX0057, PX0058, PX0059).

Respondents have sponsored approximately 10 published studies on humans evaluating the effect of pomegranate juice and/or its extracts on cardiovascular health. (PX0004, PX0005, CX0611, PX0014, PX0020, PX0021, PX0023, PX0038, PX0127, PX0139).

Respondents' 10 published human clinical studies confirm and support the benefits found in the basic research and together, the totality of the evidence constitutes competent and reliable scientific evidence that pomegranate juice and/or its extracts promote cardiovascular health by, among other things, having the following beneficial benefits:

- decrease of LDL susceptibility to aggregation and retention;
- increase in PON1;
- protection against oxidation of LDL;
- reduction in the activity of angio-tensin converting enzyme ("ACE"), an enzyme which produces "angiotensin II", a protein that causes blood vessels to constrict;
- lowering of systolic blood pressure;
- reduction in CIMT; and
- increase blood flow or myocardial perfusion.

(RFF 1089-1099; PX0025; PX0192; PX0004, PX0005, CX0611, PX0014, PX0020, PX0021, PX0023, PX0038, PX0127, CX0934).

In total, Respondents' human clinical studies confirm and support the benefits found in the basic and animal research and together, the totality of the evidence constitutes competent and reliable scientific evidence that pomegranate juice and/or its extracts promote cardiovascular health by, among other things, helping to reduce arterial plaque, lower blood pressure, and improve blood flow. (PX0004, PX0005, CX0611, PX0014,

PX0020, PX0021, PX0023, PX0038, PX0127, CX0934, PX0002, PX0007, PX0008, PX0009, PX0010, PX0015, CX0543, PX0017, PX0022, CX0053, PX0055, PX0056, PX0057, PX0058, PX0059)).

The Aviram CIMT/BP Study (2004) and Davidson CIMT Study (2009) constitute competent and reliable scientific evidence that the consumption of the Challenged Products are beneficial to cardiovascular health by, among other things, reducing arterial plaque. (RFF 1111-1126; 1139-1146; 1288-1302; 1427-1504; PX0014; PX0611; PX0025-0009-0010; 0019-0022; PX0192-0036-0037, 0039; 0048, 005; Heber Tr. 1979-86; PX0014).

The Ornish MP Study (2005) constitutes competent and reliable scientific evidence that the consumption of the Challenged Products are beneficial to cardiovascular health by, among other things, improving blood flow. (RFF 1127-1138; 1303-1414; PX0023; PX0025-0011-0018; PX0192-0037-0038; 0053, Ornish, Tr. 2354-55).

The Aviram ACE/BP Study (2001) and Aviram CIMT/BP Study (2004) constitute competent and reliable scientific evidence that the consumption of the Challenged Products are beneficial to cardiovascular health by, among other things, improving blood pressure. (RFF 1107-1126; 1280-1302; CX0542; CX0611; PX0025-0009-0011; PX0192-0035-0037; 0052).

2. Heart Disease Studies

a. Aviram Studies

788. Dr. Aviram is a professor and head of the Lipid Research Laboratory, Technion Faculty of Medicine, Rappaport Institute for Research in the Medical Sciences and Rambam Medical Center, in Haifa, Israel. (CX1116_0001).

Response to Finding No. 788:

Respondents have no specific response.

789. Dr. Aviram has a Ph.D. in biochemistry. (CX1116_0001). He is not a medical doctor. (CX1116_0001; CX1363 (S. Resnick, TCCC Dep. at 64)).

Response to Finding No. 789:

Respondents have no specific response other than to object to the extent Complaint Counsel implies that Dr. Aviram's scientific research is inferior or inadequate because he is not a medical doctor. 1067. Dr. Aviram is considered an internationally renowned researcher, pioneer, and one the leading experts in the world on cholesterol, lipid oxidation and the protective role of dietary antioxidants related to cardiovascular disease. (RFF 1067; Heber, Tr. 1957-58). Dr. Frank Sacks, Complaint Counsel's expert on cardiovascular health, acknowledges that Dr. Aviram does good basic science and that Technion is a good research institution. (RFF 1068; Sacks, Tr. 1571).

790. Dr. Aviram has worked with Respondents since 1998. (CX1358 (Aviram, Dep. at 4)). Respondents have paid Dr. Aviram approximately $4 million dollars for his retainer, research, and consulting fees. (CX1276_0003-04; S. Resnick, Tr. 1641-42; *see also* CX1380_0005 (Response to Request for Admission No. 42); CX1358 (Aviram, Dep. at 66-72) (testifying he was paid between $350,000 to $500,000 per year for his research, including a retainer for his services); CX1353 (Tupper, Dep. at 268) (stating he expected Dr. Aviram to join a meeting with the FTC for free in consideration of payment for his services); CX1349 (Gillespie, Dep. at 265-67) (agreeing that Aviram would be paid a $150,000 retainer and an additional $150,000 for research)). POM would also pay Dr. Aviram for any "a-la-carte analytical projects." (CX1349 (Gillespie, Dep. at 266-67).

Response to Finding No. 790:

Respondents object to Complaint Counsel's proposed Finding No. 790 to the extent it implies that Dr. Aviram, not his institute or university, somehow directly received funding to conduct scientific research. Regardless of whatever funding received by Dr. Aviram and/or the Technion Institute during the past 14 years, there is absolutely no evidence in the record challenging the integrity or credibility of Dr. Aviram's research. In fact, Dr. Aviram testified that Mr. Resnick "always said that 'I like you to have truth and only the truth.'" (CX1348 (Aviram, Dep. at 128-29)). In addition, Mr. Resnick has never improperly interfered with the publication of any report or dictated the

contents of a report. (CX1372 (S. Resnick, Tropicana Dep. at 33)). Mr. Resnick has never asked or told any scientist or researcher not to publish a manuscript or report. (CX1360 (S. Resnick, Dep. at 75); CX1358 (Aviram, Dep. at 76); CX1339 (Ornish, Dep. at 85)). CX1380 does not support the proposition that Dr. Aviram received "approximately $4 million dollars for his retainer, research, and consulting fees."

791. Dr. Aviram also served as an expert endorser for Respondents, providing POM with quotes for marketing and advertising materials for the POM Products. For example, on June 30, 2006, Dr. Aviram provided POM with a quote that "[POMx] is a better protector against cardiovascular and other disease, than pomegranate juice." (CX0813 0001). On January 22, 2007, Dr. Dreher asked Dr. Aviram to provide a statement to "support our structure-function claim that POMx promotes cardiovascular health" for POM's files. (CX0865; CX1358 (Aviram, Dep. at 50-51)). In response, Dr. Aviram provided a statement describing his studies on pomegranates and stating "in my opinion it is justified to claim that POMx . . . indeed promotes cardiovascular health." (CX0865_003; CX1358 (Aviram, Dep. at 50-51)).

Response to Finding No. 791:

Respondents object to the characterization of Dr. Aviram as an "expert endorser" as contrary to the evidence cited. As the emails and testimony make clear—he was asked to provide a statement similar to what was suggested (with whatever changes he felt appropriate) for use in the company's file and not for submission to any federal agency. (CX0813, 0865; CX1358 (Aviram, Dep. at 50-51)). It was also his opinion of the state of the research which he believed showed a robust effect of pomegranate juice and POMx on cardiovascular health.

792. Despite giving these statements to POM to be used in publicity, at his deposition in March 2011, Dr. Aviram admitted that "[v]ery little was done with POMx" and that he could not confidently say POMx would work the same as POM Juice before testing it. (CX1358 (Aviram, Dep. at 48)). Indeed, in May 2009, Dr. Aviram stated that "I feel that it is important to learn more about the relationships between POM ([Juice], and the Pill, which, unlike PJ, we know very little on it from mechanistical point of view) . . . ." (CX1060_0001; CX1358 (Aviram, Dep. at 48)).

Response to Finding No. 792:

Respondents object to the proposed finding as contrary to the evidence cited. As the emails and testimony make clear—he was actually noting that he personally had done very little work on POMx but others had done quite a bit, including the equivalency studies conducted by Dr. Heber, Rock and others. (CX1358 (Aviram, Dep. at 47-52)). He noted that he is a basic science and mechanism based scientist and so he wants to know exactly how something works thus his interest in studies performed with POMx. But as noted in his testimony, it was clear to him that the research showed a robust effect of pomegranate juice and POMx on cardiovascular health. He just simply wanted to see the same tests performed with POMx to see if the mechanism of action was identical. (CX1358 (Aviram, Dep. at 47-52)).

793. Dr. Aviram conducts primarily mechanistic studies (*in vitro* and animal studies) and pilot human studies (studies on a small number of patients). (CX1363 (S. Resnick, TCCC Dep. at 69) ("[H]e does a lot of the research in the mechanistic, of how it works and why it works and the cellular levels . . . different measures of all things around cholesterol and heart issues"); CX1358 (Aviram, Dep. at 17); *see also* CX1029_0002 (POM Medical Research Portfolio describing Aviram's heart disease research as "mechanistic.")). As Dr. Aviram explained in his deposition, "I always do my human studies on a small number of patients because that's my profession. I'm a biochemist, a basic scientist. I'm interested in mechanism of action, and I want to show that this mechanism of action has relevance to the disease itself, to the cardiovascular disease, to the atherosclerosis process." (CX1358 (Aviram, Dep. at 17)).

Response to Finding No. 793:

Dr. Aviram testified that if a pilot study is preceded by good mechanistic studies, including *in vitro*, cell culture, test tube, or animal studies, then a subsequent study on a small number of human subjects is simply called a "pilot" study. (CX1348 (Aviram, Dep. at 17)). Dr. Aviram considers pilot studies to be positive and disputes that a pilot study cannot be good enough to substantiate a claim. (CX1348 (Aviram, Dep. at 17)). A study with a small number of subjects or conducted without a placebo does not weaken the importance of the result, especially if the results are in agreement with previously

published, findings conducted through *in vitro*, mechanistic, and animal models. (CX1348 (Aviram, Dep. at 18)).

As Dr. Ornish testified, a very well-designed animal study may actually provide a higher level of evidence than a poorly designed human study. (PX0355 (Ornish, Dep. at 65)). Dr. Sacks admits there is value in conducting *in vitro* studies and animal studies because it is possible to isolate mechanisms of action and accomplish toxicity or safety testing. (PX0361 (Sacks, Dep. at 89-91)). In an animal study, Dr. Sacks acknowledges that researchers can examine specific mechanisms by taking out their organs and cells, which you cannot do in humans. (PX0361 (Sacks, Dep. at 91)). Pilot studies and non-double blind, placebo-controlled studies are valid, accurate, and reliable studies and generally considered by other scientists and clinicians in the scientific community to be valid. (CX1336 (Davidson, Dep. at 232-33)).

794. Among other things, Respondents commissioned Dr. Aviram to conduct two small human studies to explore mechanisms involving patients with heart disease and their reaction to pomegranate juice: (1) Aviram M. and Dornfeld L., *Pomegranate juice consumption inhibits serum angiotensin converting enzyme activity and reduces systolic blood pressure*, 158 Atherosclerosis 195 (2001) ("**Aviram ACE/BP Study (2001)**") (CX0542; *see* JX0003 ¶ B.15); and (2) Aviram M, *et al.*, *Pomegranate juice consumption for 3 years by patients with carotid artery stenosis reduces common carotid intima-media thickness, blood pressure and LDL oxidatio*n, 23 Clin. Nutr. 423 (2004) ("**Aviram CIMT/BP Study (2004)**") (CX0611; *see* JX0003 ¶ B.15).

Response to Finding No. 794:

Respondents have no specific response.

795. Dr. Aviram's human studies were small exploratory pilot studies that were unblinded and not placebo-controlled. (CX1358 (Aviram, Dep. at 12-13, 28); *see also* PX0353 (Heber, Dep. at 173) (agreeing that Dr. Aviram's studies were unblinded and uncontrolled)). The purpose of these human studies was to confirm his mechanistic and animal studies. (CX1358 (Aviram, Dep. at 28)).

Response to Finding No. 795:

Respondents object to Complaint Counsel's proposed Finding No. 795 on the grounds that is overbroad, vague and ambiguous as to the meaning of "small exploratory studies," lacks foundation, and misstates the record. Respondents incorporate by reference their response to Complaint Counsel's proposed Finding No. 793.

As the record demonstrates, Dr. Sacks acknowledges that some of Respondents' *in vitro* studies have shown pomegranate juice's favorable effects on the mechanisms involved in cardiovascular disease and that *in vitro* studies, like Dr. Aviram's, can be competent and reliable evidence of an agent's effect on a particular mechanism. (Sacks, Tr. 1578). For example, Dr. Sacks agrees that Dr. Aviram's *in vitro* studies showed that pomegranate juice inhibits macrophage uptake of oxidized LDL, which is one component of atherosclerosis, and a significant reduction in atherosclerotic vessels. (Sacks, Tr. 1572; 1579). Dr. Sacks also concedes that Dr. Aviram's animal studies have demonstrated favorable effects for pomegranate juice in promoting cardiovascular health. (Sacks, Tr. 1578-79).

Dr. Sacks concedes that blinding is one component of a good study design, but acknowledges, that in some instances, the blinding of patients is not possible and if a study becomes unblinded, it can still have value. (Sacks, Tr. 1435; PX0 361(Sacks, Dep. at 104-105)). Dr. Sacks agrees that some studies cannot be conducted with a placebo, ***i.e.*** foods and nutrients, and a study is not thrown out because it does not have a placebo.(PX0361 (Sacks, Dep. at 111, 137)).

There is a common misconception that a larger study is a better study, but the opposite can be argued. (Ornish, Tr. 2362; PX1339 (Ornish, Dep. at 22-23)). When a study has a smaller number of patients, the treatment has to be that much more powerful and that much more consistent for it to be statistically significant. (Ornish, Tr. 2362-63; PX1339

(Ornish, Dep. at 22-23)). A pilot study simply means that a researcher is conducting a study that has not been done before, but that does not mean that it is not as scientifically valid as a larger study. (PX1339 (Ornish, Dep. at 23; 119-20)).

(1) Aviram ACE/BP Study (2001)

(a) About the Study

796. In the Aviram ACE/BP Study (2001), ten elderly patients with high blood pressure drank 50 ml of pomegranate concentrate daily, for two weeks. (CX0542_002; CX1358 (Aviram, Dep. at 21) (Respondent POM provided the concentrate)). In addition to being unblinded (CCFF ¶ 795), the study had no control group; instead, each patient's "before" measures were compared to his or her "after" measures. (CX1358 (Aviram, Dep. at 22-24); CX0025_0012 (describing study design as "uncontrolled"); CX1339 (Ornish, Dep. at 66) (agreeing sample size was small and study was controlled)).

Response to Finding No. 796:

Respondents dispute the characterization of the Aviram ACE/BP Study (2001) as described in Complaint Counsel's proposed finding to the extent it insinuates that the Aviram ACE/BP Study (2001) purportedly lacks validity. Dr. Aviram testified that the use of each patient as his or her own control and without a placebo represents another method to conduct an animal or human study, but is not a less appropriate method. (RFF 1282; CX1348 (Aviram, Dep. at 12-13)). Indeed, Complaint Counsel's expert, Dr. Sacks, concedes that a group taking nothing can serve as a control. (RFF 1298). Secondly, a study with a small number of subjects or conducted without a placebo does not weaken the importance of the result, especially if the results are in agreement with previously published, findings conducted through *in vitro*, mechanistic, and animal models. (RFF 1285; CX1348 (Aviram, Dep. at 18)). The real issue or reason studies are blinded is the expectation that something might have a positive benefit can sometimes be self-fulfilling, but in this case, there is no reason why the subjects would have necessarily thought that, even if they knew they were drinking pomegranate juice that was likely to provide them a benefit. (RFF 1396). Complaint Counsel expert Dr. Sacks concedes that blinding is one component of a good study design, but acknowledges, that in some

instances, the blinding of patients is not possible and if a study becomes unblinded, it can still have value. (Sacks, Tr. 1435; PX0361 (Sacks, Dep. at 104-105)). Finally, if Dr. Aviram's study design was not sufficient, no peer-reviewed journal would have published the study. (RFF 1302).

797. This study measured angiotensin-converting enzyme ("ACE") activity and blood pressure. (CX0542_0001). ACE is an enzyme that alters the function of angiotensin, which relates to blood pressure for each patient. (Stampfer, Tr. 742). POM's own website explained, "ACE inhibitors make blood vessels relax, helping lower blood pressure and allowing more oxygen-rich blood to reach the heart." (CX0473 (Compl. Ex. E-2 at 04:15)).

Response to Finding No. 797:

Respondents have no specific response.

798. According to the published article, seven of the ten patients experienced a statistically-significant 36% reduction in serum ACE activity from their baseline measure. (CX0542_0001). The article does not reveal what happened to the ACE levels of the other three patients or analyze the overall results in all ten patients. (CX1291 (Sacks, Report at 0016-17); CX0542_0002-03; *see also* Stampfer, Tr. 741-42; CX1293 (Stampfer, Report at 0017-18)). Dr. Aviram testified that there was "no effect" from pomegranate juice on the other three patients' ACE levels. (CX1358 (Aviram, Dep. at 23)).

Response to Finding No. 798:

Respondents have no specific response.

799. The article reports that all ten patients experienced a statistically significant 5% reduction in systolic blood pressure from their baseline blood pressure measure. (CX0542_0002-03; CX1291 (Sacks, Report at 0016-17)).

Response to Finding No. 799:

Respondents have no specific response.

800. The article concludes that, "pomegranate juice consumption can offer a wide protection against cardiovascular disease." (CX0542_0003). Dr. Aviram stated that this was his "thinking" and "opinion." (CX1358 (Aviram, Dep. at 26)).

Response to Finding No. 800:

Respondents disputes portions of this proposed finding as contrary to the evidence in the record. Complaint Counsel takes Dr. Aviram's testimony out of context and do not consider and/or provide the entirety of Dr. Aviram's testimony regarding the conclusion that "pomegranate juice consumption can offer a wide protection against cardiovascular disease." In the full testimony cited in this proposed finding, Dr. Aviram states: "What I am saying is that in every paper you have several parts: You start with the introduction, you move on to methods, you move on to results, you finish with discussion. Discussion is where you have to put your thinking and, even if you think that this may say too much in your opinion, that's the place where, in discussion, you do." (CX1358 (Aviram, Dep. at 26)). Respondents further dispute this proposed finding to the extent Complaint Counsel seeks to devalue the scientific conclusions reached by the primary researcher.

801. The co-author of this study was Leslie Dornfeld, POM's former medical director and personal family doctor of the Resnicks, which was not disclosed in the study. (CX0542_0001; CCFF ¶ 158; CX1375 (L. Resnick, TCCC Dep. at 32)).

Response to Finding No. 801:

Respondents object to the extent Complaint Counsel insinuate that Dr. Dornfeld's affiliation as the personal family doctor of the Resnicks, somehow suggests he was biased or that the study was not a scientifically valid, peer-reviewed and published study. Dr. Dornfeld, like every author on the Aviram ACE/BP Study, listed only their academic affiliation which is commonly done on research papers. (CX1350 (Liker, Dep. at 98)).

(b) Expert Analysis

802. Drs. Sacks and Stampfer opined that: (1) the sample size of ten patients is too small to provide reliable evidence that the observed effects would be generally applicable to a larger population (CX1291 (Sacks, Report at 0017); Stampfer, Tr. 748); (2) the two-week period of the study was too short to provide reliable evidence that the reported improvement in ACE activity and blood pressure would be enduring. (CX1291 (Sacks, Report at 0017); *see also* Stampfer, Tr. 748); and (3) ACE (one of the study endpoints) is not a recognized surrogate marker of cardiovascular disease. (CX1291 (Sacks, Report at 0017)).

Response to Finding No. 802:

Respondents dispute this proposed finding as Complaint Counsel expert's opinions noted in this proposed finding is without merit and not supported by the evidence in the record. Respondents expert Dr. Ornish states that Dr. Aviram's study should be viewed in the larger context of other studies in this area, as its findings are congruent with and supportive of other research. (PX0025-0009). Dr. Ornish also testified, that there is a common misconception that a larger study is a better study, but the opposite can be argued. (RFF 1249). In fact, with a smaller number of patients, the treatment has to be more powerful and consistent in order to show a statistically significant effect. (RFF 1250) Finally, a study with a small number of subjects or conducted without a placebo does not weaken the importance of the result, especially if the results are in agreement with previously published, findings conducted through *in vitro*, mechanistic, and animal models. (CX1348 (Aviram, Dep. at 18); RFF 1285). Complaint Counsel's suggestion that ACE is not a reliable function/marker for cardiovascular disease is false, given that a reduction in ACE results in lower blood pressure, which is universally accepted as a surrogate for CVD.

803. Although blood pressure reduction is a validated surrogate for heart disease, this study does not provide competent and reliable evidence to support a heart benefit claim, because it was not a blinded, placebo-controlled study. (Sacks, Tr. at 1453; CX1291 (Sacks, Report at 0017); Stampfer, Tr. 748, 771; CX1293 (Stampfer, Report at 0019)). Given the lack of a control group, it is not possible to conclude what caused the reported improvements in the subjects' blood pressure levels. (CX1291 (Sacks, Report at 0017); Sacks, Tr. at 1452-54; *see also* Stampfer, Tr. 748, 771). Without a control group, this study was simply an observational study on patients given pomegranate juice concentrate. (CX1291 (Sacks, Report at 0017)).

Response to Finding No. 803:

Respondents dispute Complaint Counsel's proposed Finding No. 802 as contrary to the evidence in the record. As explained by Respondents' experts, the totality of scientific evidence should be examined, not just RCTs, given that: (1) pomegranate juice and its

extracts are safe; (2) no one suggests that pomegranate juice or its extracts should be offered in lieu of conventional medical treatment or surgery; (3) the expenses associated for conducting a FDA drug study for a non-patentable, natural food is exorbitant and prohibitive; and (4) the potential benefit or information gained by the public outweighs any plausible harm. (RFF 1184-1205). As Dr. Davidson testified RCTs are not the only kinds of studies considered to be valid. (CX1336 (Davidson, Dep. at 232)). Pilot studies and non-double blind, placebo-controlled studies are valid, accurate, and reliable studies and generally considered by other scientists and clinicians in the scientific community to be valid. (CX1336 (Davidson, Dep. at 232-33)).

The use of each patient as his or her own control and without a placebo represents another method to conduct an animal or human study, but is not a less appropriate method. (CX1348 (Aviram, Dep. at 12-13)). Complaint Counsel's expert Dr. Sacks also agrees that a group taking nothing can serve as a control. (RFF 1298).

Additionally, Complaint Counsel's expert, Dr. Sacks, concedes that a causal influence cam be demonstrated between an agent and its effect on humans without the use of RCTs. (RFF 647). Dr. Sacks testified that you don't need RCT trials to test the benefit of food categories that are included in a diet already tested, like the DASH diet, which includes pomegranates.(RFF 648). Further, a study is not thrown out because it is does not have a placebo control. (RFF 654). Dr. Ornish noted most of Dr. Sacks' published studies have been epidemiological and observational in nature, rather than RCTs, and include relatively small numbers of patients. (RFF 1186).

Finally, the fact that the Aviram ACE/BP Study (2001) is a published peer-reviewed study after being subjected to the usual rigors of the peer review process is significant indication that it is taken seriously by other scientists, i.e., that it meets at least the minimal criteria of good science. (RFF 391; 394). If the study design was not good

enough, no peer-reviewed journal would have published Dr. Aviram's study. (CX1348 (Aviram, Dep. at 28)).

804. Respondents' expert Dr. Ornish agreed with Drs. Sacks and Stampfer that "this study was limited in scope." (PX0025 (Ornish, Report at 0009); *see also* Heber, Tr. 2094-95 (describing study as "exploratory")).

Response to Finding No. 804:

Respondents object to this proposed finding on the ground that Complaint Counsel does not consider the entirety of Dr. Ornish's expert opinion. Dr. Ornish continues to state that Dr. Aviram's study "should be viewed in the larger context of other studies in this area, as its findings are congruent with and supportive of other research." Dr. Ornish next cites a recent review article where, "There was some evidence to suggest that fruits containing relatively high concentrations of flavonols, anthocyanins and procyanindins, such as pomegranate, purple grapes and berries, were effective at reducing CVD risk factors, particularly with respect to anti-hypertensive effects, inhibition of platelet aggregation and increasing endothelial-dependent vasodilation than other fruits investigated." Dr. Ornish then states that an RCT of adolescents with metabolic syndrome found that flowmediated dilation (a measure of vascular health) improved significantly at 4 hours and at 1 month. (PX0025 (Ornish, Report at 0009).

Respondents further dispute this proposed finding as contrary to the record evidence to the extent it seeks to disregard the fact that pilot studies and non-double blind, placebo-controlled studies are valid, accurate, and reliable studies and generally considered by other scientists and clinicians in the scientific community to be valid. (CX1336 (Davidson, Dep. at 232-33)). Respondents incorporate by reference their response to Complaint Counsel's proposed Finding No. 803. (*See also* RFF 1212-1251; 1280-1287).

(2) Aviram CIMT/BP Study (2004)

(a) About the Study

805. In the Aviram CIMT/BP Study (2004), a group of ten patients with severe carotid artery stenosis consumed 50 ml of concentrated pomegranate juice daily for one year and five of them continued for up to three years. (CX611_0001-02). Dr. Aviram described the study population as "people who [were] very sick." (CX1358 (Aviram, Dep. at 28); JX0003 ¶¶ A.3-4).

Response to Finding No. 805:

Respondents dispute portions of this proposed finding as Complaint Counsel does not provide and/or consider the entirety of Dr. Aviram's testimony in the quoted passage. In the testimony cited, when asked whether the control group received any treatment, Dr. Aviram responded by stating "you cannot stop the treatment that such patients with carotid arteries stenosis are getting. They are getting high-potency drugs. They are getting drugs if they are diabetic. They are people who are very sick. So we don't stop whatever they take, but they continue to take the same drugs." (CX1358 (Aviram, Dep. at 28)).

806. A second group of nine patients who did not consume pomegranate juice acted as a "control." (CX0611_0002). The article sometimes described the two groups as "randomized" and at other times as "matched." (CX0611_0002, 0004). Dr. Aviram testified that he decided who should go into the control group, by trying to "match" control group participants to active group participants based on characteristics such as age, gender, and medical drug use. (CX1358 (Aviram, Dep. at 29)).

Response to Finding No. 806:

Respondents have no specific response.

807. Although the study report sometimes used the term "placebo" to refer to this control group, no actual placebo was used in this study. (CX0611_0002, 06; CX1358 (Aviram, Dep. at 28)). Dr. Ornish and Mr. Resnick acknowledged this study was not placebo-controlled. (PX0355 (Ornish, Dep. at 106); CX1339 (Ornish, Dep. at 66); CX1360 (S. Resnick, Dep. at 201) (indicating he did not believe this study was placebo-controlled); *see also* CX1350 (Liker, Dep. at 89) (control group did not drink a placebo)). The study also was unblinded. (CX1358 (Aviram, Dep. at 31)).

Response to Finding No. 807:

Respondents object to Complaint Counsel's proposed Finding No. 807 on the grounds that it lacks foundation and misstates the record. Dr. Aviram's deposition testimony does not support the proposition that the Aviram CIMT/BP Study (2004) was not placebo-controlled. Similarly, Mr. Resnick never "acknowledged" the Aviram CIMT/BP Study (2004) was not placebo-controlled in his deposition. (CX1360 (S. Resnick, Dep. at 201)). Complaint Counsel's proposed fact, therefore, is a gross misstatement of the record.

In any event, Respondents further object to the extent Complaint Counsel insinuate the study lacks merit because it purportedly was "unblinded and not placebo controlled." (RFF 1289-1302). As Dr. Ornish testified, "there's common sense" at work here and "the lack of a control group in and of itself doesn't mean that there's no useful information or validity to the study." Dr. Ornish goes on to state that it would be an extreme statement to say some other factor caused the improvement in arterial plaque when there was no other factor that was reported. (PX0355 (Ornish, Dep. at 106)).

808. The patients in the two groups received dissimilar treatment. Patients in the first group (pomegranate juice group), had "blood analyses and echo Doppler of the carotid arteries performed at the beginning of the study and 3, 6, 9, 12, 22, 28 and 36 months after PJ consumption." For the second "control" group, "echo Doppler of the carotid arteries was only performed at the beginning of the study and after 1 year." (CX0611_0002; CX1358 (Aviram, Dep. at 29-30)).

Response to Finding No. 808:

In his deposition, Dr. Aviram clarified that for the second control group, the echo Doppler of the carotid arteries was performed at the beginning of the study and after 1 year because for the control group the expected IMT was about a 10% increase every year. (CX1358 (Aviram, Dep. at 29-30)). Dr. Aviram's calculations turned out to be correct. (CX0611_0004). Dr. Sacks provided no expert testimony at trial or in his report

in support of this proposed fact. As a result, no negative conclusions can be drawn from this proposed fact.

809. The article reports that in the group of patients that consumed pomegranate juice, mean CIMT was reduced by 35% at 12 months in comparison to their baseline values. (CX0611_0004). It should be noted that the abstract stated instead that "PJ consumption resulted in a significant CIMT reduction, *by up to 30%*, after 1 year." (CX0611_0001 (emphasis added)). No additional improvements in CIMT were seen in the five patients who continued drinking the juice for two additional years. (CX0611_0002). In the nine patients who did not consume pomegranate juice, their mean CIMT increased by 9% over one year when their one year measurement was compared to a baseline measurement. (CX0611_0001-02, 04, 08).

Response to Finding No. 809:

No inferences can be drawn from Complaint Counsel's citation to the 30% and 35% calculations given that the 30% figure cited in the abstract does not explain whether this was a "mean" calculation or some other measure. (CX0616_0001, 0004). In addition, Dr. Sacks provided no expert testimony on this issue and, therefore, no negative conclusions can be drawn from this alleged observation.

810. The article reports that the pomegranate juice group members' systolic blood pressure was significantly ($p < 0.05$) reduced by *12%* after one year of PJ consumption compared to their baseline values. (CX0611_0005). By contrast, the abstract stated instead that systolic blood pressure was reduced after one year of PJ consumption by *21%* . (CX0611_0001). In the group that did not consume pomegranate juice, blood pressure was unchanged. (CX0611_0005).

Response to Finding No. 810:

It appears that the 21% figure cited in the abstract was subsequently corrected to 12% based upon a review of the PubMed.gov website (www.ncbi.nlm.nih.gov/pubmed/15158307) and erratum in Clin Nutr. 2008 Aug; 27(u):671.

811. The CIMT and blood pressure changes described above are all *within-group* analyses. (Sacks, Tr. 1456-57). The article did not provide any *between-group* statistical analysis, that is, analysis of changes in CIMT and blood pressure between the active and control groups at the end of the study. (Sacks, Tr. 1456-57; CX0163_0017 (stating that between group analysis was not performed for any of the outcomes)). Dr. Aviram explained that

each subject in the study served as his or her own control. (CX1358 (Aviram, Dep. at 27-28, 32)).

Response to Finding No. 811:

Dr. Sacks did not provide any expert testimony in his report regarding this issue. The use of each patient as his or her own control and without a placebo represents another method to conduct an animal or human study, but is not a less appropriate method. (RFF 1282; CX1348 (Aviram, Dep. at 12-13)). Indeed, Complaint Counsel's expert Dr. Sacks concedes that a group taking nothing can serve as a control. (RFF 1298).

812. The article concludes that, "[c]linical trials are now needed to further prove the beneficial effect of dietary antioxidants in general and of flavonoid-rich antioxidants in particular in patients with cardiovascular diseases." (CX0611_0009).

Response to Finding No. 812:

It is standard practice among researchers to qualify studies with language such as "further studies are required" regardless of the results. (deKernion, Tr. 3103-04). This fact does not diminish the value of Dr. Aviram's study which was the first study ever published indicating that pomegranate juice may affect the progression of carotid atherosclerosis. (PX0025-0011). The study confirmed that, "as previously shown in atherosclerotic mice also in humans pomegranate juice consumption (by patients with carotid artery stenosis) possess anti-atherosclerotic properties, as it substantially decreased serum oxidative stress and, in parallel, reduced common carotid intima-media thickness." (CX0611_0031). Science usually progresses when someone publishes a study of a series of patients with a non-randomized control group that shows an unprecedented finding which is then replicated by one or more subsequent randomized controlled trials, such as the one published by Dr. Davidson. (PX0025-0011). The study reported significant reductions in carotid IMT decreased systolic blood pressure, and a substantial inhibition of lipid peroxidation in serum and in LDL. (PX0025-0011).

813. The article identified co-author Dr. Liker as being from the David Geffen School of Medicine. (CX0611_0001). It did not disclose his position as the Medical Director of Respondents Roll and POM. (Liker, Tr. 1930; CX1350 (Heber, Dep. at 92, 98-99)).

Response to Finding No. 813:

Respondents object to proposed Finding No. 813 to the extent Complaint Counsel implies that Dr. Liker's affiliation as the Medical Director for Respondents Roll and POM somehow invalidates the results of the Aviram CIMT/BP Study (2004). Dr. Liker, like every author on the Aviram CIMT/BP Study listed only their academic affiliation which is commonly done on research papers. (CX1350 (Liker, Dep. at. 98)).

(b) Expert Analysis and Respondents' Understanding of the Study

814. Dr. Sacks concluded that, given the lack of a randomized, placebo-controlled group, the fact that the patients in the active and "control" groups received different treatment, the small sample size, and the lack of any between-group statistical analysis, a qualified scientist would not be able to conclude with any credibility that the reported improvements in the treatment group were caused by their consumption of pomegranate juice and not some other factor. (Sacks, Tr. at 1459, 1585 ("the control group did not receive anything . . . there was no placebo or control substance or control agent given"); CX1291 (Sacks, Report at 0019)).

Response to Finding No. 814:

Respondents dispute Compliant Counsel's proposed finding as the conclusion reached by Complaint Counsel's expert Dr. Sacks is unsupported by the record evidence.

First, the lack of placebo does not support Dr. Sack's contention that a qualified scientist would not be able to conclude with any credibility that the reported improvements in the treatment group were caused by their consumption of pomegranate juice. Dr. Sacks agreed that some studies cannot be conducted without a placebo, i.e. foods and nutrients, and a study is not thrown out because it does not have a placebo. (RFF 1248). Although he complains this study lacked a control group, Dr. Sacks admits that a group taking nothing can serve as a control. (Sacks, Tr. 1585-86). Dr. Sacks, concedes that a causal

influence can be demonstrated between an agent and its effect on humans without the use of RCTs. (RFF 647; PX0361 (Sacks, Dep. at 134-135)).

Second, the study's small sample size does not support Dr. Sack's contention that a qualified scientist would not be able to conclude with any credibility that the reported improvements in the treatment group were caused by their consumption of pomegranate juice. There is a common misconception that a larger study is a better study, but under some circumstances, a relatively small study can be more informative than a large study. (RFF1122, 1249).. Dr. Aviram's study reported significant reductions in carotid IMT, decreased systolic blood pressure, and a substantial inhibition of lipid peroxidation in serum and in LDL. (RFF 1292). These findings are all the more astounding given the relatively small number of participants because when a study has small numbers of patients, the treatment has to be that much more powerful and that much more consistent for it to be statistically significant. (RFF 1250).

Third, Dr. Sacks opinion with respect to the lack of between-group statistical analysis is improper. Dr. Sacks did not properly raise this opinion in his expert report. Therefore, because the opinion was not properly offered Complaint Counsel cannot use it as a basis to support any contentions about Dr. Aviram's study. This was issue was not raised in Dr. Sacks in his expert reportFurthermore, Dr. Sacks testified that you do not need RCT trials to test the benefit of food categories that are included in a diet already tested, like the DASH diet, which includes pomegranates. (RFF 648; Sacks, Tr. 1545-46). Dr. Ornish noted that most of Dr. Sacks' published studies have been epidemiological and observational in nature, rather than RCTs, and include relatively small numbers of patients. (RFF 1186; PX0025-0007). Dr. Sacks concedes that he has no basis to disagree with Dr. Aviram's numbers. (Sacks, Tr. 1589-90; RFF 1299). Dr. Sacks confirms that the CIMT test is "a worthy test" and is relevant to cardiovascular health. (Sacks, Tr. 1589-90)(RFF 1300). According to Dr. Sacks, CIMT is an indicator that the treatment

may be beneficial and, in this case, the treatment was pomegranate juice. (Sacks, Tr. 1590; RFF 1301).

Dr. Aviram's study was the first study ever published indicating that pomegranate juice may affect the progression of carotid atherosclerosis. (PX0025-0011). The study confirmed that, "as previously shown in atherosclerotic mice also in humans pomegranate juice consumption (by patients with carotid artery stenosis) possess anti-atherosclerotic properties, as it substantially decreased serum oxidative stress and, in parallel, reduced common carotid intima-media thickness." (CX0611_0031). Science usually progresses when someone publishes a study of a series of patients with a non-randomized control group that shows an unprecedented finding which is then replicated by one or more subsequent randomized controlled trials, such as the one published by Dr. Davidson. (RFF 1291; PX0025-0011). The study reported significant reductions in carotid IMT decreased systolic blood pressure, and a substantial inhibition of lipid peroxidation in serum and in LDL. (RFF 1292; PX0025-0011).

815. Similarly, Dr. Stampfer concluded this study does not support Respondents' heart disease prevention and treatment claims or their lower blood pressure claims. (CX1293 (Stampfer, Report at 0018)).

Response to Finding No. 815:

As an initial matter, Respondents object to the "heart disease prevention and treatment claims" and "blood pressure claims" as vague, ambiguous, overly broad, and argumentative. Furthermore, POM never states, expressly or by implication, conspicuously on the face of any of the Challenged Ads that scientific tests "prove" that the Challenged Products "prevent, treat or reduce the risk of heart disease or even that they "prevent, treat or reduce the risk of heart disease." (Appendix of Adveritsements). Throughout its advertising, POM highlights that POM Juice is a 100% juice product wholly-derived from the pomegranate fruit, and that POMx has the same content as the

pomegranate fruit itself and is 100% derived from the exact same fruit. (*See* RFF 494). Indeed, Respondents have never advertised their products as a pharmaceutical drug, nor intended to advertise their products as drugs. (RFF 495-96). Rather, Respondents have always marketed the Challenged Products for what they intrinsically are: whole-food products. (RFF 497-99). Accordingly, it is far more logical (and the evidence demonstrates) that reasonable consumers would view the Challenged Products the way they perceive any other extremely healthy whole food, like broccoli, blueberries, grapes or tomatoes, which may help prevent or improve your odds against heart disease disease and high blood pressure, but which would not "stop" anything, like a drug with a single target of action against a particular disease or condition.

Furthermore, Dr. Stampfer's assertion that the data from Dr. Aviram's "small pilot" study alone does not provide a sufficient basis for Respondents alleged heart disease prevention and treatment claims. (CX1293_0001). There is a common misconception that a larger study is a better study, but under some circumstances, a relatively small study can be more informative than a large study. (RFF1122, 1249).. Dr. Aviram's study reported significant reductions in carotid IMT, decreased systolic blood pressure, and a substantial inhibition of lipid peroxidation in serum and in LDL. (RFF 1292). These findings (including the blood pressure data showing a reduction of 12% after one year) are all the more astounding given the relatively small number of participants because when a study has small numbers of patients, the treatment has to be that much more powerful and that much more consistent for it to be statistically significant. (RFF 1250). Moreover, Dr. Aviram's study was the first study ever published indicating that pomegranate juice may affect the progression of carotid atherosclerosis. (PX0025-0011). The study confirmed that, "as previously shown in atherosclerotic mice also in humans pomegranate juice consumption (by patients with carotid artery stenosis) possess anti-atherosclerotic properties, as it substantially decreased serum oxidative stress and, in parallel, reduced

common carotid intima-media thickness." (CX0611_0031). Science usually progresses when someone publishes a study of a series of patients with a non-randomized control group that shows an unprecedented finding which is then replicated by one or more subsequent randomized controlled trials, such as the one published by Dr. Davidson. (RFF 1291; PX0025-0011). The study reported significant reductions in carotid IMT decreased systolic blood pressure, and a substantial inhibition of lipid peroxidation in serum and in LDL. (RFF 1292; PX0025-0011).

816. Dr. Ornish generally agreed with Dr. Sacks' assessment of the "many" limitations of the Aviram CIMT/BP Study (2004), which was "not at all conclusive," but he also described its results as "provocative" and "interesting." (PX0025-0010-11); PX0355 (Ornish, Dep. at 107)). Dr. Heber agreed that this study was unblinded and uncontrolled (PX0353 (Heber, Dep. at 173-78)), and opined only that this study was a start leading to a "much larger, controlled trial and also triggered basic mechanistic investigations to provide scientific substantiation." (PX0046 (Heber, Welch Report at 0019)).

Response to Finding No. 816:

Respondents object to Complaint Counsel's proposed finding as it mischaracterizes Dr. Ornish's opinion with respect to Dr. Aviram's 2004 study. Dr. Ornish did not state that no conclusions could be drawn but that as with any study, the results should be "interpreted with caution." (PX0025-0011). Furthermore, Complaint Counsel deceptively omit a portion of sentence to construct an argument that Dr. Ornish believed that Dr. Aviram's study was "not at all conclusive." In fact, Dr. Ornish write, "Thus, while at all not conclusive, *the study suggests a benefit*. (PX0025-0011, emphasis added). Furthermore, Complaint Counsel also fail to include the crux and full context of Dr. Ornish's statement in deposition. Dr. Ornish testified, "So I think it's very provocative and interesting and laid the groundwork for even more conclusive studies." Thus, Dr. Ornish was not belittling the results of Dr. Aviram's study but was explaining the extraordinary nature of the findings.

Furthermore, it is factually accurate that Dr. Heber agreed that Dr. Aviram's study was unblinded and uncontrolled.

Complaint Counsel's assertion that Dr. Heber stated that "this study led to a much larger controlled trial and also triggered basic mechanistic investigations to provide scientific substantiation" is factually accurate but is taken out of context. (PX0046 (Heber, Welch Report at 0019)). Dr. Heber also stated that the results of the Aviram study "suggest that PJ consumption by patients with CAS decreases carotid IMT and systolic blood pressure and these effects could be related to the potent antioxidant characteristics of PJ polyphenols. Thus, it is an inherently positive statement that Dr. Aviram's study led to larger trials because by common sense dictates that if a study were not valid or the results not reliable then further resources would not be expended to explore the benefit. Moreover, Complaint Counsel's implication that Dr. Heber believed that the results were somehow unreliable or scientifically invalid because Dr. Aviram's study only had ten participants is also unsupported. In fact, Dr. Heber also testified that "smaller studies are sometimes superior to larger studies for generating new information about biological mechanisms." (Heber, Tr. 177-178). Thus, Complaint Counsel's inference that Dr. Heber's notation that Dr. Aviram's study led to larger studies was a criticism as to the studies limitations is unsupported.

817. Respondents were aware of the limited, exploratory nature of the Aviram CIMT/BP Study (2004). According to a *Wall Street Journal* article dated April 5, 2005, and an email to POM staff, the Aviram CIMT Study was "unlikely to impress the scientific community" because "using patients with only severe blockage makes the effects look more significant than they would in normal patients." In the article, POM was quoted as saying that the 10-person study was meant to be only a preliminary test. The article went on to note that POM had "also funded an 18 month study that involves 360 patients with a range of conditions . . . . [P]reliminary results won't be released until December [2005], the company says." (CX0039_0001). The 360-patient study was a reference to the Davidson CIMT Study (2009). (*See* CCFF ¶¶ c.875-c(2)(b)919).

Response to Finding No. 817:

Respondents object to the terms "limited" and "exploratory" because they are vague, ambiguous and argumentative.

Respondents also object to statements in the WS Journals for lack of foundation. Statements written by a journalist trying to attract a readership is hardly a reliable barometer for what is likely to impress the scientific community. Thus, awareness of the alleged limitations of Dr. Aviram's study via criticism in a news article is an inference not supported here.

Respondents also object to Complaint Counsel's back-door attempt to argue that Dr. Aviram's study is unreliable because it tests sick as opposed to healthy participants is as a practical matter. Conducting a trial on healthy participants will necessarily require more participants than a trial conducted on sick participants to show that an intervention has an effect. (CX1345 (deGroof, Dep. at 63-66); CX1336 (Davidson Dep. at 228-229)). This is because if the participants tested are healthy it is more difficult to show an effect in a study on health conditions. (CX1345 (deGroof, Dep. at 65-66)). A benefit or change effected by an intervention on sick patients may be more easily and timely identified and measured. (CX1345 (deGroof, Dep. at 63-66); CX1336 (Davidson Dep. at 228-229)). Thus, studying a sick population was optimal from a financial standpoint and also to more easily assess if a heart health benefit existed.

Respondents also object to Complaint Counsel's implied assertion that the study's small sample size make the Dr. Aviram's study unreliable. Even the NAD 2005 ruling held that the Aviram study was a credible study and not too small from which to make qualified claims. (CX0037) There is a common misconception that a larger study is a better study, but under some circumstances, a relatively small study can be more informative than a large study. (RFF 1122, 1249). Dr. Aviram's study reported

significant reductions in carotid IMT, decreased systolic blood pressure, and a substantial inhibition of lipid peroxidation in serum and in LDL. (RFF 1292). These findings are all the more astounding given the relatively small number of participants because when a study has small numbers of patients, the treatment has to be that much more powerful and that much more consistent for it to be statistically significant. (RFF 1250). Dr. Hill testified that there is no difference between a pilot and regular study where there is statistical significance; the reason researchers conduct a pilot study, in part, is to determine how many subjects it will take to power the study, so when you achieve statistical significance the smaller study has shown itself to be at least as scientifically valid as the larger study. (RFF 1526, 1527-1532).

The fact that Dr. Davidson's larger CIMT trial followed Dr. Aviram's study does not infer that Dr. Aviram's study was inconclusive or scientifically unreliable. Indeed, the opposite is true. Common sense dictates that if a study was not valid or the results unreliable then further resources would not be expended to explore the benefit.

818. In another example of Respondents' awareness of the limitations of the Aviram study results, the American Botanical Counsel draft monograph circulated to POM employees by Dr. Dreher in December 2007 described the "main limitation of this study is that both groups were not treated equally . . . there was no placebo, and the PJ group received many more interventions than the control group. The article went on to note that "between group analysis was not conducted of any of the outcomes, only within group analysis." (CX0163_0017).

Response to Finding No. 818:

While Respondents were aware of the parameters of Dr. Aviram's study, this does not establish that Respondents were warned or aware that the science did not provide competent and reliable support for POM's advertising representations. Indeed, there are limitations to every stud; Dr. Aviram's study does provide a competent and reliable basis on which to base claims with respect to heart health in POM's advertising. Respondents incorporate by reference response to proposed finding no. 814.

819. Respondents acknowledge that the relevance of this study to the general population is limited. Dr. Gillespie, Vice President of Clinical Development at POM, told a POM customer that "this study enrolled older patients with severe plaque buildup. Therefore, the results observed in this population may not represent all patients. . . . It's difficult to estimate the long-term effect of pomegranate juice based on this limited sample size." (CX0456_0009-100; *see also* Tupper, Tr. 1054 (agreeing with Dr. Gillespie's characterization of the study's limitations); CX1353 (Tupper, Dep. at 218-19)).

Response to Finding No. 819:

Respondents object to the phrase "acknowledge the relevance" as vague, ambiguous, and argumentative.

Respondents cite to a cautionary statement made by Dr. Gillespie to an inquiring consumer to encourage her to consult her physician as evidence of an acknowledgement of Dr. Aviram's limitations. For the reasons set forth above, Dr. Aviram's study properly formed the basis for qualified claims (RRFF 814), and POM as a matter of policy does not suggest to consumers that POM products are being offered as a substitute for traditional medical advice. Indeed, Dr. Gillespie made these statements in the context of encouraging a consumer to consult a physician. (CX0456_0010-0011; Tupper, Tr. 3018).

Furthermore, Dr. Gillespie's statement inferring that the results showing a benefit to a sick population may not confer a correlating benefit to a healthy population is unsupported. Although conducting a trial on healthy participants will necessarily require more participants than a trial conducted on sick participants to show that an intervention has an effect, this is because if the participants tested are healthy it is more difficult to show and measure an effect in a study on health conditions. (CX1345 (deGroof, Dep. at 65-66); (CX1345 (deGroof, Dep. at 63-66); CX1336 (Davidson Dep. at 228-229)). The fact that a benefit or change effected by an intervention on sick patients may be more easily and timely identified in a sick population is not evidence that the same benefit will not be experienced by a healthy population. (CX1345 (deGroof, Dep. at 63-66); CX1336 (Davidson Dep. at 228-229)).

Next, there is a common misconception that a larger study is a better study, but under some circumstances, a relatively small study can be more informative than a large study. (RFF1122, 1249). Dr. Aviram's study reported significant reductions in carotid IMT, decreased systolic blood pressure, and a substantial inhibition of lipid peroxidation in serum and in LDL. (RFF 1292). These findings are all the more astounding given the relatively small number of participants because when a study has small numbers of patients, the treatment has to be that much more powerful and that much more consistent for it to be statistically significant. (RFF 1250).

Last, Dr. Aviram's studies conducted on sick people, is relevant to the general population. Indeed, there could be tens of millions of people in the United States who are sick with conditions such as, CAS, who could be helped by pomegranate juice who are unaware of their health risks. (Heber, Tr. 1985).

820. Following the completion of the Aviram ACE/BP and CIMT/BP Studies, POM contacted Dr. Ornish in "an effort to confirm and reproduce the . . . carotid IMT data from Israel [Aviram]" and commissioned him to conduct a larger clinical trial, which began in January 2002. (CX0579_0003). The protocols for the Ornish studies describe the Aviram studies as having "a small number of patients or participants and no randomized control group for comparison. Thus, we propose a randomized controlled trial to address these limitations." (*See e.g.,* CX0552_0001 (June 12, 2002 Beverage Study Protocol); CX0613_0006, 17 (June 2003 Beverage I and II protocols)).

Response to Finding No. 820:

Respondents object to the proposed finding to the extent that Complaint Counsel construe Dr. Ornish's statements in his protocol as evidence that he did not wholeheartedly support the benefits that can be drawn from the Aviram study. Dr. Ornish, in fact, stated that, "*the study suggests a benefit*." (PX0025-0011, emphasis added). Furthermore, Dr. Ornish testified, "So I think it's very provocative and interesting and laid the groundwork for even more conclusive studies." Thus, Dr. Ornish was not belittling the results of Dr. Aviram's study, but was explaining the extraordinary nature of the findings. Moreover, RCTs are not the only means of provided competent and reliable support for POM's

advertising representations. Indeed, Dr. Ornish's opinion is just the opposite. Dr. Ornish states that a more thoughtful way of analyzing therapeutic efficacy is to carefully examine the totality of scientific evidence, including but not limited to RCTs that are perfectly conducted. (PX0025_0008). Furthermore, RCTs even when conducted perfectly do not control for all sources of bias and may inject new ones unique to RCTs. (PX0025_0008). It is thus an extreme position to state that only RCTs should be considered in evaluating the therapeutic efficacy. (PX0025_0007). The fact that Dr. Ornish's Bev II study was designed to test the same endpoint as the Aviram 2004 study in no way suggests that Dr. Aviram's study was not competent or reliable. There is absolutely no scientific support for this baseless position.

821. Despite the acknowledged limitations of this study, from 2004 through 2009, the Aviram CIMT/BP Study (2004) results became the centerpiece of Respondents' marketing claims that science establishes that both POM Juice and POMx can treat, prevent, or reduce the risk of heart disease. (*See* CCFF ¶ 674).

Response to Finding No. 821:

Respondents object to complaint counsel's proposed finding as vague and ambiguous as to the meanings of "acknowledged limitations" and "'centerpiece' of Respondents' marketing claims." Moreover, the 2004 Aviram results were astounding, and there is no basis to suggest Respondents should not disclose the results of study. Respondents note that the USDA has made claims regarding the health benefits of blueberries, noting that they "May Help Control Cholesterol and Battle Colon Cancer" based on a single 9 rat study. (PX0311-0002). Respondents also deny making any marketing claims that the science is "clinically proven" that POM Juice and POMx can treat, prevent, or reduce the risk of heart disease. Further, the proposed finding is argumentative, without merit, and unsupported by the record evidence. (*See* Respondents' Reply Appendix of Advertisements).

Additionally, Respondents dispute this proposed finding to the extent that Complaint Counsel ignore that taken as a whole, the preponderance of the scientific evidence from basic scientific studies, animal research, and clinical trials in humans reveals that the pomegranate in its various forms (including POM Wonderful 100% Pomegranate Juice, POMx Pills, or POMx Liquid) is likely to be beneficial in maintaining cardiovascular health and is likely to help reduce the risk of cardiovascular disease. (RFF 1206; PX0025-0005). The universe of existing science provides significant evidence that pomegranate juice is likely to, among other things, reduce arterial plaque, improve blood flow, and reduce blood pressure. (RFF 1207; PX0025-0005; PX0355 (Ornish, Dep. at 42); Ornish, Tr. 2374-75). Although the consumption of pomegranate juice or its derivatives is not a "silver bullet" or a substitute for conventional treatments for heart disease, Respondents have never suggested otherwise in their advertising. (RFF 1208; PX0025-0005).

b. Ornish Studies

822. Dr. Ornish conducted two studies for Respondents: (1) Sumner M., et al., *Effects of Pomegranate Juice Consumption on Myocardial Perfusion in Patients with Coronary Heart Disease*, 96 Am. J. Cardiology 810 (2005) ("Ornish MP Study (2005)") (CX1198; *see* JX0003 ¶ B.16); and (2) the Ornish CIMT Study (unpublished, 2005) (CX0754; *see* JX0003 ¶ B.16). These were the only studies ever conducted by Dr. Ornish to consider whether a single food product has health benefits. (Ornish, Tr. 2464).

Response to Finding No. 822:

Respondents have no specific response other than to note that Complaint Counsel's cardiovascular expert, Dr. Sacks, has only studied "fruits and vegetables as a *category*," not individually, and notably has not conducted any studies on the effects of antioxidants on human health. (PX0361 (Sacks, Dep. at 54-56)) (emphasis added).

823. The contract setting forth the terms of the two studies was a September 19, 2003, letter agreement between Stewart A. Resnick and Linda Resnick, as Trustees of the Stewart and Linda Resnick Revocable Trust, and Dr. Ornish's organization, Preventative Medicine Research Institute ("PMRI"). (CX0613_0001). Attached to the letter agreement were the protocols for the two studies. The Ornish MP Study (2005) was also referred to as "Beverage Study I," and the Ornish CIMT Study was referred to as

"Beverage Study II." (CX0613_0001, 0003, 0005, 0016). The Ornish MP Study budget was $708,436, and the CIMT Study budget was $496,390 (together, $1,204,827). (Ornish, Tr. 2431-35).

Response to Finding No. 823:

Dr. Ornish testified that the attached documents to CX0613 were not the correct protocols for the Beverage I Study ("Bev I Study" or "Ornish MP Study (2005)") and Beverage II Study ("Bev II Study" or "Ornish CIMT Study") submitted for approval by the institutional review board. (PX0355 (Ornish, Dep. at 124-125; 174-175)). In addition, although the budgets for the Bev I Study and Bev II Study may have been listed on CX0613 as $708,436 and $496,390, respectively, Dr. Ornish testified that the funding of his studies were cut short. (Ornish, Tr. 2436, 2441, 2454).

(3) Ornish MP Study (2005)

(a) About the Study

824. The Beverage Study I had two arms: a "cardiac" group and a "carotid" group. (CX0613_0008 (Beverage Study I protocol, describing the two-arm study)). The results of the 45-person "cardiac" group were published as the Ornish MP Study (2005). (CX1198). The results of the 17-person "carotid" group, which underwent CIMT testing, were not published, but were presented by Dr. Gerdi Weidner, PMRI's Vice President and Director of Research, at the 2004 POM Summit. (CX1306 (Weidner, Decl. at 0001-02). Both arms of the study were randomized, double-blind, and placebo-controlled. (CX0613_0008).

Response to Finding No. 824:

Dr. Ornish testified that the attached documents to CX0613 were not the correct protocols for the Bev I Study or Bev II Study submitted for approval by the institutional review board. (PX0355 (Ornish, Dep. at 124-125; 174-175)). In any event, CX0613 does explain how the Bev I Study consisted of a "cardiac" group and a "carotid" group. Complaint Counsel's suggestion that the "results of the 45-person 'cardiac' group were published as the Ornish MP Study (2005)" is not supported by the evidence cited. While CX1198 represents the published study Bev I Study, no reference is made to the study consisting of the results from the "cardiac" group whatsoever.

CX1306 is a declaration from Dr. Gerdi Weidner, a former researcher at the Preventive Medicine Research Institute ("PMRI"), in which she, among other things, purportedly authenticates an attached power point presentation at the request of Complaint Counsel. In their interrogatories dated November 15, 2010, Respondents asked Complaint Counsel to "[i]dentify and describe every communication between Complainant and any scientist, researcher, investigator, or author of studies involving pomegranate or any POM Wonderful product." (PX0263; PX0267). In their initial responses December 15, 2010 and supplemental responses dated March 11, 2011, Complaint Counsel provided the names of 26 researchers, scientists, and/or doctors with whom they communicated, but *did not disclose any communication with Dr. Weidner whatsoever* or *indicate that they had obtained a written declaration from her*. (PX0263; PX0267). Complaint Counsel's discovery responses, therefore, are inaccurate as Dr. Weidner indicated that she received an email from Complaint Counsel on December 28, 2010 and presumably had further, multiple communications with counsel in preparation of her declaration. (CX1306_0003, ¶ 9.) Based on Complaint Counsel's incomplete discovery responses, Dr. Weidner's declaration and supporting document should be stricken from the record.

825. The patients in the "carotid" group had documented coronary artery disease. (CX1306 (Weidner, Decl. at 0002)). The results of the 17-person "carotid" group that underwent CIMT testing were negative, in other words, they did not show that POM Juice provided a benefit. (CX1306 (Weidner, Decl. at 0029-32)). Further, in the "cardiac" group, other biomarkers including ACE, Thiobarbituric Acid Reactive Substances ("TBARS"), and paraoxonase ("PON" or "PON1") were measured in the "cardiac" group at baseline and three months. (CX1306 (Weidner, Decl. at 0041-44)). There were no statistically significant effects of pomegranate juice consumption on any of these measures. Thus, the Aviram ACE/BP Study (2001) measures were not replicated by this study. (CX1306 (Weidner, Decl. at 0035-44)). None of these results were published. (*See* CX1198 (published report of Ornish MP Study)).

Response to Finding No. 825:

Dr. Ornish testified that the attached documents to CX0613 were not the correct protocols for the Bev I Study or Bev II Study submitted for approval by the institutional review board. (PX0355 (Ornish, Dep. at 124-125; 174-175)). In any event, CX0613 does

explain how the Bev I Study consisted of a "cardiac" group and a "carotid" group. Respondents incorporate by reference their response to proposed Finding No. 824 regarding Dr. Weidner's improperly disclosed declaration.

Respondents further object to Complaint Counsel's proposed Finding No. 825 on the grounds that it is vague and ambiguous with respect to the term "replicated," lacks foundation, assumes facts not in evidence and seeks to offer expert testimony in the form of a third-party declaration. In the "cardiac" group, only seven subjects received pomegranate juice. The absence of any statistically significant changes in certain biomarkers, which were not primary end points, cannot be construed to prove the negative, i.e. that pomegranate juice had no benefit on cardiovascular health. (RFF 1412, 1426).

826. The Beverage Study I results that were published as the Ornish MP Study (2005) (the "cardiac" group) were based on testing to evaluate whether daily consumption of pomegranate juice for 12 months would affect myocardial perfusion, or blood flow to the heart, in 45 patients with CHD and myocardial ischemia. (CX0613_0005, 0009; *see also* PX0025 (Ornish, Report at 0017)). Patients consumed 240 ml (about eight ounces) of POM Juice or a placebo beverage daily. (CX1198_0002). Measurements included before and after imaging of blood flow to the heart, plasma lipids (cholesterol, HDL, LDL, and triglycerides), body weight, blood sugar, and blood pressure. (CX1198_0003-04; CX1306 (Weidner, Decl. at 0037-44); *see also* CX1291 (Sacks, Report at 0019-24)).

Response to Finding No. 826:

Dr. Ornish testified that the attached documents to CX0613 were not the correct protocols for the Bev I Study or Bev II Study submitted for approval by the institutional review board. (PX0355 (Ornish, Dep. at 124-125; 174-175)). In any event, CX0613 does explain how the Bev I Study consisted of a "cardiac" group and a "carotid" group. Respondents incorporate by reference their response to proposed Finding No. 824 regarding Dr. Weidner's improperly disclosed declaration. The Ornish MP Study (2005) "investigated whether daily consumption of pomegranate juice for 3 months would affect myocardial perfusion in 45 patients who had CHD and myocardial ischemia in a

randomized, placebo-controlled, double-blind study." (PX0023-0001). Although other measurements may have included certain lipids and blood pressure, the primary endpoint of the Ornish MP Study (2005) was myocardial perfusion. (PX0023-0001).

827. The published report provides data on three imaging measures at baseline and *three months* for myocardial perfusion: the summed rest score, or "SRS" (imaging results before the pharmacologic or exercise challenge), the summed stress score, or "SSS" (imaging results after the pharmacologic or exercise challenge) and the summed difference score, "SDS" (calculated by subtracting the SRS from the SSS). (CX1198_0003 (Table 2); CX1291 (Sacks, Report at 0020)). According to the report, after three months there was a significant ($p = 0.05$) improvement of 17% in the SDS score in the POM Juice group, as compared to an average worsening of 18% in the control group. (CX1198_0004). However, there were no statistically significant differences between the two groups in SSS and SRS at the end of the reported three-month period. (CX1198_0003 (Table 2)).

Response to Finding No. 827:

Respondents have no specific response.

828. The authors concluded that:

> [A]lthough the sample in this study was relatively small, the strength of the design and the clinically significant and statistically significant improvements in myocardial perfusion observed in the experimental group over a rather short period *suggest* that daily consumption of pomegranate juice *may* have important clinical benefits in this population . . . . Further studies appear to be warranted to determine the effects of pomegranate juice on myocardial perfusion in a larger sample of patients over a longer period. In addition, it would be of interest to assess the effects of pomegranate juice on coronary atherosclerosis using methods such as quantitative coronary arteriography and intravascular ultrasound.
>
> ((CX1198_0004) (emphasis added)).

Response to Finding No. 828:

Complaint Counsel omits from the conclusion the following sentence: "In a recent study of 2,686 patients, the best predictor of nonfatal myocardial infarction was the amount of ischemia as indicated by the SDS." (PX0023-0004). At trial, Dr. Ornish testified that the phrase "further research is needed" is common language in a study and in good science, a researcher is always trying to be his or her most intense critic. (Ornish, Tr. 2366).

829. The published study also reported no significant changes in blood pressure, cholesterol, LDL, HDL, or triglycerides. (CX1198_0003-04, Table 3 (notation below table); CX1291 (Sacks, Report at 0024)).

Response to Finding No. 829:

The fact that other factors such as blood pressure and cholesterol did not improve does not in any way provide evidence that pomegranate juice was not beneficial, as its effects may have been mediated via other pathways. (PX0025-0017-0018). Indeed, Dr. Sacks concedes the lack of statistical significance for a positive result is not proof of a negative. (Sacks, Tr. 1608).

830. At trial and in his expert report, Dr. Ornish acknowledged that "some problems" occurred during the study that were not "optimal." (Ornish, Tr. 2394; PX0025 (Ornish, Report at 0016)).

Response to Finding No. 830:

In his expert report, Dr. Ornish acknowledged that although "mistakes" were made when six patients in the placebo group became unblinded (i.e., they discovered which beverage they were consuming) which were not optimal, these "do not undermine the validity of the study or its conclusions." (PX0025-0016). Dr. Ornish testified that although the study only provides data on 39 patients, an analysis of all 41 patients did not change the conclusions of the study and only made them stronger. (Ornish, Tr. 2394). Dr. Ornish explained that an unbiased doctor could not throw out his positive myocardial perfusion study because of the criticisms raised by Dr. Sacks. (Ornish, Tr. 2351).

831. First, 41 patients completed the study, but the published report provided data on only 39. (Ornish, Tr. 2394; *see* CX1198_0003 (Table 2). Dr. Ornish admitted that this was a mistake. (PX0025, (Ornish, Report at 0015)). In practice, a researcher should publish all patient results, consistent with the "intention to treat" standard. (CX1291 (Sacks, Report at 0022, 24); *see also* Sacks, Tr. 1469; CX664)**.** Alterations in the original sample size may be critical when there is a borderline "*p*" value. (CX1291 (Sacks, Report at 0022)). One of the patients whose data were excluded from the published analysis was in the pomegranate juice group; he had a myocardial infarction (or silent heart attack) while drinking the juice. (Sacks Tr. 1478-79; CX1198_0003). Drinking pomegranate juice did not appear to have prevented his myocardial infarction. (CX1198_0003; CX1339 (Ornish, Dep. at 55-56); Sacks, Tr. 1478-79; CX664_0001).

Response to Finding No. 831:

The basic principle of intention to treat is that participants in the trials should be analyzed in the groups to which they were randomized, regardless of whether they received or adhered to the allocated intervention. (RFF 1376; PX0025-0016 *citing* Hollis S, Campbell F., *What is meant by intention to treat analysis? Survey of published randomised controlled trials*. BMJ 1999; 319: 670). Dr. Ornish agrees that a mistake was made in not reporting data on the remaining 41 patients. (RFF 1377; PX0025-0015). However, when data on all 41 patients were analyzed, the difference in SDS remained statistically significant and, therefore, the conclusions of the study remain valid. (RFF1378; PX0025-0015; Ornish, Tr. 2347-48). If anything, the results were more statistically significant and even stronger because the sample size was slightly larger. (RFF 1379; Ornish, Tr. 2347-48; 2394).

The idea that clinical trials must use the intention to treat analysis or they are not valid is a rather extreme position, especially because the Ornish MP Study (2005) is a randomized, double-blind, placebo-controlled trial, which is considered to be the most rigorous experimental design. (RFF1380; PX0025-0015-0016). A published survey shows that per-protocol was the basis of at least 50 percent of the studies published by four of the top-tier scientific journals: the New England Journal of Medicine, the Journal of the American Medical Association, Lancet, and British Medical Journal and less than half of the studies were even randomized, controlled trials, much less using intention-to-treat method. (RFF 1381; Ornish, Tr. 2350-51; PX0025-0016). Dr. Sacks' assertion that it was not a RCT and therefore is not good science, is not borne out by the top-tier journals who publish these studies all the time. (RFF 1382; Ornish, Tr. 2350-51). Most of Dr. Sacks' own research would not meet this standard. (RFF 1383; PX0025-0016).

Dr. Ornish used the intention-to-treat method in reporting all available data. (RFF 1384; Ornish, Tr. 2349). In this case, if Dr. Ornish used the last value carried forward, i.e. baseline values of patients who did not receive the intervention, that would mean there would be no change and that would be introducing a negative bias. (RFF 1385;Ornish, Tr. 2349). The "last observation carried forward" analysis is not appropriate when only baseline measurements are available in dropouts, as imputing missing data may introduce its own set of biases. (RFF 1386; PX0025-0016 *citing* Julious SA, Mullee MA., *Issues with using baseline in last observation carried forward analysis*. Pharmaceut. Statist. 2008; 7: 142–146.)

If studying a new drug, such as a chemotherapy agent that has major toxicities, it would be appropriate to use the most conservative method of analysis before you release that information to the American public. (RFF 1387; Ornish, Tr. 2349). But when evaluating a fruit juice, it is not necessary to go to the extreme of biasing against showing the effect. (RFF 1388; Ornish, Tr. 2349-50). Dr. Ornish also used the per-protocol method as well and reported all available data. (RFF 1389; Ornish, Tr. 2350).

Both Dr. Ornish and Dr. Sumner testified that they were unsure if the patient's data were included in Table 2 of the Ornish MP Study (2005). (CX 1339 (Ornish, Dep. at 55-56); CX1344 (Sumner, Dep. at 28)). Dr. Ornish did not provide any testimony on the issue of whether pomegranate juice would have "prevented" a patient's myocardial infarction during the study period. (CX 1339 (Ornish, Dep. at 55-56). Neither the published Ornish MP Study (2005) nor CX0664, cited by Complaint Counsel, indicate *when* the subject experienced the "suspected silent myocardial infarction." (PX0023; CX0664). Accordingly, no conclusions can be drawn from the isolated incident of one person drinking POM Juice given the duration of the study period. In addition, it appears that one person in the placebo group also experienced a "nontransmural myocardial infarction." (PX0023-0003).

832. Second, two subjects in the placebo group did not receive a placebo treatment. They were tested at baseline and three months, with no intervention, and their data were included in the final study results. (CX1339 (Ornish, Dep. at 168-70); CX0580, patients' names *in camera*; Sacks, Tr. 1475-77).

Response to Finding No. 832:

Complaint Counsel does not cite Dr. Ornish's full deposition testimony in which he explains what occurred with respect to the two patients. Initially, the two patients had been randomized to the control group in the Bev I Study and their measurements taken at baseline. (CX1339 (Ornish, Dep. at 169). As a result of funding issues, however, the study was put on hold. (CX1339 (Ornish, Dep. at 169-70). Three months later, the myocardial perfusion study resumed. (CX1339 (Ornish, Dep. at 169-70). Because these patients were already in the control group and their measurements taken at baseline, the decision was made to include them in the control group. Dr. Ornish explained his rationale for doing as follows: "effectively, having nothing is the same as having a placebo beverage. I think it is probably worth putting in context that in any study there are things that are not optimal because you are dealing with human beings and all the vagaries of that and particularly in a study where the funding was changed midstream…But the question is whether those things are considered likely to have impacted the validity of the study, including in this case the answer is no." (CX1339 (Ornish, Dep. at 169-71).

833. Third, Dr. Ornish admitted at his deposition that at least eight patients were unblinded before their three-month test dates -- meaning the study patients knew whether they were in the active or placebo groups. (CX1339 (Ornish, Dep. at 146-47); Ornish, Tr. 2403). On two occasions in late 2002, study patients received notices showing what group they were assigned to, and alerted the study staff to their assignments. (CX0555_0001 (22 patients unblinded in September 2002, including six in "cardiac" group and four in "cardiac/carotid" group); CX0560 (four unblinded on Nov. 15, 2002), patients' names *in camera*; *see also* CX0561 (Nov. 18, 2002 PMRI document showing eight patients whose baseline treadmill stress test dates occurred prior to, and three-month test dates occurred after, the unblinding dates), patients' names *in camera*). Dr. Liker and Mr. Resnick were made aware of the unblinding problems. (CX0555_0001).

Response to Finding No. 833:

Dr. Ornish testified at trial that only six patients, not eight, became unblinded in the Ornish MP Study (2005). (Ornish, Tr. 2345-46, 2405-09). CX0555 does not support the proposition that "Mr. Resnick w[as] made aware of the unblinding problems" as suggested by Complaint Counsel. The email was written only to Dr. Liker and there is no suggestion anywhere in CX0555 that the contents of the email were communicated to Mr. Resnick.

In any event, the unblinding of the patients did not undermine the validity of the study or its conclusions. (RFF 1398; PX0025-0016). The expectation that an intervention is beneficial has the potential for confounding the outcome of a study, but such an outcome was unlikely to have occurred in this study. (RFF 1393; PX0025-0016). At the time that the study was conducted, there was not an awareness in the general population that pomegranate juice was beneficial or even that the subjects were drinking pomegranate juice (the study was entitled a "beverage study"). (RFF 1394; PX0025-0016; (CX1339 (Ornish, Dep. at 148-149)). At the time of the unblinding, people did not know that pomegranate juice might even be beneficial to them and if they found they were drinking Gatorade, there was a greater likelihood that that they would have thought that was the intervention. (RFF 1395; Ornish, Tr. 2345-46; (CX1339 (Ornish, Dep. at 148-149)).

The real issue or reason studies are blinded is the expectation that something might have a positive benefit can sometimes be self-fulfilling, but in this case, there is no reason why the subjects would have necessarily thought that, even if they knew they were drinking pomegranate juice that was likely to provide them a benefit, because this was before people even knew what pomegranate juice was other than an exotic juice. (RFF 1396; Ornish, Tr. 2346; (CX1339 (Ornish, Dep. at 148-149)). It would be a stretch to say that subjects simply thinking they were getting something beneficial could affect blood flow

to the heart, but even if one assumed that were true, they might just as well thought that the Gatorade would be as beneficial as the pomegranate juice. (RFF 1397; Ornish, Tr. 2347).

834. Fourth, Dr. Ornish admits that the Ornish MP Study (2005) was designed as a twelve-month study, not a three-month study. (PX0025 (Ornish, Report at 0017)). Dr. Ornish and the Resnicks had agreed to a twelve-month study, with testing at baseline, three months, and one year, at a cost of $708,437. (*Compare* CX1198 *with* CX591_0001 (May 2003 email); CX613_0010 (Sept. 2003 protocol)). The published report, however, described the Ornish MP Study as a three-month study. (CX1198_ 0001).

Response to Finding No. 834:

In his expert report, Dr. Ornish did not indicate that the Ornish MP Study (2005) was only "designed as a twelve-month study" as contended by Complaint Counsel. Instead, Dr. Ornish wrote in his expert report that "[w]e originally planned to test these patients *after three months* *and* after twelve months. We were unable to do the twelve-month testing because there was not sufficient funding to do so after the funding was reduced." (PX0025-0017) (emphasis added). The evidence cited by Complaint Counsel, CX591 does not support the conclusion that "Dr. Ornish and the Resnicks had agreed to a twelve-month study, with testing at baseline, three months, and one year, at a cost of $708,437." As Dr. Ornish explained at trial: "If you want the answer, the rest of the answer is that they said that instead of 35 patients for baseline, three months, and one year, we would do the 45 patients at three months, which would be a stronger study." (Ornish, Tr. 2428). The Ornish MP Study (2005) speaks for itself: "We evaluated the effects of daily consumption of pomegranate juice or a placebo for 3 months on myocardial perfusion in patients who had CHD and inducible ischemia as measured by single-photon emission computed tomography in a randomized double-blind study." (PX0023-0001).

835. Documents show that as late as January 26, 2004, the Beverage Study I was expected to include twelve-month test measures. (Ornish, Tr. 2436-38 (regarding Sept. 29, 2003, PMRI email advising a researcher that the Beverage Study I was a twelve-month study); CX1339 (Ornish Dep. at 139) (regarding Oct. 10, 2003 patient data sheet showing that ten patients had completed their twelve-month testing). On October 10, 2003, PMRI advised Dr. Liker that the three-month testing would be completed in January 2004 and

that the one-year testing would be completed in October 2004. (Ornish Tr. 2437-38). On January 26, 2004, a PMRI staff member wrote to Dr. Aviram to say that the 12 month testing for Beverage Study I would be done in November 2004. (Ornish, Tr. 2438 (testifying that "that was our intention at the time")).

Response to Finding No. 835:

At trial, Dr. Ornish testified that "[w]e originally planned to do the testing at baseline, three months, and one year…but the Resnicks cut our funding to such a degree that we couldn't afford to pay for that, and that's why we didn't do it." (Ornish, Tr. 2435). Dr. Ornish explains that study was terminated after three months only because the Resnicks did not provide the funding that they had previously committed to this study, not because the p-value was statistically significant at three months. (RFF 1402; PX0025-0017). Dr. Ornish originally planned to study these patients at three months and at one year, but because he did not have the funding to do it for one year, he only measured patients for three months. (RFF 1403; PX0025-0017; Ornish, Tr. 2351-52). Dr. Ornish clearly intended to do a twelve-month follow-up which is why nine of the patients completed their 12-month testing before the funding was cut. (RFF 1404; PX0025-0017). The only reason Dr. Ornish did not test all of the patients at 12 months is that the funding was no longer available to do so for reasons beyond his control. (RFF 1405; PX0025-0017).

836. On February 7, 2004, however, Dr. Michael Sumner, a Ph.D. in Social Psychology and the Ornish MP Study (2005) co-author who conducted the data analysis, provided Dr. Ornish's research team at PMRI with analysis of the MP study patients' three-month test data, showing a statistically significant improvement in the SDS measure. (CX0632; Ornish, Tr. 2438-39).

Response to Finding No. 836:

Respondents have no specific response.

837. When the interim three-month study results turned out to be positive, minutes for a research team meeting held on February 9, 2004 at Dr. Ornish's PMRI facility reported that "Dean says the good news is, after reviewing the data, the research shows that ischemia is reduced with a sum[med] difference score of 4.33 to 3.63. *Dean wants to quit while we are ahead and wants to call the Resnicks with the news*. . . . Dean will talk

with Resnicks . . . after Erin provides him with financials." (CX0633_0001 (emphasis added); Ornish, Tr. 2439-40)). Dr. Ornish wanted cost information from PMRI's financial officer to use in conversations with the Resnicks. (Ornish, Tr. 2440).

Response to Finding No. 837:

Complaint Counsel fails to cite the remainder of Dr. Ornish's trial testimony in which clarifies: "What we found in those budgets was that we didn't have the money to do this for a year. *It wasn't quitting while we were ahead because we wanted to quit while we were ahead. It was good that we could quit while we were ahead, but it was because we didn't have the money to finish the study*." (Ornish, Tr. 2440) (emphasis added). In his deposition, when asked about CX0633, Dr. Ornish explained: "So I'm never one to quit while we're ahead. I've always wanted to find out what happens. Because, again, my goal…is not to prove that something works or doesn't work; my goal is to find out what's true. And so with respect to the pomegranate juice study, it wasn't like, oh, let's quit because we've shown it works…So the sole reason for concluding the study at three months is that we didn't have the funding to continue it longer than that. And I know that in one of the e-mails I might have made some comment that, oh, you know, it's great -- at least we have something -- it was more like, well, at least we have something to show for all this trouble after three months. It wasn't, let's stop now because we have something to show for our efforts, because that was never the intention. We would never have tested the people at 12 months to begin with." (PX0355 (Ornish, Dep. at 164-165)).

838. Although there is no record evidence of those conversations between Dr. Ornish and the Resnicks, on March 12, 2004, Dr. Weidner sent the Beverage Study I data, for both the myocardial perfusion results ("cardiac" results) and the CIMT results ("carotid" results), to Dr. Liker for review. (CX0642_0001, 03-06 (cardiac arm), 09-10 (carotid arm)).

Response to Finding No. 838:

Complaint Counsel's statement that "there is no record evidence of those conversations between Dr. Ornish and the Resnicks" is vague and ambiguous as to the meaning of "those conversations" and no inference or conclusion can be drawn from the document

cited, CX0642, which is an email between Dr. Weidner and Dr. Liker. The document speaks for itself.

839. Dr. Ornish has repeatedly insisted that he ended the study at three months because his funding got cut. (Ornish, Tr. 2351-52, 2435-36 ("we didn't have the money to do it because our funding got cut")). The documents show that the agreed-to budget for the study was set at $708,437 as early as May 2003, and that this was the amount that PMRI was paid. (*Compare* CX0591_0001 *with* CX1237_0004). It appears that PMRI experienced cost over-runs that it could not afford to absorb. (Ornish, Tr. 2441 ("[t]he cost of the study was significantly higher than" the budget)). As a result, Dr. Ornish and Respondents terminated the study at three months, at a time when the results were statistically significant, rather than at twelve months as originally set forth in the protocol. (*See* CCFF ¶¶ 826, 837).

Response to Finding No. 839:

At trial, Dr. Ornish testified that "[w]e originally planned to do the testing at baseline, three months, and one year…but the Resnicks cut our funding to such a degree that we couldn't afford to pay for that, and that's why we didn't do it." (Ornish, Tr. 2435). Dr. Ornish explains that study was terminated after three months only because the Resnicks did not provide the funding that they had previously committed to this study, not because the p-value was statistically significant at three months. (RFF 1402; PX0025-0017). Because he did not have the funding to do measurements for one year, Dr. Ornish only measured patients for three months. (RFF 1403; PX0025-0017; Ornish, Tr. 2351-52). Dr. Ornish clearly intended to do a twelve-month follow-up which is why nine of the patients completed their 12-month testing before the funding was cut. (RFF 1404; PX0025-0017). Thus, the only reason Dr. Ornish did not test all of the patients at 12 months is that the funding was no longer available to do so for reasons beyond his control. (RFF 1405; PX0025-0017). While Dr. Ornish did not have 12 months of follow-up data, this does not undermine the confidence in the three-month findings, which stand on their own. (RFF 1406; PX0025-0017). Bias is not an issue because outside factors precluded obtaining twelve-month data. (RFF 1407; PX0025-0017).

Complaint Counsel fails to cite the remainder of Dr. Ornish's trial testimony in which clarifies: "What we found in those budgets was that we didn't have the money to do this for a year. *It wasn't quitting while we were ahead because we wanted to quit while we were ahead. It was good that we could quit while we were ahead, but it was because we didn't have the money to finish the study*." (Ornish, Tr. 2440) (emphasis added). In his deposition, when asked about CX0633, Dr. Ornish explained: "So I'm never one to quit while we're ahead. I've always wanted to find out what happens. Because, again, my goal…is not to prove that something works or doesn't work; my goal is to find out what's true. And so with respect to the pomegranate juice study, it wasn't like, oh, let's quit because we've shown it works…So the sole reason for concluding the study at three months is that we didn't have the funding to continue it longer than that. And I know that in one of the e-mails I might have made some comment that, oh, you know, it's great -- at least we have something -- it was more like, well, at least we have something to show for all this trouble after three months. It wasn't, let's stop now because we have something to show for our efforts, because that was never the intention. We would never have tested the people at 12 months to begin with." (PX0355 (Ornish, Dep. at 164-165)).

840. In August 2004, Dr. Ornish advised Dr. Liker that the MP Study abstract had been rejected by the American Heart Association ("AHA"). (CX0672). He asked the AHA's chairman of scientific sessions to reconsider, but the chairman responded that "[m]ultiple qualified, blinded graders scored this abstract below acceptable range." (CX0680).

Response to Finding No. 840:

Complaint Counsel does not provide the full response contained in CX0680. In CX0680, the chairman of the American Heart Association writes to Dr. Ornish: "*The process is admittedly not perfect*…*I have personally had an abstract rejected 3 times that became a Circ paper*…My lab had an excellent abstract rejected this year…" (CX0680_0001) (emphasis added). When asked about this letter, Dr. Ornish explained: "And that's the nature of abstracts because they are not given the same level of review that a full paper is.

There are biases in this case against a non-surgical non-pharmacological intervention. You're much more likely to see that in an abstract than in a full paper." The Ornish MP Study (2005) was ultimately published in the *American Journal of Cardiology*. (PX0023).

841. In November 2004, the *Journal of the American Medical Association* ("JAMA") also rejected the Ornish MP Study manuscript. (CX699_0002). In response to Dr. Ornish's request for feedback, the Deputy Editor of JAMA responded that "the study appears very preliminary, with small sample size, apparent baseline imbalances between groups, use of an intermediate endpoint as main outcome measure, and modest differences with large variability." (CX0699_0001-02).

Response to Finding No. 841:

Complaint Counsel strategically omits the very first sentence in the response from the Deputy Editor of JAMA to Dr. Ornish which reads: "*The biggest issue is our 7% acceptance rate for unsolicited papers*, making for very keen competition for space in JAMA." (CX0699_0001) (emphasis added). In his deposition, Dr. Ornish explained: "This is a form letter and anyone who gets rejection receives and it is entirely -- as he indicates, only seven percent of their manuscripts are accepted. *It in no way implies that the science is not valid because it didn't get accepted into JAMA* as he -- and he went on to say, "I'm sure that your paper will be published in a more specialized journal", as it was." (CX1339 (Ornish, Dep. at 196)). In CX0699, Dr. Ornish explicitly disagreed with the editor's comments and responded that: (1) the primary endpoint measure, summed difference score ("SDS"), is not intermediate endpoint measure; (2) the baseline differences in SDS were not statistically significant; (3) the differences in SDS after three months were statistically significant; and (4) it is more difficult to show statistical significance in a small sample size than in a large sample because "the intervention has to have greater impact and/or more consistent effects to reach statistical significance." (CX0699_0001). The editor's comments also lack merit for the reasons discussed in Dr. Ornish's expert report and for those described extensively in the record. (PX0025-0011-0018; RFF 1303-1414). At trial, Dr. Ornish testified: "they only accept 8 to 9 percent

of the articles that are submitted to them. So, it's not at all uncommon for an article to be rejected by them and it's published by another top-tier journal. In fact, that's the norm, by definition." (Ornish, Tr. 2444).

842. Dr. Ornish then submitted the manuscript to the *American Journal of Cardiology*. (CX1339 (Ornish, Dep. at 200)). The editor accepted it without external peer reviews. (CX0715_0001). The editor was a personal friend of Dr. Ornish. (CX0714_0001 (post-script from editor stating "I'm proud to be included as a friend")).

Response to Finding No. 842:

The evidence cited by Complaint Counsel, CX0714 and CX0715, does not support the conclusion whatsoever that the *American Journal of Cardiology* published the Ornish MP Study (2005) simply because Dr. Ornish was an acquaintance of the editor. (CX0714; CX0715). In addition, Dr. Ornish testified that the publication of an article without peer review, but by the editor-in-chief, is not unusual:

> Q. And did -- did the editor of the American Journal of Cardiology tell you in February of 2005 that he was not able to get any external reviews on that manuscript?
>
> A. He did. *That's not unusual*.
>
> Q. Okay.
>
> A. It wasn't something related to the manuscript. It happens all the time. People get busy.
>
> ***
>
> Q. Oh. Did you, on March 10, 2005, write to Dr. Michael Sumner and say, "He didn't hear back from the reviewers, so I -- so he accepted it anyway"?
>
> A. *What happened is he reviewed it himself, which is the highest form of review, because he's the editor in chief. He personally reviewed it*.
>
> ***

Q. -- you wrote back saying, "He didn't hear back from the reviewers, so he accepted it anyway," correct?

A. After he reviewed it himself.

Q. Thank you.

A. He personally -- the editor in chief -- *this is, by the way, a journal that Dr. Sacks has published many papers in. He personally reviewed the article, which makes it even a higher bar*.

(Ornish, Tr. 2446-47) (emphasis added).

(b) Expert Analysis

843. Dr. Sacks and Dr. Stampfer testified about problems with the design and conduct of the Ornish MP Study (2005). (Sacks, Tr. 1464-79; Stampfer, Tr. 750-51; CX1291 (Sacks, Report at 0019-24)).

Response to Finding No. 843:

Respondents object to proposed Finding No. 843 on the grounds that the word "problems" is vague and ambiguous, overly broad, and lacks merit. As discussed by Respondents' experts, Dr. Ornish and Dr. Heber, The Ornish MP Study (2005) constitutes competent and reliable scientific evidence that the consumption of the Challenged Products are beneficial to cardiovascular health by, among other things, improving blood flow. (RFF 1127-1138; 1303-1414; PX0023; PX0025-0011-0018; PX0192-0037-0038; 0053, Ornish, Tr. 2354-55).

844. Drs. Sacks and Stampfer agreed that the MP study did not use a recognized surrogate marker of heart disease. (CX1291 (Sacks, Report at 0020-21); Sacks, Tr. 1464 (myocardial perfusion, a measure of blood flow, is not used as the primary outcome in studies of treatment efficacy for CHD); Stampfer, Tr. 771-72 (blood flow is a research tool but not a recognized surrogate marker); *see also* CCFF ¶ (a)841 (JAMA editor citing use of intermediate endpoint as a flaw in the study)). Even where blood flow is shown to have been improved, it will not necessarily result in improved cardiovascular health, such as reductions in heart attack and stroke. (CX1291 (Sacks, Report at 0020-21)). Dr. Heber, too, characterizes the blood flow markers as "intermediate" in his expert report. (PX0192 (Heber, Report at 0053)).

Response to Finding No. 844:

As Dr. Ornish stated in his expert report and at trial, blood flow is essential to life, an important measure of heart disease, and *the bottom line in coronary heart disease* (along with how well the heart is pumping blood, called the ejection fraction). (RFF 1305-1306; Ornish, Tr. 2331; PX0025-0012). Blood carries oxygen and nutrients that feed the heart. (RFF 1307; PX0025-0012). If the blood flow to the heart (perfusion) is reduced, then the heart is no longer receiving enough blood flow to maintain itself. (RFF 1308; PX0025-0012). Coronary heart disease, which is the most common form of heart disease, occurs when the heart does not get enough blood to fuel itself and blood carries oxygen, which is the fuel for the heart. (RFF 1309; Ornish, Tr. 2331-32).

Dr. Sacks concedes that if blood flow is reduced, then this is not desirable. (RFF 1310; PX0361 (Sacks, Dep. at 179)). If this is temporary, then the person often experiences angina, or chest pain. (RFF 1311; PX0025-0012). If this reduction in blood to the heart lasts more than a few hours, then that portion of the heart that is underperfused may die and turn in to scar tissue—this is commonly referred to as a "heart attack." (RFF 1312; PX0025-0012). If this scar tissue is small, then the person may live; if this scar tissue is large or affects a critical part of the heart (e.g., the conduction system), then the person may die. (RFF 1313; PX0025-0012). Any increase in myocardial perfusion would reduce the risk of cardiovascular or coronary problems and improve heart health because, even with a blockage of a minor artery, a patient could have a stent inserted at a hospital or allow him or her to survive the ride in the ambulance, and in the case of a blockage in a major blood vessel, there would be an increased chance of recovery. (RFF 1314; Heber, Tr. at 1972-73).

A surrogate is either a sign or a symptom that is associated along the pathway to a disease. (RFF 1315; Heber, Tr. 1973). The FDA approves of LDL cholesterol as

surrogate for cardiovascular disease. (RFF 1316; Ornish, Tr. 2334). Dr. Ornish testified, however, that LDL cholesterol is really a risk factor for heart disease, and because it is not actually heart disease, it cannot be a valid surrogate. (RFF 1317; Ornish, Tr. 2334). While the FDA for the purposes of drug registration and testing only accepts a limited number of surrogate markers, such as LDL cholesterol and blood pressure, the number of indicators that physicians and scientists use are much greater and can be at many points along the pathway of heart disease. (RFF 1318; Heber, Tr. 1973). Clinical decisions are made, the health of the patient assessed and certain procedures are undertaken based on things that are surrogate markers, but may not be officially accepted by the FDA. (RFF 1319; Heber, Tr. 1973). Doctors want a surrogate marker to be something as closely related as possible to the actual disease, so that studying the surrogate may allow us to predict the likelihood of the disease or its progression. (RFF 1320; Heber, Tr. 1973-74).

In comparing myocardial perfusion and LDL cholesterol, myocardial perfusion is more closely connected as a surrogate for cardiovascular disease. (RFF 1321; Ornish, Tr. 2334). When a person has a biomarker like high LDL cholesterol which increases his or her risk, that is very distal or far away from the actual event of a heart attack which may be affected by many other factors, such as inflammation and oxidation. (RFF 1322; Heber, Tr. 1974). There are a number of people who have low cholesterol levels, but get heart disease. (RFF 1323; Ornish, Tr. 2334-35). About 50 percent of the people who die from a heart attack actually have cholesterol in the normal range. (RFF 1324; Heber, Tr. 1974). There are people who have high cholesterol levels who do not have heart disease, and the same is true blood pressure. (RFF 1325; Ornish, Tr. 2334-35). When measuring myocardial perfusion, researchers are actually measuring what matters most, which is how much blood flow the heart is getting. (RFF 1326; Ornish, Tr. 2334-35).

Dr. Sacks concedes that proper blood flow from the coronary artery and to the heart is fundamental to lowering the risk of cardiovascular disease. (RFF 1327; Sacks, Tr. 1593).

Dr. Ornish explains that for many years, it has been recognized that change in myocardial perfusion (blood flow to the heart) is actually a better predictor of cardiac events (thus a better surrogate marker) than coronary angiography. (RFF 1328; PX0025-0012). Coronary angiography measures how much blockage is in the coronary arteries that feed the heart. (RFF 1329; PX0025-0012).

However, the degree of blockage is only one of several mechanisms that affect perfusion, or blood flow to the heart. (RFF 1330; PX0025-0012). These include changes in vasomotor tone (how dilated or constricted the coronary arteries are), platelet aggregation (how sticky the platelets are that can form blood clots which may partially or complete occlude the flow of blood to the heart), and collateral blood flow (the heart can grow new blood vessels that provide additional blood flow around partial or even completely blocked arteries if the blockage occurs slowly overtime). (RFF 1331; PX0025-0012). In addition, conventional coronary angiography (the most commonly performed type in clinical practice) provides only a two-dimensional view of the inside of the lumen of the coronary artery. (RFF 1332; PX0025-0012). In a study a entitled *Compensatory enlargement of human atherosclerotic coronary arteries*, N Engl J Med. 1987 May 28;316(22):1371-5, Dr. Glagov and others demonstrated that the majority of the coronary atherosclerosis (blockage) is inside the vessel wall and cannot be visualized using conventional coronary angiography—somewhat analogous to only being able to view the tipoff an iceberg but not the bulk of it below the surface of the ocean. (RFF 1333; PX0025-0012).

In a major study directly comparing the value of thallium 201-scintigraphy (the test used in Dr. Ornish's study to measure the effects of pomegranate juice on blood flow to the heart) and coronary angiography, the authors found measures of blood flow were more predictive of subsequent clinical events (e.g., heart attacks) than coronary angiography, and both were equivalent in predicting subsequent mortality. (RFF 1334; PX0025-0012

citing Gibson RS, Watson DD, Craddock GB, et al., *Prediction of cardiac events after uncomplicated myocardial infarction: a prospective study comparing predischarge exercise thallium-201 scintigraphy and coronary angiography*, Circulation. 1983;68(2):321-336). The authors wrote: "Scintigraphy predicted low-risk status better than exercise testing ($p = .01$) or angiography ($p = .05$). Each predicted mortality with equal accuracy. However, scintigraphy was more sensitive in detecting patients who experienced reinfarction or who developed class III or IV angina….the overall sensitivity of angiography was lower than that of scintigraphy (71% vs. 94%; $p < .01$)." (RFF 1335; PX0025-0012-13). This study was published in Circulation, the American Heart Association's lead scientific journal. (RFF 1336; PX0025-0013).

A more recent study that compared perfusion (blood flow) studies with an extensive variety of other cardiac measures, including coronary angiography, concluded: "Myocardial perfusion abnormalities at rest and after stress are still the best predictors of cardiac event–free survival in patients with known or suspected IHD, even when compared with an extensive diagnostic work-up." (RFF 1337; PX0025-0012-13 *quoting* Gimelli A, Rossi G, Landi P, et al., *Abnormalities by gated SPECT: still the best predictor of cardiac events in stable ischemic heart disease*, J Nucl Med 2009; 50:546–553). Thus, studies have shown that measures of myocardial perfusion or blood flow to the heart are actually not only as predictive, but are often more predictive of who is going to get a subsequent heart attack or dies than the blockages alone. (RFF 1338; Ornish, Tr. 2333-34).

For the reasons discussed above, Complaint Counsel's simple categorization of myocardial perfusion as an "intermediate" marker does not somehow detract from its scientific and clinical significance in predicting heart disease.

845. Another problem was that the primary endpoint measurement reported in the published study as the main proof of benefit (SDS) was not identified as the primary endpoint in the protocol. The protocol for the Ornish MP Study (2005) provided for measurement of

perfusion, but did not identify whether the primary endpoint would be SSS, SRS, SDS or some other imaging measurement. (CX1291 (Sacks, Report at 0021); *see also* CX0613_0009-10). Dr. Ornish conceded that he did not specify that changes in SDS would be the primary endpoint measure. (PX0025 (Ornish, Report at 0014); *see also* Sacks, Tr. 1475)).

Response to Finding No. 845:

In his myocardial perfusion study, Dr. Ornish examined three measures: (1) the sum of the segmental scores at stress ("SSS") (amount of infarcted, ischemic, or jeopardized myocardium); (2) the sum of the segmental scores at rest ("SRS") (amount of infarcted or hibernating myocardium); and (3) the sum difference score ("SDS") (the difference between SRS and SSS or amount of ischemic or jeopardized myocardium). (RFF 1339; Ornish, Tr. 2341; PX0025-0013). "Ischemia" and "jeopardized" mean that part of the heart muscle (myocardium) is not receiving enough blood flow. (RFF 1340; PX0025-0014). "Infarcted" means part of the heart muscle has died and turned into scar tissue and is nonfunctioning. (RFF 1341; PX0025-0014). "Hibernating" means part of the heart muscle is also nonfunctioning and on the way to becoming infarcted. (RFF 1342; PX0025-0014).

SDS is considered a valid surrogate for coronary heart disease. (RFF 1343; Ornish, Tr. 2341-42). Dr. Ornish observes, however, that the study protocol made it clear that the primary endpoint measure of the study was improvements in reversible ischemia as measured by exercise or pharmacologic perfusion studies (this is why one of the primary selection criteria for patients enrolled in this study was that they needed to have a reversible perfusion defect at baseline). (RFF 1346; PX0025-0013). The primary end point, stated a priori, was how much blood flow the heart is getting when compared to rest and stress, which is what SDS measures. (RFF 1347; Ornish, Tr. 2341). While SRS is a good predictor of who is likely to die earlier from heart disease since it measures dead or scarred heart tissue, this was not the question that Dr. Ornish attempt to answer in his myocardial perfusion study. (RFF 1348; Ornish, Tr. 2342). Instead, Dr. Ornish was

trying to determine whether areas of the heart that were not getting enough blood flow during peak exercise improve blood flow after drinking pomegranate juice, which is what he found. (RFF 1349; Ornish, Tr. 2342-43). In other words, the SDS measures what Dr. Ornish stated a priori that he was most interested in: in plain English, would parts of the heart that were not receiving enough blood flow at baseline improve in patients who drank pomegranate juice compared to those in the randomized control group who drank a placebo? (RFF 1350; PX0025-0014).

While Dr. Ornish did not specify that changes in SDS would be the primary endpoint measure, it was not necessary to do so since SDS is a measure of how much of the heart was not receiving enough blood flow. (RFF 1351; PX0025-0014). Because SDS is derived by subtracting SRS from SSS, it is a way of factoring out the amount of infarcted or hibernating myocardium so Dr. Ornish could focus on what he was most interested in: SDS. (RFF 1352; PX0025-0014). Dr. Michael Sumner, who authored the study with Dr. Ornish, confirmed, through literature and discussions with a number of cardiologists, that SDS was the key variable to study. (RFF 1353; CX1344 (Sumner, Dep. at 181)). Dead heart muscle does not get better, so the condition was not going to improve from pomegranate juice or from any other intervention. (RFF 1354; PX0025-0014). Pomegranate juice improves blood flow to the heart but it does not bring dead tissue back to life. (RFF 1355; PX0025-0014). Dr. Ornish did not expect to find any changes in either SSS or SRS, since these are measures of infarction, and that is just what he found. (RFF 1356; PX0025-0014).

Dr. Ornish, therefore, did not cherry-pick the data, and he did not ignore the SSS and SRS measures which were reported in the *American Journal of Cardiology* manuscript. (RFF 1357; PX0025-0014). An improvement in myocardial perfusion is associated with decreased cardiac events (heart attacks, strokes, etc.) whether or not accompanied by

improvements in angina or other clinical symptoms, which are much more subjective and less predictive than changes in myocardial perfusion. (RFF 1358; PX0025-0014).

Dr. Ornish testified that the attached documents to CX0613 were not the correct protocols for the Bev I Study or Bev II Study submitted for approval by the institutional review board. (PX0355 (Ornish, Dep. at 124-125; 174-175)).

846. As previously stated, a study protocol should identify the primary endpoint in advance and set forth the planned statistical analysis, so that the researcher cannot pick and choose among results after the study is done. (CCFF ¶ 772; CX1291 (Sacks, Report at 0021). POM's documents indicate Respondents were advised that the lack of a "detailed statistical analysis plan" was an issue with the Ornish study. (*See* CX0576_0001).

Response to Finding No. 846:

Respondents incorporate by reference their responses to proposed Finding No. 845. In addition, Respondents previously objected to CX0576 (listed on Attachment B to JX2 as a conditionally admitted exhibit) on the grounds that it constitutes unreliable hearsay, lacking any exception. The document appears to be offered as proof of the matters stated therein. Respondents also objected to this exhibit on the grounds that it lacks foundation. The document itself does not support the conclusion that Respondents were purportedly on notice of the lack of "statistical analysis plan." Complaint Counsel has not cited to any deposition or trial testimony explaining and/or authenticating this document. For this reason, it should be stricken from the record.

847. Dr. Sumner, arrived at PMRI in January 2004, after the three month testing was done. (CX1344 (Sumner, Dep. at 13, 16-21); CX1136_0003). When Dr. Sumner started working for PMRI, he was told that SSS, SDS, *and* SRS were the "main variables." (CX1344 (Sumner, Dep. at 37-38) (emphasis added)). Dr. Sumner testified that SDS was chosen as the "key variable" based on his review of literature and conferring with cardiologists including Dr. Ornish, and his brother-in-law, a cardiologist researcher. (CX1344 (Sumner, Dep. at 181)).

Response to Finding No. 847:

Respondents incorporate by reference their responses to proposed Finding Nos. 845 and 846. Dr. Sumner actually conferred "*with a number of cardiologists*," including Dr. Ornish, several registered nurses, and his brother-in-law, a cardiologist researcher. (CX1344 (Sumner, Dep. at 181)) (emphasis added).

848. The "35 percent improvement" in myocardial perfusion claimed in the published report pertained only to the SDS scores. It ignored the SRS and SSS data. (Sacks, Tr. 1622-24). Dr. Sacks and Dr. Stampfer both stated that the .05 "*p*" value of the reported SDS improvement is not very persuasive where, as here, there were three possible outcome measures (SSS, SRS, and SDS) and only one just met significance. (CX1198_0003; Sacks, Tr. 1467 ("when there are . . . multiple outcomes . . . then a p-value of .05 . . . doesn't convey the same level of confidence than in a situation where there is one primary outcome"); CX1291 (Sacks, Report at 0021-22); Stampfer, Tr. 751 ("[T]he second reason I don't put a lot of weight on this is that the results were only slightly significant just for one of the three endpoints that was not specified as the primary outcome in advance.")).

Response to Finding No. 848:

Respondents incorporate by reference their responses to proposed Finding Nos. 845-847. While the Ornish MP Study (2005) did report a statistically significant change in the SDS, Dr. Ornish did not ignore the SSS and SRS measures which were reported in Table 2 of the study. (RFF 1357; PX0023-003; PX0025-0014). In his deposition, Dr. Ornish explained that Dr. Sacks (including Dr. Stampfer) is confused as to what the Ornish MP Study (2005) was actually measuring:

> He was saying that we were looking at all three measures, and therefore .05 is not considered to be a statistically significant effect. *We were interested -- our primary hypothesis was that we would show improvements in SDS, which is a measure of the heart not receiving enough blood flow, but it's not dead*. We wouldn't expect there to be measurements in dead tissue. Okay?
>
> Now, he gets confused here because he's saying, well, the SSS and the SRS, which are really measures of dead or hibernating tissue, are predictors of natural history; in other words, who's going to do badly. And of course they are,

> because the more of your heart muscle is dead, the worse your prognosis. *But that's a different question than what we're trying to answer, which is, is part of the heart that's not getting enough blood that's not dead likely to improve?* You're not going to show improvement in dead tissue, so it wasn't like we were saying, well, let's measure all three of them and see which one looks the best. We were measuring all three because you need to derive the summed difference score, which is really what we're most interested, from the other two, not because we expected there to be any changes in the other two.
>
> * * *
>
> So I just want to emphasize again, so Dr. Sacks was totally wrong here when he says that, oh, you know, you were looking at changes in all three measures and so, therefore, .05 is not, you know, the proper standard of improvement. Because we weren't. *We were only looking to those to the extent that you need those to derive what we were looking at, which is the changes in the tissue that we thought would either get better or worse*. But we certainly knew that the dead tissue wasn't going to get better or worse, which is what the other two measures are.

(PX0355 (Ornish, Dep. at 128-129; 139)) (emphasis added). Thus, as Dr. Ornish explained, although the authors' primary hypothesis was that pomegranate juice would result in an improvement in SDS (which is a measure of the heart not receiving enough blood), the Ornish MP Study (2005) actually examined all three measurements in an effort to divine the SDS. Dr. Ornish did not "cherry pick" the best result. For these reasons, Dr. Sacks' and Dr. Stampfer's criticisms should be disregarded.

849. Moreover, Dr. Sacks made clear that it is not appropriate to focus on the SDS data, and ignore SRS and SSS scores. (CX1291 (Sacks, Report at 0021-24)). Dr. Ornish acknowledged that SSS shows the presence of dead cardiac tissue, thus revealing whether or not a patient has had a silent heart attack; this information is not shown in the SDS measure. (Sacks, Tr. 1468). It also is not clear that the reported change in SDS was clinically meaningful, because the authors did not show that the patients experienced improvement in their clinical symptoms. (CX1291 (Sacks, Report at 0022)). For example, there was no statistically significant improvement in angina, which is chest pain due to insufficient blood flow to the heart. (CX1198_0003; Sacks, Tr. 1463-64).

Response to Finding No. 849:

Respondents incorporate by reference their responses to proposed Finding Nos. 845-848. As discussed above, Dr. Ornish did not ignore SRS and SSS scores. The testimony from Dr. Sacks cited by Complaint Counsel does not support the statement whatsoever that "Dr. Ornish acknowledged that SSS shows the presence of dead cardiac tissue, thus revealing whether or not a patient has had a silent heart attack; this information is not shown in the SDS measure." (Sacks, Tr. 1468). The Ornish MP Study (2005), however, did report improvements in clinical symptoms: "*[a]ngina episodes decreased by 50% in the experimental group (from 0.26 to 0.13) but increased by 38% in the control group* (from 0.53 to 0.75), although this difference was not statistically significant." (PX0023-0003) (emphasis added). At trial, Dr. Ornish acknowledged the result was not statistically significant, but explained "That wasn't statistically significant, because there's so much variability in angina that it's hard to show the statistical significance in a smaller group of people when you have something that's as variable, but it certainly is consistent with the findings. And if we go back to the common sense rule, if you show that the amount of chest pain is reduced by 50 percent and the blood flow is clearly getting better, that's a real finding." (Ornish, Tr. 2338-2339).

850. Another problem with the study was the large discrepancy in the blood flow values between the placebo and active groups at baseline. The baseline SSS for the placebo group was 9.6±6.5, and the baseline SSS of the juice group was 6.4±3.5, meaning that the placebo group was sicker than the juice group when the study started. Similarly, the baseline SRS for the placebo group was 3.8±4.7, and the baseline SRS for the juice group was 1.9±2.6, again showing that the placebo group was sicker at the beginning of the study. (CX1198_0003 (Table 2); CX1291 (Sacks, Report at 0022-23); Sacks, Tr.1469-72, 77; Stampfer, Tr. 750-52). Study documents from Dr. Ornish's clinic files show that the difference between the baseline SSS values of the placebo and juice groups was so large as to be statistically significant. (CX0701_0001 (email from M. Sumner to M. Eller, forwarded to D. Ornish, stating, "[t]here was a baseline difference in SSS between the experimental and the control groups ($p<.04$). We don't have to mention this, but we should keep this in mind.")). This imbalance in baseline values was mentioned by the JAMA Editor as a reason for rejecting the study for publication. (*See* CCFF ¶ (a)841).

Response to Finding No. 850:

Dr. Ornish clarified there was no difference in SRS and SDS at baseline, only a difference in SSS. (RFF 1361; Ornish, Tr. 2343; PX0025-0015). Although there was a difference in SSS at baseline, Dr. Ornish employed an "analysis of variance," which took into account any baseline differences. (RFF 1362; Ornish, Tr. 2343). Specifically, in his study, Dr. Ornish reported: "To test for the effects of experimental condition and time (and their interaction) on medical characteristics, 2 (experimental vs. placebo) X 2 (baseline vs. 3 months) analyses of variance for repeated measurements were run." (RFF 1369; PX0025-0015). Thus, controlling for baseline differences is built into this analysis. (RFF 1370; PX0025-0015; Ornish, Tr. 2394). In other words, it is concerned with whether the change over time is different between groups, so the groups do not have to start at the same place. Therefore, "statistical adjustment" is not necessary and could easily introduce bias. (RFF 1371; PX0025-0015).

The statistical phenomenon called "regression to the mean," holds that if someone is measured more than once, the outliers tend to come towards the middle, and any differences between the groups would be narrowed. (RFF 1366; Ornish, Tr. 2344; PX0025-0015). As a result, if someone were sicker, all other things equal, if there was no effective intervention, it would be expected for the subsequent measures to show that the subjects were a little better, not that they were necessarily worse. (RFF 1367; Ornish, Tr. 2344). As Dr. Sacks concedes out, "in any study involving a large number of variables, it is likely that some will be positive, simply due to chance." (RFF 1368; PX0025-0015).

When researchers recruit randomly and look at a number of different measures, it is not uncommon that one difference may be statistically significant in the group. (RFF 1364; Ornish, Tr. 2343-44). In his myocardial perfusion study, there were no differences

between the groups in their cholesterol, blood pressure, blood sugar, and weights levels at baseline. (RFF 1365; Ornish, Tr. 2344-45).

Even if there had been a difference in SSS at baseline, this would not have undermined the validity of the study, particularly since it was not Dr. Ornish's primary end point measure. (RFF 1363; Ornish, Tr. 2343; PX0025-0015).

If anything, CX0701 only suggests there was just a baseline difference in SSS, not SRS as contended by Complaint Counsel. (CX0701_0001). In any event, the exact baseline measurements were reported in Table 2 of the Ornish MP Study (2005). (PX0023-0003).

Finally, contrary to Complaint Counsel's suggestion, JAMA did not reject the Ornish MP Study (2005) from publication because of alleged "imbalance in baseline values." As discussed in response to Complaint Counsel's proposed Finding No. 841, the primary reason for non-publication of the manuscript was the following: "*The biggest issue is our 7% acceptance rate for unsolicited papers*, making for very keen competition for space in JAMA." (CX0699_0001) (emphasis added). In response to the JAMA editor, Dr. Ornish explained: "[s]ince the SDS was a little lower in the experimental group than the control group at baseline, *regression to the mean would have worked against showing further reduction in SDS in the experimental group*." (CX0699_0001) (emphasis added). Respondents incorporate by reference their response to proposed Finding No. 841.

851. This imbalance in baseline values shows that randomization did not produce an active and placebo group that were similar on relevant characteristics. (Stampfer, Tr. 751-52; CX1293 (Stampfer, Report at 0019); CX1291 (Sacks, Report at 0023)). It could be predicted that the control group, having worse coronary perfusion than the POM Juice group at baseline, would have a more accelerated form of the disease and show worsening on follow-up. (CX1291 (Sacks, Report at 0022-23); Sacks, Tr.1469-72, 77; *see also* Stampfer, Tr. 751 ("[H]ere, the placebo group was worse off at the start, and it's easy to imagine that if you're worse off at the start, you are going to get worse faster over time. So, the evidence isn't persuasive.")). Dr. Sacks stated that the baseline difference should have been reported in the publication. (Sacks, Tr. 1477; CX1291 (Sacks, Report at 0023)).

Response to Finding No. 851:

Respondents incorporate by reference their response to proposed Finding No. 850. For the reasons discussed above, any alleged difference at baseline of SSS simply would not have undermined or changed the validity of the Ornish MP Study (2005).

852. According to Dr. Sacks, the errors admitted by Dr. Ornish in the conduct of the study in CCFF ¶¶ (a)830-34 are inconsistent with widely-accepted standards for conduct of clinical trials. (CX1291 (Sacks, Report at 0023-24)).

Response to Finding No. 852:

Respondents object to this proposed Finding No. 852 on the grounds that it is argumentative, conclusory, lacks foundation, and misstates the record with respect to the use of the word "errors." Although no study is perfect, Dr. Ornish explains that an unbiased doctor could not throw out his positive myocardial perfusion study because of the criticisms raised by Dr. Sacks. (RFF 1413-1414; (PX0025-0005; Ornish, Tr. 2351). For the reasons discussed above, the Ornish MP Study (2005) constitutes competent and reliable scientific evidence that the consumption of the Challenged Products are beneficial to cardiovascular health by, among other things, improving blood flow. (RFF 1127-1138; 1303-1414; PX0023; PX0025-0011-0018; PX0192-0037-0038; 0053, Ornish, Tr. 2354-55).

853. Also inconsistent with accepted clinical trial conduct standards was the termination of the Ornish MP Study (2005) at a time the *p*-value was considered significant, rather than at the time the trial was originally set to end, as set forth in CCFF ¶¶ (a)835-39. (Sacks, Tr. 1474-75; CX1291 (Sacks, Report at 0023-24); *see also* Stampfer, Tr. 752-53, 771; CX1293 (Stampfer, Report at 0019)). If a researcher is forced to end a study because of a funding problem, this fact should be reported in the published report. "[I]n a controlled trial, it's essential to state what was the original plan and what was actually done. . . . Otherwise, the study could . . . develop biases." (Sacks, Tr. 1474-75). There is no mention of the 12 month planned study in the published results. (CX1198).

Response to Finding No. 853:

Respondents incorporate by reference their responses to proposed Findings Nos. 835-839. While Dr. Ornish did not have 12 months of follow-up data, this does not undermine the confidence in the three-month findings, which stand on their own. (RFF 1406; PX0025-0017). Bias is not an issue because outside factors precluded obtaining twelve-month data. (RFF 1407; PX0025-0017). Dr. Ornish explains that study was terminated after three months only because the Resnicks did not provide the funding that they had previously committed to this study, not because the p-value was statistically significant at three months. (RFF 1402; PX0025-0017). Dr. Ornish originally planned to study these patients at three months and at one year, but because he did not have the funding to do it for one year, he only measured patients for three months. (RFF 1403; PX0025-0017; Ornish, Tr. 2351-52).

854. The interpretation of the Ornish MP Study (2005) that is most consistent with principles of clinical study design and conduct is that the pomegranate juice treatment had no effect on any measure of cardiac health. (CX1291 (Sacks, Report at 0024)). Experts in the field of cardiovascular disease would not consider the Ornish MP Study to support the proposition that pomegranate juice provides a heart disease benefit, either in terms of prevention or treatment. (Sacks, Tr. 1472, 1526-28). In light of the problems in the design and conduct of the study, and the discrepant results of the SSS, SDS, and SRS measures, the study does not even support the conclusion that pomegranate juice had a favorable effect on coronary perfusion (blood flow to the heart). CX1291 (Sacks, Report at 0024); CX1293 (Stampfer, Report at 0018-19)).

Response to Finding No. 854:

Respondents incorporate by reference their responses to proposed Findings Nos. 824-854. As discussed *infra*, Dr. Ornish found that after only three months of patients drinking an eight ounce glass of pomegranate juice daily, those patients showed an 18 percent improvement in blood flow to their heart compared to the randomized, placebo control group, which experienced a 17 percent worsening. (RFF 1130; PX0023; Ornish, Tr. 2337; Heber, Tr. 1970-71). The comparative benefit of the pomegranate juice group to the placebo group was about 35 percent. (RFF 1131; PX0023; Ornish, Tr. 2337-38;

Heber, Tr. 1972). Those differences were statistically significant and the results were published in the *American Journal of Cardiology*. (RFF 1132; PX0023; Ornish, Tr. 2337-39); Heber, Tr. 1971-72). The finding of a 35 percent improvement in myocardial perfusion is likely to benefit a substantial number of people in the United States because it could reduce the risk of coronary heart disease, which is a leading cause of death. (RFF 1133; Ornish, Tr. 2338). In the study, Dr. Ornish concluded: "The results of this study demonstrates, for the first time, that daily consumption of pomegranate juice for 3 months may decrease myocardial ischemia and improve myocardial perfusion in patients who have ischemic CHD [coronary heart disease] as measured by the SDS." (RFF 1134; PX0023-0004). Because the natural history of heart disease is to get worse over time and it is unusual for people to get better, especially in such a short period of time, Dr. Ornish discovered that the mechanisms that affect blood flow to the heart are more dynamic than he once realized and that his findings are real. (RFF 1135; Ornish, Tr. 233). Dr. Ornish's finding is also consistent with his earlier studies in which he found that blood flow could be improved to the heart after just one month when people made intensive changes in diet and lifestyle. (RFF 1136; Ornish, Tr. 2338). Dr. Ornish drinks POM Juice and takes POMx. (RFF 1137; PX0355 (Ornish, Dep. at 72)). In short, the Ornish MP Study (2005) constitutes competent and reliable scientific evidence that the consumption of the Challenged Products are beneficial to cardiovascular health by, among other things, improving blood flow. (RFF 1127-1138; 1303-1414; PX0023; PX0025-0011-0018; PX0192-0037-0038; 0053, Ornish, Tr. 2354-55).

(4) Ornish CIMT Study

(a) About the Study

855. The Ornish CIMT Study (also known as the Beverage Study II) was a randomized, double-blind, placebo-controlled 73-person study that measured CIMT, blood pressure, and other related mechanisms for 12 months. (CX0754_0002). The treatment group drank one cup (eight ounces) of pomegranate juice concentrate daily, and the control group drank one cup of placebo beverage, daily, for one year. (CX0613_0020).

Response to Finding No. 855:

Although "blood pressure" and "other related mechanisms" may have been measured as part of the study, the primary endpoint of the Ornish CIMT Study was to investigate the effects of pomegranate juice on CIMT: "[w]e investigated the effects of daily consumption of pomegranate juice…for 1 year on carotid intima-media thickness (IMT) and indices of arterial stiffness for the common carotid arteries (CCA) in patients with at least 1 cardiovascular risk factor." (CX0754_0002). The document cited by Complaint Counsel, CX0754, purports to be study results, not the actual protocol for the Ornish CIMT Study. (CX0754). Dr. Ornish testified that the attached documents to CX0613 were not the correct protocols for the Bev I Study or Bev II Study submitted for approval by the institutional review board. (PX0355 (Ornish, Dep. at 124-125; 174-175)). The correct protocol for the Bev II Study, identified by Dr. Ornish during his deposition, as PX0355a007 which provides: "The goal for the total number of study participants is N=200, randomly divided into either an experimental (N=100) or control (N=100) group." (PX0355a007-0010). Thus, according to the protocol, the Ornish CIMT Study was designed to include 200, not 73 subjects. In preparing his power analysis for this study, and based on earlier studies in the field, Dr. Ornish estimated that he would need at least 200 patients to show a statistically significant difference in CIMT and budgeted his study accordingly. (RFF 1416; Ornish, Tr. 2352). During the Bev II study, however, because recruitment took longer than anticipated (since most patients with heart disease ended up having angioplasty, stents, and/or bypass surgery at a much higher rate than anticipated), the funding was cut, so Dr. Ornish was only able to recruit 73 patients, from which 56 patients pre and post data was collected. (RFF 1417; Ornish, Tr. 2352).

856. The protocol for the Ornish CIMT Study called for measurement of CIMT, cholesterol, LDL, HDL, triglycerides, and systolic and diastolic blood pressure at baseline, six, and twelve months. (CX0613_0019-20). The data analysis section stated that the data would be analyzed for statistical significance using a conventional test. (CX0613_0022).

Response to Finding No. 856:

Dr. Ornish testified that the attached documents to CX0613 were not the correct protocols for the Bev I Study or Bev II Study submitted for approval by the institutional review board. (PX0355 (Ornish, Dep. at 124-125; 174-175)). In any event, the correct protocol identified by Dr. Ornish in his deposition, indicates that although certain measurements would be taken, the primary purpose of the Ornish CIMT Study was to "determine if pomegranate juice will affect the progression of early/subclinical carotid atherosclerosis…" (PX0355a007-0010). In the "Methods of Data Analysis" section of the protocol, the document indicates that: "[d]ifferences in baseline characteristics of experimental and control group participants will be analyzed for statistical significance by use of conventional t-tests. Between group differences will be analyzed using standard ANOVA methods." (PX0355a007-0022).

857. According to the unpublished final report, there were no significant changes in the treatment group relative to the placebo for CIMT thickness or elastic properties. (CX0754_0002) (transmitting "Bev 2 Summary 6-16-05.doc")).

Response to Finding No. 857:

In preparing his power analysis for this study, and based on earlier studies in the field, Dr. Ornish estimated that he would need at least 200 patients to show a statistically significant difference in CIMT and budgeted his study accordingly. (RFF 1416; Ornish, Tr. 2352). During the Bev II study, however, because recruitment took longer than anticipated (since most patients with heart disease ended up having angioplasty, stents, and/or bypass surgery at a much higher rate than anticipated), the funding was cut, so Dr. Ornish was only able to recruit 73 patients, from which 56 patients pre and post data was collected. (RFF 1417; Ornish, Tr. 2352).

In his findings, Dr. Ornish nevertheless observed an improvement in the carotid artery significant to the 0.13 level as opposed to the 0.15 level. (RFF 1418; Ornish, Tr. 2352-

54). If that degree of change had occurred in the larger number of patients he had projected (i.e. 200 instead of 73), it would have been clearly at the 0.05 level or less and it would have been a strong study showing pomegranate juice affected the progression of carotid disease. (RFF 1420; Ornish, Tr. 2352-54). In the Bev II Study, Dr. Ornish also found a similar, almost statistically significant improvement in the elasticity of the arteries. (RFF 1421; Ornish, Tr. 2353). If he recruited and tested the number of patients in the protocol, Dr. Ornish would have reached statistical significance because there is no reason to think the next 127 patients would have been different than the first 73. (RFF 1422; Ornish, Tr. 2353-54).

It would have been inaccurate to report that pomegranate juice did not affect the progression of carotid atherosclerosis, since the study was underpowered for this purpose, and it would have been what is known as a type II error: that there may have been a statistically significant difference but the sample size was not sufficiently large to detect it. (RFF 1423; PX0025-0019; (CX1339 (Ornish, Dep. at 70-71; 81-82).

858. There also were no significant differences in the treatment group relative to the placebo group over time for any of the other heart-related measurements, including systolic and diastolic blood pressure, cholesterol, LDL, HDL, or triglycerides. (CX0754_0003,05; CX1291 (Sacks, Report at 0024-25); Stampfer, Tr. 754-55; CX1293 (Stampfer, Report at 0019-20)).

Response to Finding No. 858:

No conclusion can be drawn from other "heart-related measurements" cited by Complaint Counsel because, as Dr. Sacks admits, the lack of statistical significance for a positive result in Bev II Study is not proof of a negative. (RFF 1426; Sacks, Tr. 1608-09).

859. An early draft of the Ornish CIMT Study (Beverage II) protocol had called for a sample size of 200 patients. (CX0584_0005; PX0355 (Ornish, Dep. at 178)). Dr. Ornish testified that the decrease in the number of patients was due to the Resnicks cutting his funding. (Ornish, Tr. 2454; *see also* CX1360 (S. Resnick, Dep. at 131) (stating that Dr. Ornish was slow and unable to get enough recruits)). The agreement signed by Dr. Ornish on September 19, 2003, however, called for a sample size of 55 patients. (CX0613_0002). PMRI was actually able to recruit 73 patients, and data on 56 patients were available for analysis. (Ornish, Tr. at 2452).

Response to Finding No. 859:

Complaint Counsel misstates the record with respect to the Bev II Study protocol and Dr. Ornish's testimony concerning the latest and/or correct version of the document, including the number of patients to be studied. To begin, CX0584 is entitled "The Beverage Study Protocol II" and purportedly reflects the date of "*March 17, 2003*." (CX0584) (emphasis added). CX0584 identifies "[t]he target sample of 200 patients." (CX0584_0005). CX0584 was also marked as Exhibit 58 to Dr. Ornish's December 10, 2010 deposition. (CX0584; PX345a58). At his December 10, 2010 deposition, when asked if CX0584 was the final protocol for the Bev II Study, Dr. Ornish answered: "I don't know." (CX1339 (Ornish, Dep. at 78-79)).

In his April 26, 2011 expert deposition, Dr. Ornish was asked to authenticate a non-bates stamped document, also labeled "The Beverage Study Protocol II," which purported to reflect the date of "*June 21, 2003*" and listed "[t]he target sample of 50 patients." (PX0355a006)). (emphasis added). During his April 26, 2011 deposition, however, Dr. Ornish identified Exhibit 7 as the correct and/or final version of the Bev II Study protocol, which is actually dated *September 17, 2003* and lists "[t]he target sample of 200 participants." (PX0355a007)).

Thus, while the *September 19, 2003* letter agreement in CX0613 indicates that the Bev II Study should include 55 participants, the protocol later identified by Dr. Ornish at his April 26, 2011 deposition, dated September 17, 2003 provides that the target sample would be 200 participants. (PX0355a007).

860. On or about October 21, 2004, PMRI finished its data collection. (CX0697). On or about March 24, 2005, Dr. Sumner provided an analysis of the study data to Dr. Weidner, stating, "very few significant interactions . . . a mixed, but relatively disappointing bag so far." (CX0717_0001; CX1344 (Sumner, Dep. at 151-52)).

Response to Finding No. 860:

When asked about the email marked as CX0697 and if PMRI concluded the Bev II Study on October 21, 2004, Dr. Sumner testified "I don't recall when if that's when the Bev II completed data collection." (CX1344 (Sumner, Dep. at 144-145)). In addition, when asked if he prepared the analysis attached to CX0717, Dr. Sumner testified "I can't specifically remember doing this exact analysis but I did Bev II analyses and there were baseline six months and twelve months data points." (CX1344 (Sumner, Dep. at 150-151)). In any event, the data attached to CX0717 appears to be preliminary in nature: "[f]or Bev 2, I have included the raw scores." (CX0717_0001). The final results were not prepared and/or finalized until August 2005. (CX0754_0001). Complaint Counsel fail to cite other language in the email, including positive statements regarding the Bev I Study, which explains the statements by Dr. Sumner who clarified: "[s]ome trends look promising, though others do not." (CX0717_0001). Thus, in this context, Dr. Sumner's statements are properly understood. Respondents incorporate by reference their responses to proposed Finding Nos. 855 and 857, which explain, among other things, that while the Ornish CIMT Study was underpowered, it nevertheless observed an improvement in the CIMT. (RFF 1418).

861. PMRI made an effort to reexamine the data to identify positive results. On March 24, 2005, Dr. Sumner stated, "I am looking into additional ways to analyze the data" and suggested sending "the CIMT results to [another researcher] to check before [sending] them to Harley [Liker] /the Resnicks." (CX0717_0001; *see also* CX0718_0001). The next day, another PMRI employee suggested having a biostatistician analyze the data "before concluding the juice had a null effect." (CX0719_0001). On April 5, 2005, Dr. Weidner also volunteered to "give Bev II another try . . . feel[ing] pretty confident that if there is something there, [she] can find it[.]" (CX0724_0001).

Response to Finding No. 861:

Complaint Counsel fail to provide evidentiary any support for the first sentence of proposed Finding No. 861. Respondents have no specific response to the second sentence of proposed Finding No. 861. The statement made in CX0719 regarding the

purported "null effect" of the Bev II Study lacks foundation. With respect to CX0719, when asked if he agreed if the Bev II Study data should be analyzed again, Dr. Sumner testified that he "I can't remember exactly, you know, what my response on March 25th was or what follow-up might have happened from this." (CX1344 (Sumner, Dep. at 155-156)). At trial, Dr. Ornish testified that it would be wrong to classify the Bev II Study as a "null" study:

> Q. And I think my question was, there were no significant changes in the experimental group relative to the placebo for either thickness or elastic properties, and that is set forth in Table 2, correct?
>
> A. If you define significance at the 0.5 level, that's correct. If you say the 0.1 -- there was an 87 percent likelihood that this was not due to chance as opposed to a 95 percent likelihood this was not due to chance. *It would have been wrong to publish this as a null finding*.

(Ornish, Tr. 2456) (emphasis added). Respondents incorporate by reference their responses to proposed Finding Nos. 855 and 857, which explain, among other things, that while the Ornish CIMT Study was underpowered, it nevertheless observed an improvement in the CIMT. (RFF 1418).

862. On March 24, 2005, Dr. Ornish told Dr. Sumner that he wanted to "publish results, even if they are non-significant." (CX0717_0001). Dr. Weidner agreed, stating that, "even if there are no effects, we need to report them." (CX0718_0001; CX1344 (Sumner, Dep. at 154)).

Response to Finding No. 862:

Complaint Counsel's citation to and/or reliance on the statement in CX0717 that "Dean said we should publish results, even if they are non-significant" is classic hearsay being offered to prove the truth of the matter asserted therein with no exception. As a result, this statement should be excluded from the record. At trial, Dr. Ornish explained this email in detail:

> You just asked me a question, and I'd like to answer it. You asked me if I had told Michael Sumner that he should publish it even if the results were nonsignificant, and the answer to that question is if they were clearly nonsignificant, if the P-value was 0.9, then I would say definitely we should publish it. But in this case, once we actually analyzed the data, and as you can see in that document you gave me a moment ago, the one dated August 4th, 2005, you actually see in the data, it was significant to the 0.13 level, which means that it was thought that it would have been grossly misleading and I think unethical to publish a study saying that pomegranate juice had no effect when, in fact, we knew from the very beginning that we needed at least 200 patients, and that if this trend had continued, it would have been statistically significant to the 0.5 level
>
> * * *
>
> Well, *I'm being quoted and that's called hearsay*. You can ask me directly what I actually said, and what I said is that if they were clearly nonsignificant, if the P-value is 0.8 or 0.9, in which case having more patients wouldn't have changed it, that would be an interesting finding. That wasn't the case here.\
>
> *The case was it was clearly a type two error, which means that the study was underpowered because we knew from the beginning we needed 200 patients*. And the only reason we didn't, which I have to tell you is just incredibly annoying to have to kind of revisit this whole experience with the Resnicks, was that they cut us off at the knees by cutting our funding.
>
> And if they had just let us finish what we wanted to do -- it took longer because it took longer to recruit the patients and we had to find a more accurate municipal lab to do the analyses in, and for that we were punished. *And so we ended with an indeterminate finding, not a clearly nonsignificant finding*.

(Ornish, Tr. 2458-61) (emphasis added). CX0718 is not part of the same email chain as CX0717 and cannot be characterized as a response by Dr. Sumner. As result, the statement that "Dr. Weidner agreed" is not supported by the record and/or the two

exhibits cited. As Dr. Ornish explained, the Ornish CIMT Study ended up being indeterminate because of a type II error and, as a result, publication was not necessary.

863. On March 24, 2005, a PMRI employee emailed Dr. Ornish stating that "Stewart [Resnick] said he was sitting with Harley [Liker] in his office, yelling at him because he wants Bev II results, and he decided to call our office to have someone else to yell at. . . . He said 'you've already been paid, I want the results.'" (CX0718_0001).

Response to Finding No. 863:

Respondents previously objected to CX0718 (listed on Attachment B to JX2 as a conditionally admitted exhibit) on the grounds that the statements: "Stewart said he was sitting with Harley in his office, yelling at him because he wants Bev II results, and he decided to call our office to have someone else to yell at" and "[h]e said 'you've already been paid, I want the results" constitute unreliable hearsay, lacking any exception, and is being offered as proof of the matters stated therein. As a result, this document should excluded from the record and no evidence supports Complaint Counsel's proposed Finding No. 863.

864. On or about March 29, 2005, Dr. Sumner ran an analysis on additional data, finding nothing significant but several positive "trends." (CX0720_0001).

Response to Finding No. 864:

At the time this email was composed, Dr. Sumner testified that "[w]e were continuing to run at this point in time power analyses to indicate what sample size would be needed, given the findings so far to be significant." (CX1344 (Sumner, Dep. at 158)). In response to CX0720, Dr. Sumner further testified that "[i]t doesn't indicate that I was continuing to re-analyze[] certain pieces." (CX1344 (Sumner, Dep. at 159)).

865. On April 5, 2005, another PMRI scientist requested more time to reanalyze the data and asked Dr. Ornish to "stall the Resnicks for another week or two." (CX0724_0001). However, on April 20, 2005, in response for another request for more time to analyze the data, Dr. Ornish denied the request, stating that "[t]he Resnicks always punish us for taking more time even when it's to improve the quality of the study." (CX0726_0001).

Response to Finding No. 865:

Complaint Counsel neglects to cite to the following sentence cited in CX0724 which reads: "I would like to give Bev II another try myself…I feel pretty confident that if there is something there, [I] can find it (see Gleason groupings and PSA – I'd like to look at the sample a bit closer and re-read Hodis' paper with a closer look at subject characteristics etc…e.g., statin situation…" (CX0724). Complaint Counsel fails to cite the sentence preceding Dr. Ornish's quoted statement in CX0726 in support of proposed Finding No. 865 which reads: "But if we have significant data now, and we're reasonably sure they're correct, let's save time and go with it." (CX0726_0001). Dr. Ornish's statement is in response to Dr. Weidner's email which reads: "Hi Dean, we met to have a close look at Bev II data – it looks like we may have sig. results in those who stay statin-free for the entire study period." (CX0726_0001).

866. The final analysis for the Ornish CIMT Study results was conducted in approximately June 2005. (CX1344 (Sumner, Dep. at 168-69)). On or about June 16, 2005, the results of the study were provided to Dr. Ornish. (CX0752; CX1344 (Sumner, Dep. at 168-69)).

Response to Finding No. 866:

Dr. Sumner testified that he "can't say with certainty exactly when the final analyses on Bev II were conducted" and "[m]y best estimate [was] that it was sometime around that time but it could be give or take months that Bev II was wrapped up." (CX1344 (Sumner, Dep. at 168)). Dr. Sumner also testified that "I couldn't say if this was the final. I could say it was a summary that we provided." (CX1344 (Sumner, Dep. at 169)). In the attached document to CX0752, Dr. Sumner clarified that "I can say in general that overall, there were some trends that were potentially positive but didn't reach significance and that there were other trends that were, you know, were not and that was enough for the summary." (CX1344 (Sumner, Dep. at 169)). Thus, it is unclear whether CX0752 contained all of the positive findings of the Bev II Study.

867. On August 4, 2005, Dr. Ornish sent Respondents the final study results, showing no benefits for patients who drank pomegranate juice on CIMT or any of the other heart related measures including blood pressure and cholesterol. (CX0754; Ornish, Tr. 2457; S. Resnick, Tr. 1682)).

Response to Finding No. 867:

Respondents object to Complaint Counsel's proposed Finding No. 867 on the grounds that it is vague and ambiguous as to the meaning "no benefits," conclusory and lacks foundation. Complaint Counsel's citation to Dr. Ornish's trial testimony to support proposed Finding No. 867 is a gross misstatement of the record. Dr. Ornish did not testify that there were purportedly "no benefits for patients who drank pomegranate juice." (Ornish, Tr. 2457). At trial, when asked if he recalled receiving the results of the Ornish CIMT Study, Mr. Resnick responded: "No." (S. Resnick, Tr. 1682).

Respondents incorporate by reference their responses to proposed Finding Nos. 855 and 857. In the Ornish CIMT Study, Dr. Ornish observed an improvement in the carotid artery significant to the 0.13 level as opposed to the 0.15 level. (RFF 1418; Ornish, Tr. 2352-54). If that degree of change had occurred in the larger number of patients he had projected (i.e. 200 instead of 73), it would have been clearly at the 0.05 level or less and it would have been a strong study showing pomegranate juice affected the progression of carotid disease. (RFF 1420; Ornish, Tr. 2352-54). Dr. Ornish also found a similar, almost statistically significant improvement in the elasticity of the arteries. (RFF 1421; Ornish, Tr. 2353). If he recruited and tested the number of patients in the protocol, Dr. Ornish would have reached statistical significance because there is no reason to think the next 127 patients would have been different than the first 73. (RFF 1422; Ornish, Tr. 2353-54).

868. Respondents were aware that the Ornish CIMT Study results showed no statistically significant benefit. (*See* CX0756_0001 (email dated August 5, 2005, from Dr. Liker to Mrs. Resnick); CX0837_0001 (email from Dr. Liker to Dr. Dreher transmitting the study results on Sept. 25, 2006); CX0262_0003 (internal POM Wonderful Medical Portfolio dated Dec. 17, 2008 describing Ornish CIMT Study results as showing "no change"); CX1265_0003, *in camera* ({

}); CX1379_0016, *in camera* (Response to Request for Admissions No. 22)).

Response to Finding No. 868:

Respondents incorporate by reference their responses to proposed Finding Nos. 855 and 857. In the Ornish CIMT Study, Dr. Ornish observed an improvement in the carotid artery significant to the 0.13 level as opposed to the 0.15 level. (RFF 1418; Ornish, Tr. 2352-54). If that degree of change had occurred in the larger number of patients he had projected (i.e. 200 instead of 73), it would have been clearly at the 0.05 level or less and it would have been a strong study showing pomegranate juice affected the progression of carotid disease. (RFF 1420; Ornish, Tr. 2352-54).

When asked if she recalled receiving CX0756, Mrs. Resnick testified that she did not specifically receiving the document. (L. Resnick, Tr. 163-164).

(CX1379_0016, *in camera*).

(b) Expert Analysis

869. The Ornish CIMT Study appears to have been well-designed and well-conducted. (Sacks, Tr. 1485-88; CX1291 (Sacks, Report at 0026)).

Response to Finding No. 869:

In reviewing Respondents' cardiovascular research, Dr. Sacks is hardly objective: when any of Respondents' studies do not reach statistical significance, he calls it an excellent, well-designed study. When Respondents' studies do show a positive result, however, Dr. Sacks calls the research flawed.

Respondents incorporate by reference their responses to proposed Finding Nos. 855 and 857. In preparing his power analysis for this study, and based on earlier studies in the field, Dr. Ornish estimated that he would need at least 200 patients to show a statistically significant difference in CIMT and budgeted his study accordingly. (RFF 1416; Ornish, Tr. 2352). During the Bev II study, however, because recruitment took longer than anticipated (since most patients with heart disease ended up having angioplasty, stents, and/or bypass surgery at a much higher rate than anticipated), the funding was cut, so Dr. Ornish was only able to recruit 73 patients, from which 56 patients pre and post data was collected. (RFF 1417; Ornish, Tr. 2352).

In his findings, Dr. Ornish nevertheless observed an improvement in the carotid artery significant to the 0.13 level as opposed to the 0.15 level. (RFF 1418; Ornish, Tr. 2352-54). If that degree of change had occurred in the larger number of patients he had projected (i.e. 200 instead of 73), it would have been clearly at the 0.05 level or less and it would have been a strong study showing pomegranate juice affected the progression of carotid disease. (RFF 1420; Ornish, Tr. 2352-54).

870. Dr. Sacks described the results of this study as "convincingly null, showing that pomegranate juice treatment did not improve CIMT or the other tested parameters" including elasticity of the arteries, blood pressure, or cholesterol. (CX1291 (Sacks, Report at 0026); *see also* CX1293 (Stampfer, Report at 0019-20); Stampfer, Tr. 755).

Response to Finding No. 870:

Respondents incorporate by reference their responses to proposed Finding Nos. 855 and 857. In the Ornish CIMT Study, Dr. Ornish observed an improvement in the carotid artery significant to the 0.13 level as opposed to the 0.15 level. (RFF 1418; Ornish, Tr. 2352-54). Dr. Sacks agrees that the Bev II Study concept and study design were fine and the measurements read by good institutions. (RFF 1419; Sacks, Tr. 1603). If that degree of change had occurred in the larger number of patients he had projected (i.e. 200 instead of 73), it would have been clearly at the 0.05 level or less and it would have been a strong

study showing pomegranate juice affected the progression of carotid disease. (RFF 1420; Ornish, Tr. 2352-54). Second, Dr. Ornish also found a similar, almost statistically significant improvement in the elasticity of the arteries. (RFF 1421; Ornish, Tr. 2353). If he recruited and tested the number of patients in the protocol, Dr. Ornish would have reached statistical significance because there is no reason to think the next 127 patients would have been different than the first 73. (RFF 1422; Ornish, Tr. 2353-54).

It would have been inaccurate to report that pomegranate juice did not affect the progression of carotid atherosclerosis, since the study was underpowered for this purpose, and it would have been what is known as a type II error: that there may have been a statistically significant difference but the sample size was not sufficiently large to detect it. (RFF 1423; PX0025-0019; (CX1339 (Ornish, Dep. at 70-71; 81-82)). In his deposition, Dr. Ornish further explained why the study cannot be characterized as a "null" study:

> We ended up spending a lot of time doing a study that we really couldn't say – *we couldn't publish a study as showing that it was a null finding, because it wasn't a null finding, because it was an underpowered study*.
>
> And this wasn't something -- this was all declared a priori, as Dr. Sacks would say. We declared a priori that we needed 200 patients. *And so it's, again, a type two error. It's not detecting a change because the study was underpowered*. That may have occurred if – it would have occurred if these trends had been seen in the large group of patients, and there's no reason to think that they wouldn't have been.
>
> *So we couldn't publish it as a study showing it was a null finding. If we had 200 patients and we showed that it wasn't a significant difference, that would have been a really interesting study and it would have shown that pomegranate juice had no effect. But that's not what we found. And if we'd had 200 patients and we saw these trends, we would have shown that pomegranate juice caused an improvement in blockages in the arteries that*

> *feed the brain. But we couldn't say that either because we only had 56 patients*. So it was unfortunate

(PX0355 (Ornish, Dep. at 187-188)) (emphasis added). Dr. Ornish further explained:

> Well, *here again, the study was underpowered, and so I'm not sure that anything can be made of any of the measurements* since we weren't -- the sample size was not what we declared a priori it should have been. But -- so I am not comfortable -- and I think it would be inaccurate to draw any conclusions from this because the study had a quarter -- approximately a quarter of the patients that we calculated we would need to show a statistically significant difference.

While Dr. Sacks states that this study proved that pomegranate juice had no effect on carotid IMT, it would be more accurate to see this study as a validation of the Dr. Aviram and Dr. Davidson studies since the differences in CIMT would have been statistically significant if the findings we measured in 73 patients were found in the 200 patients that we originally planned to enroll. (RFF 1424; PX0025-0019).

Although he disputes Dr. Ornish's suggestion that this study was underpowered, Dr. Sacks admits that the Bev II Study was indeed "underpowered" and concedes it is possible there could have been statistically significant differences if the sample size were larger. (RFF 1425; Sacks, Tr. 1607-08; PX0361 (Sacks, Dep. at 210)). Dr. Sacks admits that the lack of statistical significance for a positive result in Bev II Study is not proof of a negative and does not mean pomegranate juice is not beneficial. (RFF 1426; Sacks, Tr. 1608-09).

871. Dr. Sacks further opined that the null results of the Ornish CIMT Study confirm that the purportedly positive results of Dr. Aviram's unrandomized, uncontrolled 19-patient CIMT/BP Study lack credibility. (Sacks, Tr. 1486-88; CX1291 (Sacks, Report at 0026)).

Response to Finding No. 871:

Respondents object to proposed Finding No. 871 on the grounds that it misstates the record and lacks foundation. Respondents incorporate by reference their responses to proposed Finding Nos. 855, 857, and 870. Dr. Ornish stated that it would be more accurate to see this study *as a validation of the Dr. Aviram and Dr. Davidson studies* since the differences in CIMT would have been statistically significant if the findings we measured in 73 patients were found in the 200 patients that we originally planned to enroll. (RFF 1424; PX0025-0019) (emphasis added).

872. Dr. Ornish ignored his own CIMT Study results in reaching his conclusions regarding the effect of pomegranate juice on heart disease. (PX0355 (Ornish, Dep. at 192-93)). He argued that the null results were caused by the fact that the study was underpowered, and stated that this is why he did not publish the study. (CX1339 (Ornish, Dep. at 82); PX0355 (Ornish, Dep. at 188). He hypothesized that if he *had* been provided with sufficient funding to enroll 200 persons, a statistically significant effect *might* have been demonstrated; however, he admitted that this is speculation on his part. (Ornish, Tr. 2352-53, 2457; CX1339 (Ornish, Dep. at 102-04); PX0355 (Ornish, Dep. at 191); *see also* Sacks, Tr. 1486-87; CX1291 (Sacks, Report at 0025-26)).

Response to Finding No. 872:

Respondents object to proposed Finding No. 872 on the grounds that it misstates the record and lacks foundation. Respondents incorporate by reference their responses to proposed Finding Nos. 855, 857, 870, and 871. Dr. Ornish did not testify that he "ignored his own CIMT Study in reaching his conclusions regarding the effect of pomegranate juice on heart disease." (PX0355 (Ornish, Dep. at 192-93)). Instead, Dr. Ornish testified that it was an indeterminate study that cannot be relied upon: "It neither proves or disproves. It would be, again, as wrong to say that it proves as it would be for Dr. Sacks to assert that it disproves it." (PX0355 (Ornish, Dep. at 192-93)). Contrary to Complaint Counsel's suggestion otherwise, the word "null" is not even mentioned once in Dr. Ornish's December 10, 2010 deposition. (CX1339 (Ornish Dep.)).

873. Dr. Sacks stated that Dr. Ornish's willingness to ignore the null results of his study is an inappropriate treatment of the data. (CX1291 (Sacks, Report at 0025)). Dr. Sacks

explained that the data are not rendered irrelevant by the fact that the study was smaller than originally planned: "Having conducted the study, the researcher and the sponsor must live with the results." (CX1291 (Sacks, Report at 0025-26); Sacks, Tr. 1487-89).

Response to Finding No. 873:

Respondents object to proposed Finding No. 873 on the grounds that it misstates the record and lacks foundation. Respondents incorporate by reference their responses to proposed Finding Nos. 855, 857, and 870-872.

874. Dr. Heber also did not consider the results of the Ornish CIMT Study in reaching his conclusions, because he had been informed that the study was "incomplete." (PX353 (Heber, Dep. at 180-81); Heber, Tr. 2134). Notably, Respondent Tupper testified that if a study was not published, it was not complete. (CX1353 (Tupper, Dep. at 82-84)).

Response to Finding No. 874:

Respondents object to proposed Finding No. 874 on the grounds that it misstates the record and lacks foundation. In his deposition, Dr. Heber testified that the Ornish CIMT Study "was not fully recruited and was terminated prematurely." (PX353 (Heber, Dep. at 180)). Dr. Heber also stated that he did review the Ornish CIMT results because he "considered it to be a fragmentary result, because he [Dr. Ornish] never completed recruiting the subjects…" (PX353 (Heber, Dep. at 181)). At trial, Dr. Heber observed that the Ornish CIMT Study "had inadequate power at that number of subjects," so no conclusions could be drawn from the study. (Heber, Tr. 2133-34). In his expert report, Dr. Heber explained: "The failure of any clinical trial to show a difference cannot be interpreted as a negative finding, however. Only a probability that any difference has been excluded can be calculated, using the so-called beta type II error calculation, which was not done by Dr. Stampfer." (PX0192-0053). In his deposition, Mr. Tupper explained that "the reason that [a] study doesn't get published is that there's nothing learned, no conclusions drawn," not because it is not incomplete. (CX1353 (Tupper, Dep. at 84)). Mr. Tupper's testimony is consistent with that of Dr. Ornish and Dr. Heber in which he acknowledges that an indeterminate cannot be relied upon. Respondents

objected to most of the questions posed to Mr. Tupper, and cited by Complaint Counsel, on the grounds that they were vague and ambiguous, lack foundation, all for speculation, and were compound. (*See* Respondents' Objections to Dep. Testimony, at p. 87).

c. Davidson Studies

875. Dr. Michael Davidson is the Medical Director of Radiant Research, Chicago. (CX1134_0001). He has been involved, in some manner, in over 700 clinical studies over the past 25 years. (JX0003 ¶ B.18). Drs. Sacks and Ornish agree that Dr. Davidson is very highly regarded for his clinical research in the field of cardiovascular disease. (Sacks, Tr. 1490; PX0355 (Ornish, Dep. at 197-98)).

Response to Finding No. 875:

Respondents have no specific response.

876. In 2003, Dr. Liker approached Dr. Davidson about conducting a CIMT and a brachial artery reactivity testing study for Respondents. (CX1336 (Davidson, Dep. at 92-93); CX0586). From the beginning, Dr. Liker indicated that the study should be randomized, double-blind, and placebo-controlled. (CX1336 (Davidson, Dep. at 92)).

Response to Finding No. 876:

In his deposition, Dr. Davidson testified that Dr. Liker *wanted* the study to be double-blind, placebo-controlled and randomized, not that it *should* or was required to be done in such a manner. (CX1336 (Davidson, Dep. at 92-93)).

877. Dr. Liker implicitly acknowledged that the Aviram ACE/BP Study (2001), the Aviram CIMT/BP Study (2004), the Ornish MP Study (2005), and the unpublished Ornish CIMT Study collectively did not provide clear evidence of heart health benefits. In a summary of cardiovascular studies sent to a scientific consultant for POM, he described these studies and stated that POM was still exploring its research options "in its efforts to understand whether or not the consumption of pomegranate juice offers cardiovascular benefits." (CX0579_0003-04).

Response to Finding No. 877:

Respondents object to proposed Finding No. 877 on the grounds that it lacks foundation, assumes facts not in evidence, and is vague and ambiguous. Complaint Counsel fails to cite to any evidence in the record to support the first sentence in support of its proposed

Finding No. 877 that Dr. Liker "implicitly acknowledged" anything or that the studies "did not provide clear evidence of heart health benefits." Complaint Counsel's reliance on CX0579 to support such an inference is grossly misleading. In CX0579, Dr. Liker writes: "[m]y hope is that you will be able to advise us on the appropriateness of the current study design, specifically looking at entry criteria for the patients in the two studies and also commenting on whether additional studies should be included in the protocol." (CX0579_0002). In the Executive Summary of the document, Dr. Liker states: "PomWonderful is currently studying its various options in terms of entry criteria for patients as well as appropriate end points in its efforts to understand whether or not the consumption of pomegranate juice offers cardiovascular benefits." (CX0579_0004). Nothing in CX0579 suggests that Dr. Liker was somehow diminishing in any way the studies by Dr. Aviram or Dr. Ornish.

878. Dr. Davidson conducted two studies for Respondents: (1) Davidson MH., *et al.*, *Effects of Consumption of Pomegranate Juice on Carotid Intima-Media Thickness in Men and Women at Moderate Risk for Coronary Heart Disease*, 104 Am. J. Cardiology 936 (2009) ("Davidson CIMT Study") (CX1065; *see* JX0003 ¶ B.17); and (2) Davidson MH, *The Effects of Pomegranate Juice on Flow-Mediated Vasodilation* (unpublished, 2004) ("Davidson BART/FMD Study") (CX0684; *see* JX0003 ¶ B.17). The two studies were covered by a single protocol that was amended over time. (*See* CX0684). The cost for the two studies, sponsored by the Stewart and Lynda Resnick Revocable Trust, was $2,940,494. (CX1134_0001).

Response to Finding No. 878:

The document cited by Complaint Counsel, CX0684, does not establish, on its face, that the Davidson CIMT and Davidson BART/FMD Study were governed by the same protocol. (CX0684).

(5) Davidson CIMT Study (2009)

(a) About the Study

879. The Davidson CIMT Study (2009) was an 18-month, 289-person randomized, double-blinded, placebo-controlled clinical trial designed to test the effect of pomegranate juice on CIMT progression rates in subjects at moderate coronary heart disease risk. (CX1065_0001; CX1291 (Sacks, Report at 0027)). Subjects were middle-aged men and women with one or more CHD risk factors (high LDL, low HDL, hypertension or use of

hypertension medication, or cigarette smoking) and baseline posterior wall CIMT of 0.2 to 2.0 mm without significant stenosis. (CX1065_0001-02; CX1291 (Sacks, Report at 0027)). The study excluded persons with actual CHD or diabetes. (CX1065_0002).

Response to Finding No. 879:

The Davidson CIMT Study (2009) analyzed the results of 289 persons, but actually screened and enrolled 876 and 383 subjects, respectively. (PX0014-0002). The subjects were required to have a baseline posterior wall common CIMT measurement of >0.7 and <2.0 mm on ≥1 side (right or left. (PX0014-0002). According to the study, "[e]vidence of carotid stenosis ≥50% was exclusionary." (PX0014-0002).

880. Study participants drank eight ounces of pomegranate juice or placebo juice daily. Adherence to study product consumption was assessed at each visit by reviewing daily consumption diaries maintained by the subjects. (CX1065_0002).

Response to Finding No. 880:

Although the Davidson CIMT Study (2009) states "[a]dherence to study product consumption was assessed at each visit by reviewing a daily consumption diary maintained by the subject," Dr. Davidson and Dr. Ornish both testified that it is unclear that patients in the intervention group continued to consume POM Juice daily after 12 months. In his 34 years of directing RCTs, Dr. Ornish notes that it is very challenging to motivate patients to continue following any intervention for more than one year. (PX0025-0020; PX0355 (Ornish, Dep. at 202-203)). Dr. Ornish further observes that is not unusual for patients to be less than honest in describing their compliance as patients often describe that it is embarrassing and even humiliating to report that they have not done what they were supposed to do. (PX0025-0020). Dr. Davidson believes the subjects may have not been taking the pomegranate juice at the end of the study. (CX1336 (Davidson, Dep. at 174-75)).

881. The study protocol called for ultrasound testing of the carotid artery at baseline, 12 months, and at 18 months. (CX0716_0018-19). The primary outcome variable identified in the protocol was the difference between placebo and pomegranate juice in posterior wall common CIMT progression rate in mm/year, using non-contrast images, and a

secondary outcome measurement was difference between placebo and pomegranate juice in the anterior wall common CIMT progression rate in mm/year, using contrast images. (CX0716_0028). Exploratory endpoints included changes in blood pressure, lipids, and various measures of inflammation and oxidative stress. (CX0716_0011; CX1291 (Sacks, Report at 0027)). The protocol identified the proposed statistical analysis. (CX0716_0012).

Response to Finding No. 881:

Dr. Davidson believes that CX0716 might be the final protocol for the Davidson CIMT Study (2009), but he "can't verify it's the final form" and "can't be sure, to be honest…" (CX1336 (Davidson, Dep. at 8-9)). Although CX0716 does state "[t]he primary outcome variable will be the difference between placebo and POM Wonderful™ juice groups in the posterior wall common carotid IMT progression rate in mm/year, utilizing non-contrast images," Dr. Davidson testified in his deposition that he believed the primary outcome was modified to be the composite of the anterior and posterior wall measurements and this decision was made before unblinding of the study. (CX1336 (Davidson, Dep. at 24-25)) ("I thought we had modified the primary outcome to be the composite of the anterior and the posterior wall measurements"). CX0716 also lists as a secondary outcome variable the "[d]ifference between placebo and POM Wonderful™ juice groups in the composite measure, which combines the measurements of the common and internal carotid artery and the carotid bifurcation…in mm/year." (CX0716_0028).

882. According to the published results, the 289-person Davidson CIMT Study (2009) showed no significant influence of 18 months of pomegranate juice consumption on CIMT progression in the overall study sample. (CX1065_0006; CX1291 (Sacks, Report at 0028); CX1293 (Stampfer, Report at 0020); PX0025 (Ornish, Report at 0019-20). This included no statistically significant changes in the anterior or posterior wall measurements, or in a "composite" measure that summed the anterior and posterior measurements. (CX1336 (Davidson, Dep. at 54-56); *see* CX1065_0004 (Table 3). Dr. Heber agreed that, on an intent-to-treat analysis, there was no difference between the active and placebo groups at the end of the study. (Heber, Tr. 2132).

Response to Finding No. 882:

Complaint Counsel selectively cites to the first sentence of the discussion section of the Davidson CIMT Study (2009), but omits the following sentence: "However, results from post hoc exploratory analyses, which should be interpreted with caution, suggest that the rate of CIMT progression may have been slowed in subgroups characterized by more rapid CIMT progression, including those with increased levels of TG-rich lipoproteins, low levels of HDL cholesterol, and greater oxidative stress." (PX0014-0006) (emphasis added). The study further notes: "consumption of pomegranate juice is very safe; thus demonstration of a benefit on atherosclerotic disease progression, even in a subset of the population, would have important public health implications." (PX0014-0006) (emphasis added). Finally, Complaint Counsel also misstates the study results by not mentioning that: "[t]he composite measurement of CIMT showed a significantly smaller value at 12 months in the pomegranate juice group compared to the control group…" (PX0014-0005; CX 1336 (Davidson, Dep. at 55-57); PX0025-0021). Dr. Heber's trial testimony is based upon his prior deposition testimony in the case of *POM Wonderful LLC v. Welch Foods, Inc*. (2:09-cv-00567) which is not part of the record in this action. Regardless of Dr. Heber's testimony, CX0716, the alleged protocol for the Davidson CIMT Study (2009) as suggested by Complaint Counsel, expressly states that a "a per protocol analysis will be completed" and "[a]dditional sub group analyses may be made." (CX0716_0030-0031). Thus, results in the Davidson CIMT Study (2009) are not limited to only those evaluated on an intent-to-treat basis.

883. There also were no statistically significant changes in blood pressure (a validated surrogate marker for heart disease studies) at the end of the Davidson CIMT Study (2009). (CX1065_0003-05; Sacks, Tr. 1492; CX1291 (Sacks, Report at 0028; Stampfer, Tr. 757-59; CX1293 (Stampfer, Report at 0020-21)).

Response to Finding No. 883:

Blood pressure was not a primary or secondary endpoint of the Davidson CIMT Study (2009). (CX0716_0010-0011). In any clinical study, it is routine to take a blood pressure, pulse, body temperature, among others, to make sure patients are healthy. (Heber, Tr. 2101). Although blood pressure is measured in many studies, a specific claim on blood pressure requires a very specific study involving special equipment and personnel. (Heber, Tr. 2040). Dr. Sacks concedes that the absence of statistically significant results with respect to blood pressure does not prove the negative. (PX0361 (Sacks, Dep. at 223-24)). The fact that certain biomarkers did not reflect a statistically significant change does not invalidate the statistically significant improvements in both the composite CIMT as well as in the subgroup of patients who were at highest risk. (PX0025-0021). The absence of evidence is not evidence of absence, so merely the fact that a research has not found something in a particular study does not mean the result does not exist. (Heber, Tr. 1981).

884. The study also evaluated the effect of consuming pomegranate juice on a number of measures of inflammation or oxidative stress, including high sensitivity C-reactive protein, PON1, and two measures of TBARS. (CX1065_0003). There were no statistically significant changes in any of these measures at the end of the study. (CX1065_0003-05; Sacks, Tr. 1492-93; CX1291 (Sacks, Report at 0028); Stampfer, Tr. 757-59; CX1293 (Stampfer, Report at 0020-21); Heber, Tr. 2125-26; CX1336 (Davidson, Dep. at 44-48)).

Response to Finding No. 884:

First, measures of inflammation or oxidative stress, including high sensitivity C-reactive protein, PON1, and two measures of TBARS were not primary or secondary endpoints of the Davidson CIMT Study (2009). (CX0716_0010-0011). Second, the Davidson CIMT Study (2009) demonstrated statistically significant changes in high sensitivity C-reactive protein and one measure of TBARS in subjects with elevated levels of oxidative stress. (PX0014-0006) ("The level of high-sensitivity C-reactive protein was significantly

decreased with pomegranate juice versus control in the top tertiles for TGs (p = 0.039), total cholesterol/HDL cholesterol ratio (p = 0.012), and apolipoprotein-B100 (p = 0.014). Levels of thiobarbituric acid-reactive substances [TBARS] plus AAPH also significantly decreased with pomegranate juice versus control in the top tertiles for TGs (p = 0.018), TG/HDL cholesterol ratio (p = 0.010), and PD = AAPH (p = 0.022)") (emphasis added). The authors also note one reason why statistically significant changes in paraoxonase-1 were not observed was due to the "relatively high baseline levels of paraoxonase-1…suggestive of adequate antioxidant status at baseline compared to previously studies." (PX0014-0006) Dr. Sacks concedes that the absence of positive results with respect to indicators of inflammation of oxidative stress or fasting lipoproteins does not prove the negative. (PX0361 (Sacks, Dep. at 223-24)). The fact that certain biomarkers did not reflect a statistically significant change does not invalidate the statistically significant improvements in both the composite CIMT as well as in the subgroup of patients who were at highest risk. (PX0025-0021). The absence of evidence is not evidence of absence, so merely the fact that a research has not found something in a particular study does not mean the result does not exist. (Heber, Tr. 1981).

885. The published report also provides CIMT absolute results at 12 months and 18 months based on a measurement of the "composite" value (*i.e.*, the sum of the posterior and anterior walls) for the pomegranate juice group versus the placebo group. The results indicated a significantly better CIMT *value* for the POM Juice group than the placebo group at 12 months, but not at 18 months. (CX1065_0005-06). The published study does not state, however, what the progression *rate* was, in mm/year, between baseline and 12 months, for the pomegranate and placebo groups; nor does it provide a "*p*" value for the difference in the *change* between those two groups at 12 months. (*See* CX1065_0005; Sacks, Tr. 1495-97, 1611-12 (testifying that he incorrectly stated, in his expert report, that the composite rate was smaller at 12 months)).

Response to Finding No. 885:

Dr. Sacks' March 3, 2011 expert report speaks for itself. In his expert report, Dr. Sacks states: "The 'composite rate' for all measured carotid artery walls had shown a significantly smaller value at 12 months in the pomegranate juice group, but this

difference was no longer significant at the end of the study." (CX1291_0028). At trial, for the first time on June 13, 2011, Dr. Sacks advanced a new theory, claiming he made an "error" in his expert report and postulating that the *rate*, not *value*, for composite measurements did not show any significant change at 12 months. Prior to trial, however, Complaint Counsel did not submit any correction to Dr. Sacks' expert report or make any attempt to inform Respondents' of the purported error. Dr. Sacks' new testimony raised at trial for the first time should be rejected by the Court as a matter of law. 16 C.F.R. § 3.31A ("Each [expert] report shall be signed by the expert and contain a complete statement of all opinions to be expressed and the basis and reasons therefor.") (emphasis added); *In the Matter of Basic Research LLC, et al*., Docket No. 9318, 2006 WL 159736, at *5, (Jan. 10, 2006) ("Direct testimony by any expert witness at trial shall be limited to the contents of his or her expert report.")

886. In fact, CIMT study data provided to Respondents, but not included in the publication, showed that the difference in CIMT progression *rates* between the active and placebo groups at 12 months was $p = .0544$, a positive trend, but *not* a statistically significant result. (CX0867_0019; CX1336 (Davidson, Dep. at 144-46) (discussing CX0784_0015, Table A.3.8.a)).

Response to Finding No. 886:

Complaint Counsel's proposed finding of fact is disingenuous. The document cited by Complaint Counsel, CX0867_0019, contains calculations that are inconsistent, incomplete and/or entirely different than those found in the published Davidson CIMT Study (2009). The results found at CX0867_0019 lists data for only two measurements: the right side posterior without contrast and left side posterior without contrast. (CX0784_0015; 867_0019). It does not contain the composite measurements, as published in the Davidson CIMT Study (2009), which consists of four measurements and which Dr. Davidson identified as the primary outcome variable. (CX1336 (Davidson, Dep. at 24-25; 55 (the composite results consist of summing and averaging the four walls: "left, right, posterior, and anterior"). The data also purports to analyze the effects

of the study for 130 subjects in the pomegranate juice group and 134 subjects in the control group. (CX0784_0015). The published Davidson CIMT Study (2009), however, lists data for 146 subjects in the pomegranate juice group and 143 subjects in the control group. (PX0014-004). The calculations are also different and/or inconsistent even when examining the poster measurements. For instance, the p-value of 0.5306 cited for "Mean Carotid IMT Intent-to-Treat 18 month Population" in CX0867 is different than the p-value cited at page 939 (Table 3) of the published Davidson CIMT Study (2009), which shows a p-value of 0.654 for the composite progression in mm/year at 18 months. (*Compare* CX0867_0019 with PX0014-0004). As a result, it is unclear whether these calculations are accurate or reliable. In his deposition, as cited by Complaint Counsel, Dr. Davidson did not specify whether the trend persisted in the value or rate at 12 months. In any event, even assuming the accuracy of CX0867, the Davidson CIMT Study (2009) showed a statistically significant progression rate at 12 months (p-value=0.0499) in the composite measurements under a per protocol analysis. (CX0784_0046).

887. Dr. Davidson's published report also included a *post hoc* analysis of changes in the CIMT measurements for some of the study subpopulations. The report stated that there were significantly lower anterior and/or composite CIMT progression rates with higher CVD risk factors. (CX1065_0001, 0006; CX1336 (Davidson, Dep. at 57-69)). A *post hoc* analysis is one that is conceived of after the researchers have seen the data and thus is generally a less valid approach than one planned for in the protocol, because it is more subject to bias. (Sacks, Tr. 1500-01). The published article described the subgroup analyses as "post hoc exploratory analyses, which should be interpreted with caution[.]" It stated that, "[b]ecause the decrease in CIMT progression in these subgroups was based on analyses that were not preplanned and had no correction for multiple comparisons (increasing the possibility of type I errors), *these findings will need to be confirmed in future investigations*." (CX1065_0006) (emphasis added). A type I error is a "'false positive'. It is the statistical term [for] a finding that a change has occurred when in fact, it has not." (CX1291 (Sacks, Report at 0028); CX1336 (Davidson, Dep. at 69); Stampfer, Tr. 762-63).

Response to Finding No. 887:

Dr. Ornish opined that while a post hoc analysis is not as rigorous as one stated *a priori*, it does provide supporting evidence that there was statistically significant lower CIMT

progression rates for pomegranate versus control subjects in those with higher cardiovascular disease risk factors. (PX0025-0021). Dr. Davidson's post hoc analysis is clinically important, as other studies, including RCTs, also showed that subpopulations of patients who are sicker often are more likely to show improvement. (PX0025-0021). Dr. Davidson's finding was appropriately qualified in his study, but it would be extreme to dismiss this finding as being irrelevant simply because it was not stated *a priori*. (PX0025-0021).

In scientific research, post-hoc analysis is routine. (Heber, Tr. 1984). Although the exploratory analysis was not called for by the protocol, such analyses, including those on subgroups, are commonly done. (CX1336 (Davidson, Dep. at 57, 221)). Dr. Davidson commonly performs subgroup analyses in the studies in which he is the lead investigator. (CX1336 (Davidson, Dep. at 221)). In Dr. Davidson's view as a clinician, important information might be available in subgroup analysis that could be ultimately very clinically beneficial to patients. (CX1336 (Davidson, Dep. at 221)).

In the Women's Health Initiative study, for example, the largest women's health study in history, the overall effects of a low fat diet on breast cancer were indeterminate, but many of its important findings, however, were so-called post hoc analyses. (Heber, Tr. 1984). In many studies, researchers often go back and look at the data in the two groups and try to find additional leads for future studies, generate additional information to clarify the findings of that study, so it is a method that is routinely done. (Heber, Tr. 1984).

Dr. Sacks admits that it is certainly fine to conduct a post hoc analysis of some groups and concedes that he has done so in his own studies because he was interested in understanding whether a treatment affected all of the different patient groups or subgroups in the study. (PX0361 (Sacks, Dep. at 221-23)). Dr. Sacks does not discount Dr. Davidson's subgroup analysis. (PX0361 (Sacks, Dep. at 268)). If there is a positive

result in the subpopulation, the post hoc analysis does not undermine the results of the research on the population as a whole. (CX1352 (Heber, Dep. at 223)).

Finally, it is not necessary to wait for a subsequent study before telling the public of the likely benefit arising from a subgroup analysis. (Heber, Tr. 1984-85). There could be tens of millions of people in the U.S. in Dr. Davidson's high risk subgroup shown to be helped by pomegranate juice who are unaware of their health risks. (Heber, Tr. 1985). If there is a 5 percent improvement in health measure and it affected tens of millions of people in the United States, a 5 percent change would not be too small to consider as an important finding, especially if there no toxicities associated with it. (Heber, Tr. 2007). The post hoc analysis done in Dr. Davidson's study has clinical relevance because it is consistent with the potential benefits of antioxidant treatment with pomegranate juice. (CX1336 (Davidson, Dep. at 221)).

In the Davidson CIMT Study (2009), the authors expressly explained that "[n]o correction for multiple comparisons was applied for exploratory analyses to minimize the risk of a type II statistical error." (PX0014-0014).

In his deposition, Dr. Davidson explained the results should be "interpreted with caution," not "because post hoc exploratory analysis may or may not turn out to be replicated in future trials," but rather he believes "post hoc studies are very important for hypothesis-generating research." (CX1336 (Davidson, Dep. at 67))(emphasis added).

888. Dr. Davidson initially submitted a manuscript of the study to the journal, *Arteriosclerosis, Thrombosis, and Vascular Biology*, in late 2008. That journal rejected the manuscript, however, concluding that it was a negative study. (CX1336 (Davidson, Dep. at 201-02 (discussing CX1016)).

Response to Finding No. 888:

Dr. Davidson testified that the manuscript was not accepted for publication and the *Arteriosclerosis, Thrombosis, and Vascular Biology* journal did not submit the article for

peer review. (CX1336 (Davidson, Dep. at 201-02)). Respondents dispute the characterization of the Davidson CIMT Study (2009) as a "negative" study. Dr. Davidson's study demonstrated that the consumption of pomegranate juice resulted in a statistically significant improvement in CIMT after 12 months and, in those subjects with increased oxidative stress, statistically significantly less anterior wall and/or composite CIMT progression versus control subjects. (PX0014; CX 1336 (Davidson, Dep. at 57)).

889. In May 2009, Dr. Davidson submitted the manuscript to the *American Journal of Cardiology*. Two expert reviewers provided recommendations and comments. (CX1336 (Davidson, Dep. at 77-78); *see* CX1057_0024-27).

Response to Finding No. 889:

Respondents have no specific response.

890. One reviewer stated that, given the large number of *post hoc* analyses performed, it would be appropriate to conduct a statistical correction for multiple comparisons. (CX1057_0025; CX1336 (Davidson, Dep. at 80-81)). Dr. Davidson did not do the statistical correction (CX1336 (Davidson, Dep. at 73)), but committed to revise the discussion section to emphasize "[t]he possibility of type I errors, the exploratory nature of these findings, and caution regarding interpretation of post-hoc subgroup analyses." (CX1057_0024-27).

Response to Finding No. 890:

Complaint Counsel does not provide relevant portions of Dr. Davidson's response to the reviewer which includes the following: "The authors acknowledge that because of the large number of comparisons beyond the primary outcome variable, some of the significant p-values may be due to random variation (type I statistical errors). However, the purpose of these exploratory analyses was to generate hypotheses and thus the authors were more concerned about the possibility of type II errors. Thus, no correction for multiple comparisons was applied. This approach is consistent with that taken in other papers published in the *The American Journal of Cardiology*." (CX1057_0025) (emphasis added).

891. Another reviewer advised that "The study needs to be reported as a negative study as it is." (CX1057_0027). In his response, Dr. Davidson "affirm[ed] that it was a negative study," and committed to revise the manuscript to emphasize that "caution is warranted" with regard to the subgroup findings, and that those findings "should be considered hypotheses that will need to be replicated in future trials designed to assess the efficacy of pomegranate juice consumption" in those subgroups. (CX1336 (Davidson, Dep. at 78-85); CX1057_0027).

Response to Finding No. 891:

In responding to the reviewer regarding his study, Dr. Davidson did not write back to "affirm that it was a negative study." (CX1057_0027). This phrase does not exist anywhere on CX1057_0027. While he may have erroneously stated or recalled that he "affirm[ed] it was a negative study" in his deposition, Dr. Davidson also testified that "we wanted to emphasize…what we think is an important point, that …there are positive findings, potentially, that deserve follow-up and more research." (CX1336 (Davidson, Dep. at 84-85) (emphasis added). Thus, Dr. Davidson explicitly stated the entire study was not "negative," but rather made several "positive findings." (CX1336 (Davidson, Dep. at 84-85). At the end of all studies, it is routine for researchers to write that further research is needed. (Ornish, Tr. 23660.

(b) Respondents' Reaction to Results

892. Dr. Davidson provided Respondents with the final CIMT study results in February 2006. (CX1336 (Davidson, Dep. at 144)). Those results showed a positive, but not statistically significant, trend at 12 months ($p = .054$); however, this trend was not sustained at 18 months. (CX1336 (Davidson, Dep. at 144-46) (discussing CX0784_0015, Table A.3.8.a)). As further set forth below, Respondents delayed publication of the results for nearly two and a half years. (*See* CCFF ¶¶ 893-98).

Response to Finding No. 892:

Although Dr. Davidson testified that he provided CX0784 to the "sponsor", it is unclear from his testimony which of the Respondents actually received or reviewed the document or when this specifically occurred. (CX1336 (Davidson, Dep. at 144)). As discussed *infra*, the calculations found at CX0784_0015 only pertain to posterior measurements, not composite measurements. CX0784_0015 ("Right Side Posterior without Contrast +

Left Side Posterior without Contrast"). As a result, Complaint Counsel's assertion that there was "not statistically significant, trend at 12 months (p = .054)" is incorrect with respect to the composite measure, which includes the sum of the anterior, posterior, left and right walls. Complaint Counsel does not provide any evidentiary support for the claim that "Respondents delayed publication of the results for nearly two and a half years." Respondents incorporate by reference their response to Complaint Counsel's proposed Finding Nos. 893-98.

893. Respondents' reaction to the study results was "disappointment, bewilderment." (CX1336 (Davidson, Dep. at 146)). Respondents then hired two independent organizations to re-evaluate Dr. Davidson's CIMT scans; those organizations reached the same results as Dr. Davidson had. (CX1336 (Davidson, Dep. at 147-48)).

Response to Finding No. 893:

Respondents objected to the question posed to Dr. Davidson during his deposition as follows:

> Q: So what was Roll's reaction to learning that there were no statistically significant results in their IMT trial?
>
> MS. DIAZ: Objection as to form, calls for speculation, vague and ambiguous as to "Roll," whole corporate entity, calls for a narrative. You can respond.
>
> A. Disappointment, bewilderment -- I mean, those kind of words.

(CX1336 (Davidson, Dep. at 146)) (emphasis added).

The question posed by Complaint Counsel lacks foundation, assumes facts not in evidence, calls for speculation, is vague and ambiguous as to the meaning of "no statistically significant results" and "Roll," and seeks a narrative. Dr. Davidson's response, therefore, should be stricken and not considered part of the record. As a result, Complaint Counsel lacks any evidence to support the first part of its proposed finding of fact. Dr. Davidson's subsequent deposition testimony is unclear as to the exact "results"

found by the two independent organizations. Dr. Davidson testified that they found "no major differences in the actual readings," but he does not explain whether the findings were limited to posterior or composite measures, the general intent-to-treat or subgroup populations. (CX1336 (Davidson, Dep. at 147-48)). Accordingly, no inference can be drawn from Dr. Davidson's testimony as to what the two independent organizations reported.

894. Under the Davidson CIMT protocol, Respondents needed to approve any publication of the results. (CX0716_0036). In October 2006, Dr. Davidson presented the subgroup analysis to Mr. Resnick, and Drs. Heber, Aviram, Liker, and Dreher, requesting permission to publish the results. (CX1336 (Davidson, Dep. at 165-68)). Starting in January 2007, Dr. Davidson worked on various drafts of the manuscript, hoping to obtain Respondents' permission to publish. (CX1336 (Davidson, Dep. at 170-71, 186 ("I was working on . . . various drafts . . . over time.")). As of March 2007, Dr. Dreher had advised one of his colleagues that "Stewart may decide not to publish" the Davidson results. (CX0108_001).

Response to Finding No. 894:

Dr. Davidson believes that CX0716 might be the final protocol for the Davidson CIMT Study (2009), but he "can't verify it's the final form" and "can't be sure, to be honest…" (CX1336 (Davidson, Dep. at 8-9)). In any event, Section 7.7 (Final Report/Publication) of CX0716 requires approval in the event confidential study data will be disclosed:

> As outlined in the Research Contract, the nature of this study and all data and information pertaining to it are confidential. Any proposed publication or presentation arising from this study may not be disclosed to any third party prior to submission of a final report/manuscript to Roll International Corporation. Since this study will produce proprietary information, the Investigator agrees not to present the results of this trial verbally or in written form without first obtaining approval from an authorized representative of Roll International Corporation.

(CX0716_0036) (emphasis added). Thus, the language makes clear that Respondents would have wanted approval in circumstances when confidential data were to be disclosed, not in situations where the results were perceived to be favorable or

unfavorable. It is unclear from Dr. Davidson's independent recollection exactly what, when, and to whom the results of his study were presented. (CX1336 (Davidson, Dep. at 166)) ("I'm not sure, to be honest with you. I don't know. I did go and present the data to -- there was – I'm not sure of the timing"). Dr. Davidson is not sure if Dr. Dreher was present at the meeting. (CX1336 (Davidson, Dep. at 167)). Dr. Davidson's deposition testimony does not support the conclusion that he was "hoping to obtain Respondents' permission to publish" as asserted by Complaint Counsel. Dr. Dreher's comment that "Stewart may decide not to publish" as cited in CX0108_0001 is speculative and taken out of context. Mr. Resnick has never asked or told any scientist or researcher not to publish a manuscript or report. (CX1360 (S. Resnick, Dep. at 75); CX1358 (Aviram, Dep. at 76); CX1339 (Ornish, Dep. at 85)). Ultimately, the 18 month and 12 month results of Dr. Davidson's CIMT study were ultimately published in the *American Journal of Cardiology*, which is one of the leading journals in cardiovascular medicine. (Liker, Tr. 1902; PX0014).

895. In May 2007, Dr. Davidson asked Respondents for permission to publish an abstract of the CIMT study results to the American Heart Association, but Stewart Resnick said no. Dr. Davidson testified that Dr. Liker and Mr. Resnick thought that the study data didn't show the "true effect" between 12 and 18 months. (CX1336 (Davidson, Dep. at 180-81); Liker, Tr. 1919-20; *see* CX0901 (Liker email transmitting proposed abstract to S. Resnick, Tupper, Dreher, and Heber)).

Response to Finding No. 895:

Dr. Davidson was not seeking permission to "publish" the abstract, but rather to "present" the abstract at meeting of the American Heart Association. (CX1336 (Davidson, Dep. at 180); CX0901_0001). Contrary to Complaint Counsel's assertion, Mr. Resnick did not make the decision himself. Instead, as Dr. Liker testified at trial, "collectively we made a decision that that wasn't something we wanted to do at that time" and "there was a group of us that made a collective decision." (Liker, Tr. 1920-

21). Respondents objected to the form of the question posed to Dr. Davidson regarding the response to his request:

> Q. Yes. And did they say why they weren't going to publish -- they didn't want to approve you publishing this abstract?
>
> MS. DIAZ: Objection as to form.
>
> A. It was . . . it was in relationship to, again, not understanding the cause of the placebo group having this lack of progression between the 12- and the 18-month period. They were concerned the data wasn't -- wasn't showing a true effect in the placebo group somehow.

(CX1336 (Davidson, Dep. at 180)). Complaint Counsel's question is vague and ambiguous, lacks foundation, and assumes facts not in evidence. In any event, Dr. Davidson believes the reason the submission did not go forward at the time was because, among other things, "not understanding the cause of the placebo group having this lack of progression between the 12- and the 18-month period." (CX1336 (Davidson, Dep. at 180)) (emphasis added). At the time, Respondents did not grant Dr. Davidson permission to present the results of the CIMT study to the American Heart Association because they were still trying to make sense of the data and alleviate confusion. (CX1350 (Liker, Dep. at 151-52)).

896. In January 2008, Dr. Aviram wrote Dr. Dreher to say, "I think that we should convince Stewart [Resnick] to agree to publish the Davidson research results, as the results after one year are VERY important to all of us. . . . Just think of a way that it will not harm you." (CX0944_0001) (capitalization in original). Dr. Dreher responded that, "Stewart, as you know, has concerns that the contradictory results of this research between 12 vs. 18 months might confound our previous CVD research[.]" (CX0948_0001). Dr. Dreher suggested that Dr. Davidson could demonstrate that "the 12-18 month data cannot be trusted[.]" (CX0948_0001).

Response to Finding No. 896:

Complaint Counsel does not cite the full text of CX0944 which reads: "I think that we should convince Stewart to agree to publish Davidson research results, as the results after

one year are VERY important to all of us and add very much to what is known by now. Just think of a way that it will not harm you." (CX00944_0001) (emphasis added). Dr. Aviram testified, when reading (and writing) this email at CX00944_0001, that Mr. Resnick was not opposed to publishing Dr. Davidson's research ("Stewart didn't oppose it") and "always said that 'I like you to have truth and only the truth.'" (CX1348 (Aviram, Dep. at 128-29)). Mr. Resnick has never improperly interfered with the publication of any report or dictated the contents of a report. (CX1372 (S. Resnick, Tropicana Dep. at 33)). Mr. Resnick has never asked or told any scientist or researcher not to publish a manuscript or report. (CX1360 (S. Resnick, Dep. at 75); CX1358 (Aviram, Dep. at 76); CX1339 (Ornish, Dep. at 85)).

In any event, as Dr. Liker testified at trial, "collectively we made a decision that that [Dr. Davidson's study] wasn't something we wanted to do at that time" and "there was a group of us that made a collective decision." (Liker, Tr. 1920-21). Respondents previously objected to CX0948 (listed on Attachment B to JX2 as a conditionally admitted exhibit) on the grounds that the statement: "Stewart, as you know, has concerns…" constitutes unreliable hearsay, lacking any exception, and is being offered as proof of the matters stated therein. As a result, this exhibit and/or statement should be excluded from record. In addition, Complaint Counsel improperly cites to CX0948 as a "response" to CX0944 when it is not. These documents are two different emails. (CX0944; CX0948). As discussed *infra*, Respondents were attempting to analyze and understand the data presented by Dr. Davidson at both 12 and 18 months. (Liker, Tr. 1895-96; CX1350 (Liker, Dep. at 146, 149-52, 163-64). Dr. Dreher's statements regarding how Dr. Davidson could explain the study results are speculative. In the final analysis, Dr. Davidson believes the subjects may have not been taking the pomegranate juice at the end of the study. (CX1336 (Davidson, Dep. at 174-75)).

897. On April 8, 2008, Dr. Liker asked Dr. Kessler to talk to Dr. Davidson about the study, noting that Dr. Davidson thought "that by not publishing the data, POM could be at risk

in the future for not being transparent[.]" (CX0962_0001). On April 12, 2008, Drs. Liker and Dreher continued to discuss the possibility of publishing the Davidson CIMT results. Dr. Liker stated that they needed to talk to Mr. Tupper; he said that he had "broach[ed] the disclosure issue with Matt [Tupper] who shares our concerns." (CX0964).

Response to Finding No. 897:

The comments attributed to Dr. Davidson in CX0962_0001 are speculative. Dr. Liker testified that he did not recall exactly how or why Dr. Kessler became involved. (CX1350 (Liker, Dep. at 162)). The statement attributed to Mr. Tupper is speculative and vague and ambiguous, and constitutes impermissible hearsay.

898. On April 14, 2008, Mr. Tupper agreed to meet with Drs. Liker and Dreher about publishing Davidson's research. (CX0965). Dr. Aviram weighed in, urging the importance of the 12 month data and suggesting that "we can convince that the last visit is problematic." (CX0969_0001). In May 2008, Dr. Dreher wrote to Mr. Tupper and Drs. Aviram, Heber, Liker, Kessler and Davidson to suggest "an alternative way to report the POM CIMT results." (CX0977_0001). As noted above, Dr. Davidson submitted the manuscript to one journal in late 2008, where it was rejected (CCFF ¶ 888) and finally to the *American Journal of Cardiology* on May 8, 2009. (*See* CX1057_0003).

Response to Finding No. 898:

Respondents have no specific response to the first sentence of Complaint Counsel's proposed Finding No. 898. Complaint Counsel's citation to CX0969 to suggest that Dr. Aviram "weighed in" is inaccurate as Mr. Tupper's planned conference call with Dr. Liker and Dr. Dreher was planned for April 18, 2008 and would have taken place before Dr. Aviram's April 19, 2008 email. (*Compare* CX0965 with CX0969). Dr. Aviram's statement that "we can convince that the last visit is problematic" is nonsensical, vague and ambiguous, and provided without any context. Complaint Counsel does not provide the full context of the statement "an alternative way to report the POM CIMT results" in CX0977. In CX0977, Dr. Dreher attaches a copy of an article entitled "Progression of Carotid Intima-Media Thickness and Plasma Antioxidants: The Los Angeles Atherosclerosis Study" in which the progression of CIMT is studied relative to plasma antioxidant levels and apparently suggests that Dr. Davidson's results could be reported

in the same fashion. Dr. Davidson testified that his manuscript was not accepted for publication by the *Arteriosclerosis, Thrombosis, and Vascular Biology* journal and was not submitted the article for peer review. (CX1336 (Davidson, Dep. at 201-02)).

899. Thereafter, on May 12, 2009, POM held a cardiovascular advisory board meeting. (*See* CX1063_0001). The meeting was designed to allow Dr. Davidson to present the CIMT research to a group of distinguished cardiologists to see whether they believed that the CIMT data showed sufficient signal of benefit to proceed with a "larger, definitive trial." (CX1336 (Davidson, Dep. at 204-05)). Planned attendees included Stewart Resnick, Tupper, Heber, Gillespie, Aviram, Kessler, Liker, and three outside experts. (CX0538_0001).

Response to Finding No. 899:

Respondents have no specific response to the first sentence of Complaint Counsel's proposed finding of fact. The purpose of the meeting, however, was not limited to the issue of whether or not to proceed with a "larger, definitive trial" as suggested by Complaint Counsel. The meeting agenda found at CX1063 explains that one of the key questions to be addressed was an overall assessment of the Davidson CIMT Study (2009). (CX1063_0001). According to Dr. Davidson, "[t]he consensus of the group was that they believed the subgroup analyses were real." (CX1336 (Davidson, Dep. at 206)). CX0538_0001 is titled "Cardiovascular Research Review 2009 Participant Roster" and does not contain a specific date. (CX0538_0001). Thus, it is unclear whether this purported participant roster may be linked to the May 12, 2009 meeting. In any event, Complaint Counsel has provided no evidentiary support that the attendees included "Stewart Resnick, Tupper, Heber, Gillespie, Aviram, Kessler, Liker" listed in the participant roster. In fact, when asked who attended the meeting in his deposition, Dr. Davidson testified that, at a minimum, Dr. Kessler was not present and did not identify Mr. Resnick, Mr. Tupper, Dr. Gillespie, Dr. Liker, or Dr. Aviram as being in attendance. (CX1336 (Davidson, Dep. at 204-205)).

900. Subsequently, on July 27, 2009, Mr. Resnick, Mr. Tupper, and Drs. Gillespie, Heber, Kessler, and Liker met to discuss future research. (CX1081_0001). Briefing materials sent to Dr. Liker in advance of the meeting posed the question, "Should POM Wonderful

consider a follow up CIMT study in high risk subjects?" (CX1081_0005). According to the briefing materials, "Study would enroll approximately 300 subjects at a cost of about 3 MUSD [*i.e.*, 3 million U.S. dollars]. The probability of success is judged to be between 20-80%." (CX1081_0005).

(CX1349 (Gillespie, Dep. at 87-88), *in camera*).

Response to Finding No. 900:

CX1081 does not support the first sentence of Complaint Counsel's proposed finding of fact. CX1081 purports to be a July 21, 2009 letter from Brad Gillespie, Vice President, Clinical Development at POM, inviting Dr. Liker to a July 27, 2009 meeting. (CX1081). CX1081, dated July 21, 2009, therefore, cannot prove that the July 29, 2009 meeting took place, much less confirm that Mr. Resnick, Mr. Tupper, and Drs. Gillespie, Heber, Kessler, and Liker actually met on such date. (CX1081). Complaint Counsel omits the last bullet point listed at CX1081_0005 which reads "[t]here is consensus that a successful trial would be extremely valuable." (CX1081_0005). Complaint Counsel misstates Dr. Gillespie's deposition testimony regarding the "probability of success."

(CX1349 (Gillespie, Dep. at 86-87), *in camera*).

901.

(CX1084_0002, *in camera* (stating that

)). As of 2011, Respondents have not pursued any follow up CIMT studies. (CX1360 (S. Resnick, Dep. at 106)).

Response to Finding No. 901:

The evidence cited, CX1084, does not support the proposition that

(CX1084_0002).

CX1084 purports to reflect an agenda and/or notes from a meeting on July 27, 2009. Despite whatever statements are reflected on CX1084_0002,

Respondents have taken Mr. Resnick's deposition testimony out of context. When asked if Respondents were conducting any CIMT studies, Mr. Resnick responded "I don't know" and "[a]s far as I know, we're not doing anything, any big studies." (CX1360 (S. Resnick, Dep. at 107)). Mr. Resnick's incomplete knowledge cannot be imputed conclusively to Respondents' actions.

902. Respondents' 2009 Medical Research Portfolio Review concluded that the Davidson CIMT Study (2009) showed "no change" in the overall population and that the CIMT result in the "hi-risk" category was only a 2-5% decrease. (CX1029_0003).

Response to Finding No. 902:

Respondents object to the term "concluded" in this proposed finding on the grounds that the 2009 Medical Research Portfolio Review speaks for itself and merely reflects the subjective views of its author (or authors). Mr. Tupper testified that the Medical Research Portfolio Review was prepared by Dr. Dreher and himself for an internal meeting with POM's advisors, including Mr. Tupper, Mark Dreher, Dr. Harley Liker, Dr. Dr. Kessler, and Dr. David Heber, and Mr. Resnick. (Tupper, Tr. 942, 939, 3008-09; CX1353 (Tupper, Dep. at 248-49); Dreher, Tr. 556). However, the science was ranked this way, not because Respondents do not believe in the high quality and caliber of their science or that this is the legal standard by which their science should be judged. The rationale for the three on a scale of ten refers to an assessment given by doctors oriented to drug approval. (Tupper, Tr. 3001). That score is also due to the fact that POM has pursued using different endpoints than those used by the FDA to approve a drug for heart disease. (Tupper, Tr. 3011). Putting aside the strict FDA requirements and FDA lens, Respondent Matt Tupper personally ranks POM's body of erectile, prostate, and

cardiovascular science each as an eight on a scale of ten. (Tupper, Tr. 3012). Furthermore, Mr. Dreher also stated that the assessment of POM's research science in the Medical Research Portfolio Review was done from a "drug perspective" or through the lens of FDA approval. (Dreher, Tr. 564)

(c) Expert Analysis

903. Dr. Sacks noted that the Davidson CIMT Study (2009) is the largest of the heart studies conducted on pomegranate juice. He stated that the Davidson CIMT Study (2009) was carefully designed – the protocol identified the endpoints to be measured, the procedures to be followed, inclusion and exclusion criteria, and the statistical analysis to be conducted. Further, there was no evidence of critical problems in the conduct or analysis of the study (except its over-emphasis on the subgroup results). The Davidson CIMT Study (2009) provides competent and reliable evidence that consumption of pomegranate juice did not improve CIMT in subjects with one or more cardiovascular risk factors. (CX1291 (Sacks, Report at 0029)).

Response to Finding No. 903:

By his own admission, Dr. Sacks essentially concedes that the Davidson CIMT Study (2009) constitutes competent and reliable scientific evidence because it was "carefully designed" and showed "no evidence of critical problems in the conduct or analysis of the study." *Brake Guard Prods., Inc.*, 125 F.T.C. 138 (1998) (defining competent and reliable scientific evidence as "tests, analyses, research, studies… conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results."). Notwithstanding the foregoing, Dr. Davidson and Dr. Ornish both testified that it is unclear that patients in the intervention group in the Davidson CIMT Study (2009) continued to consume POM Juice daily after 12 months. In his 34 years of directing RCTs, Dr. Ornish notes that it is very challenging to motivate patients to continue following any intervention for more than one year. (PX0025-0020; PX0355 (Ornish, Dep. at 202-203)). Dr. Ornish further observes that is not unusual for patients to be less than honest in describing their compliance as patients often describe that it is embarrassing and even humiliating to report that they have not done what they were

supposed to do. (PX0025-0020). Dr. Davidson believes the subjects may have not been taking the pomegranate juice at the end of the study. (CX1336 (Davidson, Dep. at 174-75)).

Based on expert testimony from Dr. Ornish and Heber, Dr. Davidson's study constitutes competent and reliable evidence that the consumption of POM Juice is beneficial to cardiovascular health by, among other things, reducing arterial plaque. (PX0025-0019-0022; PX0192-0039, 0053; Heber Tr. 1979-86; PX0014).

In his expert report, Dr. Ornish expressly stated the following:

- "the bottom line is that pomegranate juice *did* show a statistically significant improvement in CIMT after 12 months in the measure that was most clinically relevant" (PX0025-0022) (emphasis in original);
- "does provide supporting evidence that there was statistically significant lower CIMT progression rates for pomegranate versus control subjects in those with higher cardiovascular disease risk factors" (PX0025-0022); and
- "I do not agree with Dr. Sacks' conclusion that the Davidson study 'provides competent and reliable evidence that consumption of pomegranate juice did not improve CIMT in subjects with one or more cardiovascular risk factors." (PX0025-0022) (emphasis added).

Dr. Ornish ultimately concluded "it is my expert opinion that clinical studies, research and trials, provide significant evidence that pomegranate juice is likely to…reduce arterial plaque, period." (RFF 1210; PX0025-0005; Ornish, Tr. 2374-75; PX0355 (Ornish, Dep. at 42)).

In his expert report, Dr. Heber stated: "these results suggest that in subjects at moderate coronary heart disease risk, pomegranate juice consumption…may have slowed CIMT progression in subjects with increased oxidative stress…" (PX0192-0039). Dr. Heber also concluded that "[t]here is credible scientific evidence that pomegranate juice and pomegranate extracts have significant health benefits for human cardiovascular systems,

including… decreases in arterial plaque…" (RFF 1209; PX0192-00045; PX0353 (Heber, Dep. at 76-80)).

As explained by Dr. Davidson, at 12 months, data showed a statistically significant reduction in CIMT in the group consuming pomegranate juice versus the placebo group in composite measurements. (PX0014; CX 1336 (Davidson, Dep. at 55)). In a post-hoc exploratory analysis of subjects with the highest risk factors of coronary heart disease, Dr. Davidson noted that those in the pomegranate juice group had significantly less anterior wall and/or composite CIMT progression versus control subjects at 18 months. (PX0014). According to Dr. Davidson's study, the consumption of pomegranate juice resulted in a statistically significant improvement in CIMT after 12 months and, in those subjects with increased oxidative stress, significantly less anterior wall and/or composite CIMT progression versus control subjects. (PX0014; CX 1336 (Davidson, Dep. at 57)).

904. Dr. Stampfer provided the opinion that that the main result from the Davidson CIMT Study (2009) provides substantial evidence *against* the hypothesis that pomegranate juice can reduce the progression of CIMT. (CX1293 (Stampfer, Report at 0020-21); Stampfer, Tr. 758-59 ("So it seems clear that this is a null study, and that's what the authors concluded")).

Response to Finding No. 904:

Respondents incorporate by reference their response to proposed Finding No. 903. In addition, in his expert report, Dr. Heber expressly disagrees with Dr. Stampfer's conclusion:

> Dr. Stampfer contends that the CIMT benefit demonstrated in the subgroup of individuals at increased oxidant stress with increased triglycerides and low HDL does not override his conclusion that "the main result from this large trial provides substantial evidence against the hypothesis that pomegranate juice can reduce progression of CIMT". I disagree. The subgroup data is particularly important because the CIMT benefit was associated with the specific subgroup that had increased risk factors. (PX0192-0053) (emphasis added).

905. Dr. Ornish agreed with Sacks' conclusion that the Davidson CIMT Study (2009) showed no significant differences in CIMT progression rates between the active and placebo groups. (PX0025 (Ornish, Report at 0019-20)). Dr. Heber acknowledged that "the results suggest that in subjects at moderate coronary heart disease risk, pomegranate juice consumption had no significant effect on overall CIMT progression rate[.]" (PX0192 (Heber, Report at 0039)

Response to Finding No. 905:

Complaint Counsel misstates and over-generalizes Dr. Ornish's expert opinion with respect to the Davidson CIMT Study (2009). Dr. Ornish merely agrees with Dr. Sacks that the Davidson CIMT Study (2009) did not report a statistically significant change in the *overall* CIMT progression rate between the pomegranate juice and control group at 18 months. (PX0025 (Ornish, Report at 0019-20)). As noted *infra*, Dr. Ornish disagrees with Dr. Sacks on other points of the Davidson CIMT Study (2009) and concludes, among other things, the study constitutes competent and reliable scientific evidence demonstrating a benefit in reducing arterial plaque. (PX0025). Similarly, Dr. Heber's acknowledgement that "the results suggest that in subjects at moderate coronary heart disease risk, pomegranate juice consumption had no significant effect on overall CIMT progression rate…" is limited to the overall findings at 18 months. (PX0192-0039). Complaint Counsel does not cite the remainder of Dr. Heber's conclusion which reads as follows "but may have slowed CIMT progression in subjects with increased oxidative stress and disturbances in the TG-rich lipoprotein/HDL axis." (PX0192-0039).

906. As for the 12 month data, showing that absolute CIMT measurements were smaller in the pomegranate juice group than those of the placebo group (*see* CCFF ¶¶ 885-86), Dr. Sacks stated that the absolute difference in CIMT values at 12 months is not relevant, because one has to look at the change in the CIMT progression, as the published report did for the primary and secondary endpoint results at 18 months. (Sacks, Tr. 1495-97). The unpublished change rate CIMT data at 12 months was *not* significant although it trended positive. (*See* CCFF ¶ 886).

Response to Finding No. 906:

Respondents incorporate by reference their response to proposed Findings Nos. 885 and 886.

907. Dr. Ornish argued that a potential reason for lack of a change in the CIMT progression rate at 18 months was that study participants may have stopped drinking the juice after 12 months. (PX0025 (Ornish, Report at 0020-21)). Dr. Davidson, however, evaluated the compliance with product consumption guidelines during the study. (CX1336 (Davidson, Dep. at 151-52); CX0788). He testified that his review of compliance diaries showed high levels of compliance with product consumption. (CX1336 (Davidson, Dep. at 151)).

Response to Finding No. 907:

Regardless of what was purportedly shown in "compliance diaries," Dr. Davidson and Dr. Ornish both testified that it is unclear that patients in the intervention group continued to consume POM Juice daily after 12 months. In his 34 years of directing RCTs, Dr. Ornish notes that it is very challenging to motivate patients to continue following any intervention for more than one year. (PX0025-0020; PX0355 (Ornish, Dep. at 202-203)). Dr. Ornish further observes that is not unusual for patients to be less than honest in describing their compliance as patients often describe that it is embarrassing and even humiliating to report that they have not done what they were supposed to do. (PX0025-0020). Dr. Davidson believes the subjects may have not been taking the pomegranate juice at the end of the study. (CX1336 (Davidson, Dep. at 174-75)).

908. With regard to the *post hoc* subgroup analysis, both Dr. Sacks and Dr. Stampfer agree with the study authors that this exploratory analysis is hypothesis-generating for future research. (CX1293 (Stampfer, Report at 0020-21); Stampfer, Tr. 762; Sacks, Tr. 1504-05). One typically can find subgroups *post hoc* in which results differ from the main in either direction. (CX1293 (Stampfer, Report at 0020)). With each additional subgroup analyzed, the chances increase that one or more will turn out to have a *p*-value of less than .05, by chance alone. (Sacks, Tr. 1505-06; Stampfer, Tr. 760-61).

Response to Finding No. 908:

In the Davidson CIMT Study (2009), the authors did not conclude or state anywhere in the report that "this exploratory analysis is hypothesis-generating for future research" as suggested by Complaint Counsel in proposed Finding No. 908. Although he did qualify the study by suggesting that "these findings will need to be confirmed in future investigations," which is typical language in scientific journals, Dr. Davidson believed the benefit in the subgroups was real. (RFF 1476; CX1336 (Davidson, Dep. at 221-22)).

Respondents have no specific comment to the remainder of Complaint Counsel's proposed Finding No. 908.

909. As a result, before it can be considered persuasive, the Davidson subgroup analysis must be evaluated *de novo* in a future study. (CX1291 (Sacks, Report at 0029-30); Stampfer, Tr. 762-63). Dr. Davidson himself stated that *post hoc* studies are very important for hypothesis-generating research, and that they provide "interesting signals of an effect that needs to be confirmed in future research." (CX1336 (Davidson, Dep. at 68)). Dr. Sacks stated "most subgroup analysis don't turn out to be true, and that's why they have to be confirmed." (Sacks, Tr. 1615). Dr. Ornish agrees that a *post hoc* analysis is "not as rigorous as one stated a priori." (PX0025 (Ornish, Report at 0021)). Dr. Heber has noted that the problem with subgroup analysis is that "one could, you know, randomly continue to divide a group of subjects until you found a positive result without rationale." (Heber, Tr. 2133).

Response to Finding No. 909:

Respondents dispute that Dr. Davidson's subgroup analysis must be evaluated de novo in a future study before it can be considered "persuasive."

Dr. Davidson's post hoc analysis is clinically important, as other studies, including RCTs, also showed that subpopulations of patients who are sicker often are more likely to show improvement. (PX0025-0021). In scientific research, post-hoc analysis is routine. (Heber, Tr. 1984). Although the exploratory analysis was not called for by the protocol, such analyses, including those on subgroups, are commonly done. (CX1336 (Davidson, Dep. at 57, 221)). Dr. Davidson commonly performs subgroup analyses in the studies in which he is the lead investigator. (CX1336 (Davidson, Dep. at 221)). In Dr. Davidson's view as a clinician, important information might be available in subgroup analysis that could be ultimately very clinically beneficial to patients. (CX1336 (Davidson, Dep. at 221)). In the Women's Health Initiative study, for example, the largest women's health study in history, the overall effects of a low fat diet on breast cancer were indeterminate, but many of its important findings, however, were so-called post hoc analyses. (Heber, Tr. 1984). In many studies, researchers often go back and look at the data in the two groups and try to find additional leads for future studies, generate additional information

to clarify the findings of that study, so it is a method that is routinely done. (Heber, Tr. 1984).

Dr. Sacks admits that it is certainly fine to conduct a post hoc analysis of some groups and concedes that he has done so in his own studies because he was interested in understanding whether a treatment affected all of the different patient groups or subgroups in the study. (PX0361 (Sacks, Dep. at 221-23)). In his deposition, Dr. Sacks does not discount Dr. Davidson's subgroup analysis. ((PX0361 (Sacks, Dep. at 268)). If there is a positive result in the subpopulation, the post hoc analysis does not undermine the results of the research on the population as a whole. (CX1352 (Heber, Dep. at 223)). It is not necessary to wait for a subsequent study before telling the public of the likely benefit arising from a subgroup analysis. (Heber, Tr. 1984-85). There could be tens of millions of people in the United States in Dr. Davidson's high risk subgroup shown to be helped by pomegranate juice who are unaware of their health risks. (Heber, Tr. 1985). If there is a 5 percent improvement in health measure and it affected tens of millions of people in the United States, a 5 percent change would not be too small to consider as an important finding, especially if there no toxicities associated with it. (Heber, Tr. 2007).

The post hoc analysis done in Dr. Davidson's study has clinical relevance because it is consistent with the potential benefits of antioxidant treatment with pomegranate juice. (CX1336 (Davidson, Dep. at 221)). Dr. Davidson has presented his post hoc analysis to members of the scientific community who believed his finding was a real, true signal of benefit in the subgroup that would be supported in a future trial. (CX1336 (Davidson, Dep. at 224)). Looking at the whole set of data in totality and at multiple subgroups showing a benefit, Dr. Davidson's study was convincing to panel members there was a potential benefit in the subgroup population. (CX1336 (Davidson, Dep. at 225)).

Complaint Counsel misstates Dr. Ornish's expert testimony regarding the Dr. Davidson's post hoc analysis by failing to include the full test of his statement which reads:

> While this is post hoc analysis, and thus not as rigorous as one stated a priori, it does provide supporting evidence that there was statistically significant lower CIMT progression rates for pomegranate versus control subjects in those with higher cardiovascular disease risk factors.
>
> This is clinically important, as other randomized controlled trials and others using repeat quantitative coronary arteriography also showed that subpopulations of patients who are sicker often are more likely to show improvement. This finding was appropriately qualified in the paper, but it would be extreme to dismiss this finding as being irrelevant simply because it was not stated a priori.

(PX0025 (Ornish, Report at 0021) (emphasis added).

Dr. Heber's trial testimony is based upon his prior deposition testimony in the case of *POM Wonderful LLC v. Welch Foods, Inc*. (2:09-cv-00567) which is not part of the record in this action. Regardless, Dr. Heber appropriately qualified his statement about the post hoc subgroup analysis by testifying that it provides some substantiation when considered together with the total body of scientific evidence on the mechanisms around intima medial thickness. (Heber, Tr. 2133).

910. Dr. Sacks also noted that the subgroup analysis had not been corrected for multiple comparisons, as stated in Dr. Davidson's published report. (CX1291 (Sacks, Report at 0030)). When multiple endpoints are being measured, the *p*-value needs to be adjusted downward to correct for multiple comparisons. (Sacks, Tr. 1505). This is known as a "Bonferroni correction" in the field of statistics. (CX1336 (Davidson, Dep. at 80)). Without the correction, with each additional subgroup analyzed, the chances increase that one or more will turn out to have a *p*-value of less than .05, by chance alone. (Sacks, Tr. 1505-06; Stampfer, Tr. 760-61). Dr. Davidson never did a correction for multiple comparisons on the subgroup analysis. (CX1336 (Davidson, Dep. at 73)).

Response to Finding No. 910:

In the Davidson CIMT Study (2009), the authors explain: "[n]o correction for multiple comparisons was applied for exploratory analyses to minimize the risk of a type II

statistical error." (PX0014-0004). Thus, if he did correct for multiple comparisons, Dr. Davidson would have increased the chance of a type II error. Dr. Sacks concedes that many researchers do not correct for multiple comparisons in their studies. (PX0361 (Sacks, Dep. at 228)). As Dr. Hill testified, the analysis or adjustment for comparisons made is a very conservative approach and not always made. (CX 1342 (Hill, Dep. at 102-103, 141)). In fact, it is probably more frequently not made, than made. (CX 1342 (Hill, Dep. at 102-103, 141)). An adjustment for comparisons made is less important where your study is hypothesis driven, such as here, versus an open-ended fishing approach. (CX 1342 (Hill, Dep. at 103))

911. Because the subgroup data is hypothesis generating only, and has not been corrected for multiple comparisons, a qualified scientist could not rely on the *post hoc* analysis of the subgroup populations as reliable scientific evidence to support claims that POM Juice or POMx prevent, reduces the risk of, or treats heart disease in the subpopulations identified in Figure 3 of the report. (CX1291 (Sacks, Report at 0030)). Correction for multiple comparisons is especially important when you want to recommend that people change their behavior, such as drinking a juice to improve their health. (Sacks, Tr. 1505-06).

Response to Finding No. 911:

Respondents incorporate by reference their responses to Complaint Counsel's proposed Finding Nos. 879-891 and 903-910. The Davidson CIMT Study (2009) constitutes competent constitutes competent and reliable evidence that the consumption of POM Juice is beneficial to cardiovascular health by, among other things, reducing arterial plaque. (PX0025-0019-0022; PX0192-0039, 0053; Heber Tr. 1979-86; PX0014).

(6) Davidson BART/FMD Study

(a) About the Study

912. Dr. Davidson's BART/FMD Study was conducted on a subset of 45 Davidson CIMT Study (2009) participants. (CX0684_0001; CX1336 (Davidson, Dep. at 37, 102-03)). It was a 13-week, randomized, double-blind, placebo-controlled trial to evaluate the effect of consuming POM Juice or placebo on brachial artery reactivity testing ("BART"), also referred to as "flow mediated dilation" ("FMD") testing. BART is a measurement of how much the brachial artery dilates (enlarges) after a blood pressure cuff is inflated, and then released. (JX0003 ¶ A.1). In addition, the study measured blood pressure, lipid parameters, and other vital signs. (CX0684; CX0716_0074-81; Sacks, Tr. 1508-10; Stampfer, Tr. 764-66).

Response to Finding No. 912:

Dr. Davidson believes that CX0716 might be the final protocol for the Davidson CIMT Study (2009), but he "can't verify it's the final form" and "can't be sure, to be honest…" (CX1336 (Davidson, Dep. at 8-9)). Blood pressure was not a primary or secondary endpoint of either the Davidson CIMT (2009) or Davidson BART/FMD Study. (CX0716_0010-0011). In any clinical study, it is routine to take a blood pressure, pulse, body temperature, among others, to make sure patients are healthy. (Heber, Tr. 2101). Although blood pressure is measured in many studies, a specific claim on blood pressure requires a very specific study involving special equipment and personnel. (Heber, Tr. 2040). Respondents have no specific response to the remainder of proposed Finding No. 912.

913. While the study was ongoing, Dr. Liker advised Dr. Davidson's group at Radiant that the Resnicks wanted the BART results immediately upon completion "for possible publication." (CX0616_0002; CX1336 (Davidson, Dep. at 113)).

Response to Finding No. 913:

Respondents previously objected to CX0616 (listed on Attachment B to JX2 as a conditionally admitted exhibit) on the grounds that the statement "Resnicks want BART results immediately upon completion of all subjects; possible publication" constitutes unreliable hearsay, lacking any exception, and is being offered as proof of the matters stated therein. As a result, this exhibit and/or statement should be excluded from record. When asked if the Resnicks wanted to publish the BART results, Dr. Davidson testified that "I really, honestly can't recall exactly" and "I don't recall that offhand." (CX1336 (Davidson, Dep. at 112-13)). Counsel for Respondents' also objected to the form of the questions being asked of Dr. Davidson. (CX1336 (Davidson, Dep. at 112-13)). As result, there is no evidentiary support in the record for proposed Finding No. 913.

914. At the conclusion of the study, there were no significantant differences between the treatment and placebo groups in BART/FMD. (CX0684_001; CX1336 (Davidson, Dep.

at 88-89); Sacks, Tr. 1510-13; CX1291 (Sacks, Report at 0030-31); CX1293 (Stampfer, Report at 0021)). As the results of the BART study were not positive, no written report was prepared. (CX0695_0001; CX1336 (Davidson, Dep. at 125)).

Response to Finding No. 914:

The absence of evidence is not evidence of absence, so merely the fact that a research has not found something in a particular study does not mean the result does not exist. (Heber, Tr. 1981). Dr. Dreher testified that BART is not "commonly used as many other methods. So, I didn't put a lot of weight on that." (Dreher, Tr. 547). Dr. Liker testified at trial that "we were told that it was a difficult study to do" and "literally too difficult to measure." (Liker, Tr. 1883). Dr. Liker also testified that Dr. Davidson said "BART testing is very difficult to do. I don't think you're going to get a positive result here, and I'd advise against doing it." (Liker, Tr. 1883). Dr. Davidson also testified that "as a side note, I'm not a – I'm not a believer in the BART as an endpoint." (CX1336 (Davidson, Dep. at 112)). Thus, based on the foregoing, Complaint Counsel cannot draw any negative inferences from the Davidson BART/FMD Study. The evidence cited by Complaint Counsel, CX0695 (meeting agenda), does not support the proposition that "results of the BART study were not positive, no written report was prepared." In his deposition, Dr. Davidson did not provide any explanation regarding this statement. (CX1336 (Davidson, Dep. at 125)).

915. Also at the end of the study there were no significant differences between treatment and placebo groups in blood pressure, cholesterol, HDL cholesterol, non-HDL cholesterol, triglycerides, ACE, PON, and two TBARS measurements. (CX1336 (Davidson, Dep. at 86-88; CX0684_0005-13, 19; CX1291 (Sacks, Report at 0031)).

Response to Finding No. 915:

Blood pressure, cholesterol, HDL cholesterol, non-HDL cholesterol, triglycerides, ACE, PON, and TBARS were not primary or secondary endpoint of the Davidson CIMT Study (2009). (CX0716_0010-0011). In any clinical study, it is routine to take a blood pressure, pulse, body temperature, among others, to make sure patients are healthy.

(Heber, Tr. 2101). Although blood pressure is measured in many studies, a specific claim on blood pressure requires a very specific study involving special equipment and personnel. (Heber, Tr. 2040). In Dr. Davidson's BART/FMD Study, because the primary endpoint was flow-mediated dilation, not blood pressure, any results for blood pressure cannot be relied upon as negative evidence to the contrary. (Heber, Tr. 2106-07; PX0353 (Heber, Dep. at 173)). Dr. Sacks concedes that just because the BART study does not show statistically significant changes with respect to blood pressure and ACE, among other measurements, that the absence of such evidence is proof there is no effect. (PX0361 (Sacks, Dep. at 230)).

(b) Expert Analysis

916. The study appears to have been properly designed and conducted. (CX1291 (Sacks, Report at 0032)). The protocol identifies the endpoints to be measured, the procedures to be followed, inclusion and exclusion criteria, and statistical analysis to be conducted. There is no evidence of critical problems in the conduct of the study. (CX1291 (Sacks, Report at 0032)).

Response to Finding No. 916:

In reviewing Respondents' cardiovascular research, Dr. Sacks is hardly objective: when any of Respondents' studies do not reach statistical significance, he calls it an excellent, well-designed study. When Respondents' studies do show a positive result, however, Dr. Sacks calls the research flawed.

917. The Davidson BART/FMD Study finding of no statistically significant difference in ACE due to POM Juice consumption contradicts Dr. Aviram's ACE/BP Study (2001) findings. (CCFF ¶ 798; Sacks, Tr. 1512-13; CX1291 (Sacks, Report at 0032); *see also* Heber, Tr. 2140 (agreeing that the ACE result was not replicated in the BART study)).

Response to Finding No. 917:

Respondents object to Complaint Counsel's proposed Finding No. 917 on the grounds that the terms "contradicts" and "replicated" are vague and ambiguous, lack foundation and misstate the record. The Davidson BART/FMD Study involved a different number

of subjects and timeframe than the Aviram ACE/BP Study (2001). The absence of evidence is not evidence of absence, so the fact that a statistically significant change in ACE was not found does not mean the result does not exist. (Heber, Tr. 1981; Sacks, Tr. 1608).

918. Although, BART/FMD is not a reliable marker of surrogate health, the study does provide information that is relevant to this case. FMD is a measure of nitric oxide production in the brachial artery, a major artery of the arm. (JX0003 ¶ A.2; Sacks, Tr. 1509-12). Brachial artery activity is a factor of nitric oxide activity. (PX0353 (Heber, Dep. at 187)). If pomegranate juice meaningfully affected nitric oxide metabolism and activity, one would have expected to see a positive result in the FMD testing. (Sacks, Tr. 1511-12).

Response to Finding No. 918:

Respondents object to Complaint Counsel's proposed Finding No. 918 to the extent that Dr. Sacks offers an expert opinion not contained in his expert report. Dr. Sacks is not an expert on nitric oxide and has not conducted any studies on the subject. (PX0361 (Sacks, dep. at 56)). In any event, no conclusion can be drawn from the absence of statistically significant changes in the Davidson BART/FMD Study. (Heber, Tr. 1981; Sacks, Tr. 1608).

919. In addition, reduction in blood pressure is a valid surrogate marker for cardiovascular health, and this study shows that there was no significant change in blood pressure between the treatment and placebo groups. (CX1291 (Sacks, Report at 0032)).

Response to Finding No. 919:

Blood pressure was not a primary or secondary endpoint of the Davidson CIMT (2009) or Davidson BART/FMD Study. (CX0716_0010-0011). In any clinical study, it is routine to take a blood pressure, pulse, body temperature, among others, to make sure patients are healthy. (Heber, Tr. 2101). Although blood pressure is measured in many studies, a specific claim on blood pressure requires a very specific study involving special equipment and personnel. (Heber, Tr. 2040). In Dr. Davidson's BART/FMD Study, because the primary endpoint was flow-mediated dilation, not blood pressure, any results

for blood pressure cannot be relied upon as negative evidence to the contrary. (Heber, Tr. 2106-07; PX0353 (Heber, Dep. at 173)). Dr. Sacks concedes that just because the BART study does not show statistically significant changes with respect to blood pressure and ACE, among other measurements, that the absence of such evidence is proof there is no effect. (PX0361 (Sacks, Dep. at 230)).

3. Additional Biomarker Studies

a. Overweight Studies

920. In 2006, POM sponsored Dr. James Hill, University of Colorado, Denver, to look at the effects of POMx on biomarkers of inflammation and oxidation in overweight people ("Denver Study"). (*See* CX0839 (study protocol)). POM provided the University of Colorado at Denver with a $266,653 gift to cover to cover the conduct of this study, as well as a study on diabetics (further described at CCFF ¶¶ 946-49). (*See* CX1342 (Hill, Dep. at 30-31, 77-79); CX1127_0001).

Response to Finding No. 920:

Respondents object to Complaint Counsel's characterization of the Denver Study. Specifically, the Denver Study, in its published form, examined the safety and antioxidant activity of POMx on overweight individuals with increased waist size. (CX0934). Specifically, TBARS was the measure used to assess antioxidant activity. (CX0934).

921. Also in 2006, POM sponsored Dr. David Heber and Accelovance to look at the effect of POMx on biomarkers and inflammation in overweight people ("San Diego Study"). (CX0819_0021-22 (protocol identifying Dr. Heber as Principal Investigator and Accelovance as Investigational Site); CX0859_0001 (Clinical Study Report)). There is no record evidence regarding the cost of this study.

Response to Finding No. 921:

Respondents object to Complaint Counsel's proposed Finding No. 921 on the grounds that it is vague and ambiguous with respect to the terms "to look at," overbroad, and misstates the record.. Specifically, the San Diego Study examined the safety of POMx. (CX0934).

(7) Denver Study

922. Dr. Hill and his colleagues conducted an unblinded, uncontrolled study of POMx capsules in Denver, Colorado. (CX1291 (Sacks, Report at 0032-35); *see* Sacks, Tr. 1514). In the course of protocol development, in May 2006, Dr. Dreher asked Dr. Hill whether it would be better to have a two-arm study, where one arm took a placebo, "to potentially enhance scientific value for a possible publication if we see any interesting trends[.]" (CX0805_0001). Dr. Hill responded that he favored keeping the study as a "quick and dirty," "pilot study to learn how to design a good study that would be publishable." (CX0805_0001; CX1342 (Hill, Dep. at 39-40, 46-47)).

Response to Finding No. 922:

Respondents object to Complaint Counsel's erroneous implication that the Denver Study was not a good study or worthy of publication or that its results are less scientifically valuable because the study design did not include a placebo control. The lack of placebo control group does not, as Complaint Counsel imply, render the results of the Denver Study unreliable, and the pre/post design was the most practical under the circumstances. Dr. Hill defended the study design and testified that neither the pre/post nor control design is better than the other. (CX1342 (Hill, Dep. at 45)). While there are advantages to a placebo controlled trial, a pre/post design can be very powerful when you are convinced that you are assessing a steady-state at baseline, and that the differences are attributed to your intervention. (CX1342 (Hill, Dep. at 131)). He also testified that a placebo-controlled study is more costly and requires a lot more effort to conduct and given that he did not have the information that would allow him to adequately power this trial, the pre/post trial design was the most efficient approach and would provided the outcome needed. (CX1342 (Hill, Dep. at 45-46)). Thus, the record does not support Complaint Counsel's inference that the Denver Study was invalid or unreliable because it did not have a placebo control.

Respondents further object that the cited quotations are deceptive excerpts which deliberately omit portions of sentences that both contradict Complaint Counsel's assertions and provide full content to the statements. Dr. Dreher asked if "there would be

any added value to increasing the number of subjects," thereby increasing the odds of statistical significance and ultimate publication. (CX0805_0001). Dr. Hill declined the suggestion to add more participants because he believed that the number of subjects would provide sufficient results and stated that it was "tempting to try to expand this one to get something publishable." (CX0805_0001). Indeed, the results of the study were published and even without the added participants the effect was large enough that results rendered a statistically significant difference. (CX1342 (Hill, Dep. at 47); CX0934). Thus, Complaint Counsel's inference that because Dr. Hill decided against adding participants that this makes the results invalid or less reliable is not supported.

923. The study enrolled 24 adults (19 females, 5 males) ages 40-70 with abdominal adiposity. Subjects took 2 POMx capsules per day for 28 days. (CX0877_0002-10).

Response to Finding No. 923:

Respondents object to the proposed finding as it misstates the parameters of the Denver Study. *Twenty-two* overweight subjects *received* two POMx capsules per day for four weeks. (CX0934_0003).

924. A "wide range of biomarkers for oxidative stress and inflammation" were measured at baseline and four weeks, including TBARS and PON1 activity. TBARS is a measure of oxidation and PON1 is a measure of anti-peroxidation. Low TBARS and high PON1 are regarded as favorable. Additional measurements included blood pressure, triglycerides, cholesterol, and C-reactive protein. (CX0877_0002-10; CX1342 (Hill, Dep. at 42-44)).

Response to Finding No. 924:

Respondents object to Complaint Counsel's definitions of "TBARS" and "PON1" as incomplete. TBARS (thiobarbituric acid reactive substances) is an important biomarker of oxidative stress in humans and strongly predictive of cardiovascular events in people with stable coronary artery disease, independent of traditional risk factors and inflammatory markers. (CX0934_0003-0004). High-density lipoprotein cholesterol ("HDL" or so called "good cholesterol") contains an antioxidant enzyme, called

"paraoxonase" or "PON1" which acts to protect the body against oxygen radicals. (Heber, Tr. 1961).

Respondents object to Complaint Counsel's mischaracterization of PON1 as one of the measurements used to assess antioxidant activity. TBARS was the biomarker chosen to assess the antioxidant activity of the POMx capsules. (CX1342 (Hill, Dep. at 41-42)). Thus, no conclusions can be drawn with respect to the effect of POMx on PON1 as the study was not designed to make such assessment.

Respondents object to the proposed "additional measurements" as vague and ambiguous. Respondents further object to the proposed finding because it mischaracterizes the measurements the study was designed to measure. Although the subjects' triglycerides, cholesterol, and C-reactive protein were measured, the study was not designed to assess those factors. (CX0934_0003). The Denver Study was "designed for antioxidant activity assessment." (CX0934_0001) Further, as a safety issue, heart rate and blood pressure were measured just to make sure there were no problems among the patients. (CX1342 (Hill, Dep. at 71-72). Thus, conclusions cannot be drawn with respect to the effect of POMx on blood pressure, triglycerides, cholesterol, and C-reactive protein.

925. Twenty-two subjects completed the study. According to the Preliminary Data Analysis, dated February 15, 2007, the participants gained an average of 1.3 pounds during the study, which Dr. Hill attributed to its conduct during the holiday season. (CX0877_0002-03; CX1291 (Sacks, Report at 0032-33); CX1342 (Hill, Dep. at 99-103)).

Response to Finding No. 925:

Respondents have no specific response.

926. After adjusting the statistical analysis for the weight change, only two significant results emerged: TBARS decreased and free fatty acids increased. There was no change in PON1. The study statistician stated that the change in TBARS was "of borderline significance [and had] not been adjusted for the number of comparisons made." (CX0877_0002-03, 0008 (TBARS), 0010 (PON1); CX1291 (Sacks, Report at 0033); CX1342 (Hill, Dep. at 97-103, 118-19 (regarding PON1)).

Response to Finding No. 926:

As an initial matter, Complaint Counsel's proposed Finding No. 926 mischaracterizes the findings of the Denver Study. Specifically, the authors of the study concluded that POMx is safe and effective in reducing oxidative stress in humans through the measure of TBARs. (CX00934_0004).

Respondents further object to Complaint Counsel's mischaracterization of PON1 as one of the measurements used to assess antioxidant activity. TBARS was the primary end point chosen to assess the antioxidant activity of the POMx capsules. (CX1342 (Hill, Dep. at 41-42)). No conclusions can be drawn from the fact that there was no change in PON1 as the study was not designed to make such assessment. Further, as repeatedly conceded by Dr. Sacks, the absence of positive information of change, does not prove the negative. (RFF 1455, 1513, 1553). Thus, lack of change does not prove that POMx has no effect on PON1.

Similarly, an increase in fatty acids is irrelevant as TBARS was the biomarker chosen to assess the antioxidant activity. Thus, no conclusions can be drawn from the fact that there was an increase.

Complaint Counsel's assertion that the Denver Study was flawed because the change in TBARS had not been adjusted for the number of comparisons is not supported. Adjusting for the number of comparisons made is not common in the scientific community. The analysis or adjustment for comparisons made is a very conservative approach and not always made. (CX1342 (Hill, Dep. at 102-103, 141)). In fact, it is probably more frequently not made, than made. (CX1342 (Hill, Dep. at 102-103, 141)). An adjustment for comparisons made is less important where your study is hypothesis driven, such as here, versus an open-ended fishing approach. Thus, this criticism lacks merit.

927. In the Denver Study there were no statistically significant changes in blood pressure. (CX0877_0008 (SBP (systolic blood pressure), DBP (diastolic blood pressure); CX1291 (Sacks, Report at 0033); CX1342 (Hill, Dep. at 111-13)).

Response to Finding No. 927:

Respondents object to the proposed finding as Complaint Counsel mischaracterizes the nature of the Denver Study and why blood pressure measurements were taken. The Denver Study was designed to measure antioxidant activity. (CX0934_0001). Although the subjects' blood pressure was taken only as a safety measure to protect the subjects, the study was not designed to assess whether or not POMx capsules had an effect on blood pressure. (CX1342 (Hill, Dep. at 71-72). Further, as repeatedly conceded by Dr. Sacks, the absence of positive information of change, does not prove the negative. (RFF 1455, 1513, 1553). Thus, lack of statistically significant changes in blood pressure does not prove that POMx has no effect on blood pressure.

928. The Preliminary Data Report concluded, "[w]e did not detect any effect of POMx on inflammation but identification of better biomarker assays for inflammation is needed . . . . [T]his pilot project suggests that a larger trial is warranted in abdominally obese subjects who may be at risk for development of metabolic diseases." (CX0877_0002-03; CX1291 (Sacks, Report at 0033)).

Response to Finding No. 928:

The lack of effect on inflammation does not support Complaint Counsel's contention that the results of the Denver Study are not valid. Inflammation was not explored as the primary endpoint. (CX1342 (Hill, Dep. at 41-42); CX0934_0001). TBARS was the chosen biomarker and the study produced statistically significant results with respect to antioxidant activity. (CX1342 (Hill, Dep. at 41-42); CX0934_0001).

Complaint Counsel's contention that the results of the Denver Study are not valid because it is a "pilot study" is also incorrect. In short, there is no difference between a pilot study and a regular study if statistically significant results are shown. (CX1342 (Hill, Dep. at 49)). Where, as here, it turns out that a researcher has adequately powered

his or her study, then the statistics confirm that it does not matter if it was a "pilot study." (CX1342 (Hill, Dep. at 48)). Thus, the fact that the Denver Study was a "pilot" study does not mean that it is not as scientifically valid as a larger study. (PX1339 (Ornish, Dep. at 23, 119-120)).

(8) San Diego Study (Heber/Accelovance)

929. The protocol for the San Diego Study was titled A Placebo-Controlled, Randomized, Double-Blind Study to Compare Antioxidant Levels in Normal Subjects with Elevated Waist Circumference When Administered 1 or 2 Pomegranate Dietary Supplement Capsules for 4 Weeks. (CX0819_0014 (Protocol, July 14, 2006); CX1291 (Sacks, Report 0033-34)).

Response to Finding No. 929:

Respondents have no specific response.

930. This randomized, double-blind, placebo-controlled study recruited 64 generally healthy male and female subjects who took either two POMx capsules, two placebo capsules, or one placebo and one POMx capsule, per day, for four weeks. (CX0859_0010 (Clinical Study Report); CX1291 (Sacks, Report at 0033-34)).

Response to Finding No. 930:

Respondents have no specific response.

931. Measurements included blood pressure and various antioxidant and inflammation markers such as oxidized phospholipids, oxidized LDL/HDL, serum nitric oxide, PON, and others. (CX0859_0003; CX1291 (Sacks, Report at 0034)).

Response to Finding No. 931:

Respondents object to Complaint Counsel's proposed Finding No. 931 on the grounds that it is vague and ambiguous as to the terms "measurements," "various antioxidant and inflammation markers," and "others." Respondents further object to the proposed finding as it incorrectly infers that blood pressure, oxidized phospholipids, oxidized LDL/HDL, serum nitric oxide, and PON were among the primary markers studied. Instead, the San Diego Study was designed as a safety assessment. (CX0934_0001). As a preliminary or

safety matter the data about blood pressure, oxidized phospholipids, oxidized LDL/HDL, serum nitric oxide, and PON may have been gathered. However, they were not primary endpoints. (RFF 1544-46).

932. A portion of the San Diego Study data was presented in a January 11, 2007 Clinical Study Report. (See CX0859). This document described the conduct of the study, adverse events, vital signs, and blood pressure data. It stated that "[t]here were no apparent treatment related changes in weight, systolic blood pressure, diastolic blood pressure, pulse rate, respirations, or temperature." (CX0859_0020). The San Diego Study report stated that the efficacy results of antioxidant and anti-inflammatory levels were reported separately. (CX0859_0018).

Response to Finding No. 932:

Respondents object to the proposed finding as it incorrectly infers that blood pressure, oxidized phospholipids, oxidized LDL/HDL, serum nitric oxide, PON were primary endpoints. Indeed, this is not the case. This study was designed as a safety assessment. (CX0934_0001). As a preliminary or safety matter the data about these may have gathered but were not primary endpoints. (RFF 1544-46). Furthermore, as repeatedly conceded by Dr. Sacks, the absence of positive information, does not prove the negative. (RFF 1547). Thus, the lack of apparent changes in weight, systolic blood pressure, diastolic blood pressure, pulse rate, respirations, or temperature does not prove that the tested products did not have a beneficial effect.

933. Dr. Heber prepared a slide presentation about efficacy results of the San Diego Study. It stated that, "there were no changes in . . . markers of oxidative stress or inflammation that were studied," including in C-reactive protein, oxidized phospholipids, lipoprotein (a), and nitric oxide. (CX1254_0001, 0006-26; Heber, Tr. 2119-21). He sent this presentation to POM employees Keith Martin, Dr. Dreher, and Pam Saltsman on January 9, 2007. (CX1352 (Heber, Dep. at 107-11) (discussing CX1254). In an accompanying email, he advised Martin and Dr. Dreher that "we have not proved or disproved efficacy at this point." (CX0858_0001). By efficacy, he meant changes in biomarkers of oxidant stress or inflammation. (CX1352 (Heber, Dep. at 110)). Dr. Heber also scheduled a meeting to discuss the San Diego Study "in detail" with Mr. Resnick on February 28, 2007. (Heber, Tr. 2121-22; CX0873_0001).

Response to Finding No. 933:

Respondents object to this proposed finding as Complaint Counsel again incorrectly infer that the San Diego was designed to test measurements other than safety or that the data conclusively disproves the efficacy of the Challenged Products. Indeed, the lack of statistically significant changes in markers of oxidative stress or inflammation does not prove that the Challenged Products do not indeed have that effect. (RFF 1547). Complaint Counsel's contention is directly refuted by the last bullet point from the page of the document that they intentionally omit. Indeed, the document states, "The variation among subjects suggests that a more focused study would be more likely to demonstrate significant changes." (CX1254_0026). Furthermore, Complaint Counsel provide a quote from Dr. Heber that directly contradicts their position that the San Diego proves that that the Challenged Products conclusively showed no effect on markers of oxidative stress or inflammation. Dr. Heber writes, "We have not proved or disproved efficacy at this point." (CX0858_0001). Indeed, a study designed specifically to test markers of oxidative stress or inflammation would "likely demonstrate significant changes." (CX1254_0026). Furthermore, as repeatedly conceded by Dr. Sacks, the absence of positive information, does not prove the negative. Thus, the lack of apparent changes markers of oxidative stress or inflammation does not prove that the tested products did not have a beneficial effect but merely that the results were "indeterminate." (Heber, Tr. 2117).

934. On February 15, 2007, Dr. Dreher advised Dr. Heber that Dr. Hill had agreed to a combined paper relating to the results of the two overweight studies, and he asked Dr. Heber how long it would take to develop a manuscript for a "relatively fast turn time journal." (CX0879_0001).

Response to Finding No. 934:

The factual statement is individually correct, but Respondents object to the proposed finding to the extent Complaint Counsel infers anything improper from Dr. Dreher's desire to develop a manuscript in an expedient manner.

935. Dr. Heber's article on the San Diego Study results was published in late 2007 as Heber D. et al., *Safety and Antioxidant Activity of a Pomegranate Ellagitannin-Enriched Polyphenol Dietary Supplement in Overweight Individuals with Increased Waist Size*, J. Agric Food Chem., Vol. 55, No. 24 (2007). (*See* CX0934).

Response to Finding No. 935:

Respondents have no specific response.

936. The published article describes the single-arm Denver Study as the "Antioxidant Activity Study" and the two-arm San Diego Study as the "Safety Study." (CX0934_0003). It states that "[p]reliminary evidence of a reduction in TBARS was seen in the subjects who were studied at the Denver site . . . . TBARS are an important biomarker of oxidative stress. . . . [T]hese pilot studies demonstrate both the safety and efficacy of POMx . . . in humans. However, further studies need to be done to confirm the antioxidant properties of pomegranate ellagitannins administered as a dietary supplement." (CX0934_0003-04).

Response to Finding No. 936:

Complaint Counsel's contention that the results of the Denver Study are not valid because it is a "pilot study" is also incorrect. In short, there is no difference between a pilot study and a regular study if statistically significant results are shown. (CX1342 (Hill, Dep. at 49)). Where, as here, it turns out that a researcher has adequately powered his or her study, then the statistics confirm that it does not matter if it was a "pilot study." (CX1342 (Hill, Dep. at 48)). Thus, the fact that the Denver Study was a "pilot" study does not mean that it is not as scientifically valid as a larger study. (PX1339 (Ornish, Dep. at 23, 119-120)).

Furthermore, Complaint Counsel's reliance on the statement "further studies need to be done to confirm" is misplaced and does not support their contention that the Denver

Study's results are inconclusive with respect to antioxidant properties. This language was included, in part, because "antioxidant activity is very difficult to study." (Heber, Tr. 2116). Furthermore, this language is boiler plate and is included in most, if not all, studies published in scientific journals. (Ornish, Tr. 2366). Furthermore, this statement also provides that the results just need to be confirmed. (CX0934_0003-004). It does not state that further studies need to be done to prove the antioxidant properties of pomegranate extracts. Thus, Complaint Counsel's contention that the Denver Study did not provide scientifically valid results is without merit.

937. The published article makes no reference to the biomarkers of antioxidant stress or inflammation measured in Dr. Heber's San Diego Study. (*See* CX0934).

Response to Finding No. 937:

Complaint Counsel erroneously imply that the data concerning antioxidant stress or inflammation were intentionally excluded in the published version of the San Diego Study. (CX0934). There were multiple reasons for not including those results as testified to by Dr. Heber at trial. Dr. Heber explained that the San Diego study did not include all the results because, "We subsequently went back and explored the Accelovance Study population, which was a group of volunteers, primarily studied for safety, with the idea that we would explore the idea of whether any inflammatory markers or oxidant stress markers were elevated in those subjects." (Heber, Tr. 2116-2117). The results may also have been unreliable. For example, Dr. Heber explained that what they found was that the studied population had a "great deal of variability" at baseline and four-week measurements. (Heber, Tr. 2117). Furthermore, it is common that scientific journals have little interest in publishing data showing indeterminate results. (CX1350 (Liker, Dep. at 235)). Indeed, Dr. Heber explained that there was no interest in publishing the results because the findings concerning anti-inflammatory effects were "indeterminate results, not negative results." (Heber, Tr. 2117). Thus, Complaint Counsel's inference

that Respondents hid or did not want the results published because the antioxidant results were negative is wrong, false, and unsupported by the record.

938. Dr. Heber acknowledged that the published article did not provide all of the results of his San Diego Study. (Heber, Tr. 2116-18). He testified that the published article contained all of the results "then available." (Heber, Tr. 2116-17). This is not true. According to the publication, the manuscript was received by the journal for review on June 8, 2007. (CX0934_0007). This is several months *after* Dr. Heber provided POM with the slide presentation showing that there were no changes in antioxidant or inflammatory markers in his San Diego Study. (*See* CCFF ¶ 933).

Response to Finding No. 938:

Respondents incorporate by reference Responses to Finding Nos. 933 and 937.

939. On January 7, 2007, POM Marketing staff, including Staci Glovsky, sought confirmation that POMx was an effective antioxidant for the purposes of preparing the POMx brochure. (CX0858_0001). Despite the results of his randomized, double-blinded San Diego Study showing no effect of POMx on numerous heart-related biomarkers, and the fact that the Denver Study was unblinded and uncontrolled, on January 16, 2007, Dr. Heber advised Dr. Dreher that "the marketing people should have their substantiation from this" for efficacy of POMx. (CX0860_0001).

Response to Finding No. 939:

Respondents object to "heart-related biomarkers" as vague and ambiguous.

Respondents object to Complaint Counsel's contention that the San Diego showed no effect on POMx on numerous heart related biomarkers and incorporate by reference Response to Finding No. 933.

Respondents object to Complaint Counsel's contention that the Denver Study was not valid as it was unblinded and uncontrolled and incorporate by reference Response to Finding No. 922.

Respondents object to Complaint Counsel's partial quotation of Dr. Heber's statement. The full statement reads as the following: "It shows that there is antioxidant activity in

the plasma. That now means that we have safety, bioavailabity, and efficacy as an antioxidant in the plasma." (CX0860).

Dr. Heber's statement that adequate substantiation for the antioxidant efficacy of POMx is supported. In combination, the San Diego Study and Denver Study constitute competent and reliable evidence that the Challenged Products are safe, bioavailable, and effective as an antioxidant. (CX0934). Indeed, the authors of the study concluded that POMx is safe and effective in reducing oxidative stress in humans through the measure of TBARS. (CX0934_0004). *See also* Responses to Finding Nos. 922-938.

(9) Expert Analysis

940. Drs. Sacks and Stampfer concluded that the methodological shortfalls in the Denver Study – especially the lack of a control group – render its findings unreliable. (CX1291 (Sacks, Report at 0035); *see also* Sacks, Tr. 1519-21; Stampfer, Tr. 768-72).

Response to Finding No. 940:

Respondents object to "methodological shortfalls" and "unreliable" as vague, ambiguous, argumentative, and unsupported by the record and incorporate by reference Response to Finding No. 922. *See also* RFF 1514, 1517-1547.

941. Dr. Heber stated in his report that the Denver Study demonstrated the efficacy of POMx as an antioxidant. (CX0934_0004). At trial, however, he described the Denver Study as a "pilot study . . . not a conclusive demonstration." (Heber, Tr. 2116). Dr. Ornish agreed that there are limitations to the Denver Study. (PX0025 (Ornish, Report at 0024). He also agreed that it was a pilot study, which only provides preliminary findings to justify doing a larger study. (PX0025 (Ornish, Report at 0024)).

Response to Finding No. 941:

Complaint Counsel erroneously conflate Dr. Heber and Dr. Ornish's characterizations of the Denver Study as "pilot" and "preliminary" with scientific invalidity. Dr. Heber was not, as Complaint Counsel contend, impeached at trial. Dr. Heber appropriately qualified his testimony. He explained that the Denver Study was not conclusive because "antioxidant activity is very difficult to study." (Heber, Tr. 2116). At no time during the

course of this trial, either in testimony or in their expert reports, did Dr. Ornish or Dr. Heber state that the results of the Denver Study were invalid because it was a pilot study. In fact, the evidence is just the opposite. For example, Dr. Heber stated in his report that the Denver Study demonstrated the efficacy of POMx as an antioxidant. (CX0934_0004). Similarly, Dr. Ornish stated in his report that he supported Dr. Heber's conclusion that the Denver Study demonstrated antioxidant efficacy. (PX0025_0025). Thus, Complaint Counsel's assertion that Dr. Ornish and Dr. Heber expressed opinions that the results of the Denver Study was scientifically invalid is wrong and not supported by the record.

942. The San Diego Study appears to have been well-designed. (CX1291 (Sacks, Report at 0035). The study concluded that there were no changes in the groups receiving one or two POMx capsules per day in markers of oxidant stress or inflammation that were studied. (CX1254_0026; CX1222_0001; CX1352 (Heber, Dep. at 100-01); CX0859_0020; CX0934_0003; Sacks, Tr. 1515-19; CX1291 (Sacks, Report at 0032-35); Stampfer, Tr. 768).

Response to Finding No. 942:

Complaint Counsel continues its intellectually dishonest with respect to POM's science: any time one of Respondents' studies does not reach statistical significance or ends with indeterminate results, it is a well-designed study. If a study, however, does not reach statistical significance, then it was somehow flawed in its design or execution.

Respondents object to the phrase "no changes" as vague, ambiguous, and argumentative.

Respondents further object to Complaint Counsel's mischaracterization of the San Diego Study with respect to oxidative stress and inflammation and incorporate by reference their Responses to Finding Nos. 933 and 943.

943. Dr. Ornish and Dr. Heber both agreed that the San Diego Study did not demonstrate efficacy since there were no significant changes in heart-related biomarkers. (PX0025 (Ornish, Report at 0025); Heber Tr. 2117).

Response to Finding No. 943:

Respondents object to Complaint Counsel's proposed Finding No. 943 on the grounds that it is vague and ambiguous with respect to the terms "agreed" and "heart-related biomarkers," lacks foundation and misstates the record.

Respondents further object to this proposed finding as Complaint Counsel again incorrectly infers that the San Diego Study was designed primarily to test measurements other than safety or that the data somehow disproves the efficacy of the Challenged Products. Indeed, the lack of statistically significant changes in markers of oxidative stress or inflammation does not prove that the Challenged Products do not indeed have that effect. In fact, a study designed specifically to test markers of oxidative stress or inflammation would "likely demonstrate significant changes." (CX1254_0026). Dr. Heber testified to this very fact at trial. Dr. Heber explained, "Anti-inflammatory effects were "indeterminate results, not negative results." (Heber, Tr. 2117). Furthermore, as repeatedly conceded by Dr. Sacks, the absence of positive information, does not prove the negative. (RFF 1455, 1513, 1553). Thus, the lack of apparent changes markers of oxidative stress or inflammation does not prove that the tested products did not have a beneficial effect but merely that the results were "indeterminate." (Heber, Tr. 2117).

Respondents further object to Complaint Counsel's outright mischaracterization of Dr. Ornish's opinion as to the antioxidant efficacy of POMx. Dr. Ornish's explained, "When Dr. Heber concluded that "these pilot studies demonstrate both the safety and efficacy of POMx," I imagine he was citing the Denver Study regarding efficacy (given the statistically significant change in TBARS)." (PX0025_0025). Thus, Dr. Ornish supports Dr. Heber's conclusion that the antioxidant efficacy of POMx was demonstrated by the Denver Study.

b. Diabetes Studies

(1) Rock Study

944. Dr. Heber relies in part on a study on diabetics conducted by Dr. Rock, a member of Dr. Aviram's team, published as Rock, W., *et al*., *Consumption of Wonderful Variety Pomegranate Juice and Extract by Diabetic Patients Increases Paraoxonase I Association with High-Density Lipoprotein and Stimulates Its Catalytic Activities*, 56 J. Agric. Food Chem. (2008) (PX0127; *see* PX0192 (Heber, Report at 0038)). This study looked at the relationship of PON1 and HDL cholesterol activity in 30 diabetic patients who used pomegranate juice or POMx Liquid for four to six weeks. (*See* PX0127; CX1291 (Sacks, Report at 0036)). It reported a reduction in oxidative stress as measured by TBARS and improved PON. (PX0127). All measurements were comparisons to baseline. (PX0127).

Response to Finding No. 944:

Respondents have no specific response.

945. This study was unblinded, unrandomized, and uncontrolled. (CX1291 (Sacks, Report at 0036); *see also* CX1358 (Aviram, Dep. at 55) (testifying that each patient served as his own control)). As a result, a qualified scientist cannot conclude whether any changes in measured parameters resulted from pomegranate juice or pomegranate extract consumption, or from some other factor, such as the placebo effect. (Sacks, Tr. 1523; CX1291 (Sacks, Report at 0037)).

Response to Finding No. 945:

Complaint Counsel's assertion is not supported. Dr. Aviram, Dr. Ornish, and Dr. Heber all disagree on the necessity of an RCT to demonstrate the efficacy of pomegranate juice and/or its derivatives on humans. (RFF 1184-1205; 1274-1279).

(2) Heber/Hill Diabetes Studies

946. Dr. Heber and Dr. Hill conducted two randomized, double-blind, placebo-controlled studies to evaluate the antioxidant effect of pomegranate extract capsule and pomegranate juice, respectively, in diabetic patients. (Heber, Tr. 2048-49, 2054; CX1352 (Heber, Dep. at 124-25); *see* CX0949_0007 (protocol for diabetes extract study); CX1082_0007-21 (protocol for diabetes juice study); CX1284). The POMx protocol called for enrolling 30 diabetics for 12 weeks. (CX949_0013). The POM Juice study protocol called for an enrollment of 40 diabetics for 12 weeks. (CX1082_0012).

Response to Finding No. 946:

Respondents have no specific response.

947. These two studies were intended to replicate the Aviram/Rock results in diabetic patients. (Heber, Tr. 2138).

Response to Finding No. 947:

Respondents object to Complaint Counsel's proposed Finding No. 947 on the grounds that it is vague and ambiguous as to the meaning of "replicate," lacks foundation and misstates the record. The Heber/Hill Diabetes Studies cannot be seen to have attempted to "replicate" the Aviram/Rock Study given that the Aviram/Rock Study featured 20 subjects, compared to 30 or 40 in the Heber/Hill Diabetes Studies, and lasted 4 weeks compared to 12 weeks. (PX0127).

948. The two studies were completed, but the results were not published. (CX1352 (Heber, Dep. at 132-33); CX1342 (Hill, Dep. at 157 (last measurement in the diabetes juice study was taken in March 2009)). After Dr. Hill completed his part of the study, he sent the data to Dr. Heber for analysis. (CX1342 (Hill, Dep. at 157-58)). Dr. Hill was not aware that Dr. Heber had analyzed the data. (*See* CX1342 (Hill, Dep. at 157-58)).

Response to Finding No. 948:

Respondents object to the proposed finding to the extent that Complaint Counsel improperly imply that Respondents purportedly interfered with the publication of the results. Indeed, the record reflects that Respondents have never interfered with or asked a scientists or researcher to not publish a manuscript or report. (RFF 441-442). Thus, Complaint Counsel's inference that Respondents are trying to hide the results of the diabetic studies is not supported.

949. According to Dr. Heber, the diabetes studies did not show a significant change in malondialdehyde, which is a TBARS measure, or in PON, both of which are heart-related biomarkers. (Heber, Tr. 2124 (malondialdehyde), 2137-38 (PON); CX1352 (Heber, Dep. at 161-70)). Dr. Heber did not include the results of his two diabetes studies in his analysis of available human clinical evidence to substantiate heart benefits of POM products. (PX0192 (Heber, Report at 0052-54)).

Response to Finding No. 949:

Respondents object to the term "heart related biomarkers" as vague and ambiguous. Respondents also object to Complaint Counsel's inference that POM relied on the results of these studies to substantiate heart health benefits representations concerning POM products. Indeed, such claims are, in facts supported by a body of competent and reliable evidence exclusive of the diabetic studies. Furthermore, the lack of a statistically significant change in malondialdehyde or PON does not support the conclusion that the Challenged Products do not have an effect on those markers. Indeed, Dr. Sacks repeatedly conceded that the absence of positive information of change, does not prove the negative. (RFF 1455, 1513, 1553).

4. Analysis of the Challenged Heart Claims in Light of the Scientific Evidence

950. Most of Respondents' marketing pieces from 2003 through 2010 have claimed (1) that a daily serving of POM Juice (eight ounces), POMx (one pill), or POMx Liquid (one teaspoon) prevents, reduces, or treats cardiovascular disease, including by decreasing arterial plaque, lowering blood pressure, and/or improving blood flow to the heart; and (2) that these benefits are established, by showcasing two Aviram studies and one Ornish study and by citing tens of millions of dollars in purportedly completed medical research. (*See* Sections V.D.1, V.D.4, V.E; *see also* CCFF ¶¶ 541-55). As summarized below, Respondents' research fails to support these representations.

Response to Finding No. 950:

Respondents object to proposed Finding No. 950 on the grounds that it is overbroad, vague and ambiguous with respect to "[m]ost of Respondents' marketing pieces," misstates the record, and lacks foundation. Respondents' advertisements did not convey the message that the Challenged Products prevent, reduce, or treat cardiovascular disease cardiovascular disease or other claims erroneously attributed to them by Complaint Counsel. In any event, Respondents possess competent and reliable scientific evidence supporting heart health claims much stronger than those purportedly made in their

advertisements. Respondents incorporate by reference their responses to Complaint Counsel's proposed Findings in Sections V.D.1, V.D.4, V.E and Finding Nos. 541-55.

b. Arterial Plaque Summary

951. With regard to arterial plaque, Respondents sponsored several studies measuring changes in CIMT. The Aviram CIMT/BP Study (2004), highlighted in Respondents' advertising through at least January 2010, showed a benefit for ten "very sick" heart disease patients compared to their own baseline data. These findings were never replicated (the Davidson study subgroup data pertain to persons who did *not* have CHD and are hypothesis-generating only), and in fact, were contradicted by results from three subsequent RCTs: the Ornish CIMT cardiac arm of 17 patients, the 73-person Ornish CIMT Study, and the large 289-person Davidson CIMT Study (2009), all of which showed no CIMT benefit for patients at mild to moderate risk for coronary heart disease. (CCFF ¶¶ 855-919).

Response to Finding No. 951:

Respondents object to proposed Finding No. 951 on the grounds that it is overbroad, vague, and ambiguous with respect to the terms "highlighted," "replicated," "hypothesis-generating," and "contradicted," misstates the record, lacks foundation, and assumes facts not in evidence. The Aviram CIMT/BP Study (2004) reported that pomegranate juice consumption resulted in a significant CIMT reduction, by up to 30%, and systolic blood pressure was reduced after one year of pomegranate juice consumption by 12%. (RFF 1118-20; CX0611). The Aviram CIMT/BP Study (2004) constitutes competent and reliable scientific evidence that the consumption of the Challenged Products are beneficial to cardiovascular health by, among other things, reducing arterial plaque. (RFF 1111-1126; 1288-1302; CX0611; PX0025-0009-0010; PX0192-0036-0037; Heber Tr. 1979-86).

Complaint Counsel's argument that Dr. Davidson's CIMT Study (2009) did not "replicate" Dr. Aviram's CIMT/BP (2004) study lacks merit. Dr. Aviram's and Dr. Davidson's studies are apples and oranges: both used the same surrogate (CIMT) in a different group of patients. (RFF 1565; Heber, Tr. 1975-76). In Dr. Aviram's study, the subjects had thickened plaque, whereas, in the Dr. Davidson's study, his patients had less

plaque to the point where it was not significant. (RFF 1561; Heber, Tr. 1975-76; 1983-84). Dr. Davidson's protocol actually excluded people with significant stenosis or plaque from his study. (RFF 1564; Heber, Tr. 1819). As a result, Dr. Aviram's and Dr. Davidson's studies are two different studies, so basically there is one group of patients who have very significant disease and the other group where it was just at risk. (RFF 1565; Heber, Tr. 1983-84). As a result, seeing a smaller result in the at-risk group than in the carotid artery stenosis group is not that surprising. (RFF 1567; Heber, Tr. 1983-84).

Dr. Aviram's and Dr. Davidson's results are also consistent with one another because Dr. Aviram examined a group of patients with high oxidative stress which is similar to the high-risk subgroup in Dr. Davidson's study and the trend can be observed in both studies. (RFF 1568; CX_1348 (Aviram, Dep. at 74)).

In deposition, Dr. Davidson testified that his findings do not contradict are consistent with previous studies conducted by Dr. Aviram, Dr. Sumner, Dr. Ornish, Dr. Ignarro, Dr. Kaplan, or Dr. Rosenblat:

> Q. Is there anything in your study that you conducted that, in your view, contradicts the results of those studies?
>
> A. No.
>
> * * *
>
> A. *I think the findings are consistent*.
>
> Q. How so?
>
> A. That -- to see an effect of an antioxidant therapy like pomegranate, you need to use it in the population that has high oxidative stress, and *the more oxidative stress that you have, the more likely you're going to see a benefit with the treatment*.
>
> *That's the general theme of our findings, and it's consistent with other research*.

(RFF 1569; CX1336 (Davidson, Dep. at 227-229)) (emphasis added); *see* RFF 1560-1569).

Similarly, Complaint Counsel's reliance on Dr. Ornish's unpublished CIMT Study, including the "cardiac arm of 17 patients," to somehow show Respondents did not replicate Aviram's CIMT/BP Study (2004) is misplaced. Dr. Ornish's unpublished CIMT study, initially sponsored by Respondents, was designed to evaluate the effects of pomegranate juice in 200 patients for one year. The study, however, only enrolled 73 subjects because funding was cut short. Although the study was "underpowered," however, Dr. Ornish testified a statistically significant result would have been achieved with 200 patients as originally contemplated. (RFF 1416-1424).

In his findings, Dr. Ornish nevertheless observed an improvement in the carotid artery significant to the 0.13 level as opposed to the 0.15 level. (RFF 1418; Ornish, Tr. 2352-54). If that degree of change had occurred in the larger number of patients he had projected (i.e. 200 instead of 73), it would have been clearly at the 0.05 level or less and it would have been a strong study showing pomegranate juice affected the progression of carotid disease. (RFF 1420; Ornish, Tr. 2352-54). In the Bev II Study, Dr. Ornish also found a similar, almost statistically significant improvement in the elasticity of the arteries. (RFF 1421; Ornish, Tr. 2353). If he recruited and tested the number of patients in the protocol, Dr. Ornish would have reached statistical significance because there is no reason to think the next 127 patients would have been different than the first 73. (RFF 1422; Ornish, Tr. 2353-54).

It would have been inaccurate to report that pomegranate juice did not affect the progression of carotid atherosclerosis, since the study was underpowered for this purpose, and it would have been what is known as a type II error: that there may have been a statistically significant difference but the sample size was not sufficiently large to detect it. (RFF 1423; PX0025-0019; (CX1339 (Ornish, Dep. at 70-71; 81-82). In any event, Dr. Sacks concedes that the lack of statistical significance in this study does not prove a negative and does not mean that pomegranate juice is not beneficial. (RFF 1426).

952. At the time the advertisements featuring the Aviram CIMT/BP Study (2004) were run, POM was aware of the subsequent results of the Ornish CIMT Study (2005) and the Davidson CIMT Study (2009). (CX1029_0003; Tupper, Tr. 960-61; CCFF ¶¶ 406-412,415-416).

Response to Finding No. 952:

Incorrect. The supporting citations refer to two specific advertisements, both published long before the Davidson study, and both mentioning the Dr. Ornish and Dr. Aviram studies together, with qualified language. First, a January 2008 advertisement called "The power of POM, in one little pill" (CCFF407), in which POM referred to both the Ornish and Aviram studies: "Two additional preliminary studies on our juice showed promising results for heart health. "Pomegranate juice improves myocardial perfusion in coronary heart patients," per D. Ornish, et al, in the American Journal of Cardiology, 2005. "Pomegranate juice pilot research suggests anti-atherosclerosis benefits," according to M. Aviram, et al, in Clinical Nutrition, 2004." (CCFF 410). Dr. Davidson's 2009 study was not mentioned, for the obvious reason that it was not published back in January of 2008. Second, a February 2008 advertisement entitled "The Antioxidant superpill" (CCFF408), in which POM referred to both the Dr. Ornish and Dr. Aviram studies:

"Two additional preliminary studies on our juice showed promising results for heart health. "Stress-induced ischemia decreased in the pomegranate group," Dr. Dean Ornish reported in the American Journal of Cardiology, 2005. "Pomegranate juice consumption resulted in a significant IMT reduction by up to 30% after one year," said Dr. Michael Aviram, referring to reduced arterial plaque in Clinical Nutrition, 2004." (CCFF 411). Moreover the cited exhibit CX1029 is dated January 13, 2009, a year after these advertisements were run, and the exhibit obviously cannot establish that Respondents were aware of Davidson's "results" more than a year prior to that date; instead it establishes exactly the opposite.

Respondents incorporate by reference their responses to Complaint Counsel's proposed Finding Nos. 406-412, 415-416.)

953. Mr. Tupper testified at trial that POM felt comfortable continuing to advertise the results of the Aviram CIMT/BP Study (2004) (*i.e.*, a 30% reduction in arterial plaque) even after learning of Dr. Davidson's CIMT Study results, because POM believes that the Davidson results were reinforcing and consistent with Aviram and the entire body of cardiovascular research. POM felt the Davidson CIMT Study results were consistent with the Aviram results even though the numbers and the percentages were different, and even though the studies involved different populations and therefore were not comparable to each other. (Tupper, Tr. 3006-07).

Response to Finding No. 953:

The proposed finding misstates Mr. Tupper's testimony. Mr. Tupper testified that POM felt comfortable continuing to summarize the results of Dr. Aviram's study because POM and its scientists believe that the results were reinforcing and consistent along with the body of cardiovascular research, particularly because these were different studies done on different populations, and therefore different numbers did not mean the results were inconsistent. (Tupper, Tr. 3006-7). In its use of the argumentative phrase "even though," Complaint Counsel's proposed finding of fact implies that there is a contradiction in that testimony, but fails to establish what that contradiction is. Respondents incorporate by reference their response to proposed Finding No. 951.

954. Mrs. Resnick has admitted that Respondents did not have enough science to make the claim that POM Juice "promotes heart health by preventing the build up of plaque in the arteries leading to the progression of atherosclerosis." (CX1375 (L. Resnick, Trop. Dep. at 105)).

Response to Finding No. 954:

Complaint Counsel's citation to Mrs. Resnick's testimony in a previous deposition does not prove that Respondents lacked a reasonable basis in their advertising regarding arterial plaque. Of course, Mrs. Resnick is not an expert on substantiation requirements under the FTC Act and, in any event, she testified at trial that "I have newer information today than I did then, and so I don't know legally what we're allowed or not allowed to

say, but I've been led to believe that our basic science is very valid…and especially for a natural food, so I'm not sure, quite frankly." (L. Resnick, Tr. 169).

c. Blood Pressure Summary

955. Respondents sponsored numerous studies involving blood pressure data. Two of Dr. Aviram's studies -- the ACE/BP Study (2001) and CIMT/BP Study (2004) – showed small improvements in blood pressure. These were unblinded, uncontrolled studies, however, and they reported only within-group data. (CCFF ¶¶ 796-820).

Response to Finding No. 955:

The Aviram ACE/BP Study (2001) and Aviram CIMT/BP Study (2004) both demonstrated a 5% and 12% reduction in systolic blood pressure and constitute competent and reliable scientific evidence that the consumption of the Challenged Products are beneficial to cardiovascular health by, among other things, improving blood pressure. (RFF 1107-1126; 1280-1302; CX0542; CX0611; PX0025-0009-0011; PX0192-0035-0037; 0052).

The record is replete with evidence confirming that it is entirely appropriate for each patient to serve as his or her own control (RFF 1283) and a study conducted without a placebo does not weaken its importance. (RFF 1285). Indeed, Dr. Sacks concedes that a group taking nothing can serve as a control. (RFF 1298). Dr. Davidson also stated that non-RCTs are accurate, reliable studies generally considered by other scientists and clinicians in the scientific community to be valid. (RFF 1287).

In addition, as Dr. Ornish testified, there is a common misconception that a larger study is a better study, but the opposite can be argued. (RFF 1249). In fact, with a smaller number of patients, the treatment has to be more powerful and consistent in order to show a statistically significant effect. (RFF 1250). If his study designs were not sufficient, no peer-reviewed journal would have published Dr. Aviram studies. (RFF 1302).

Respondents incorporate by reference their responses to Complaint Counsel proposed Finding Nos. 796-820.

956. Five subsequent RCTs sponsored by Respondents showed no benefit to blood pressure. These include the Ornish MP Study (2005) (CCFF ¶ 829); the Ornish CIMT Study (CCFF ¶ 858); the Davidson BART/FMD study (CCFF ¶ 915); the Davidson CIMT Study (2009) (CCFF ¶ 883); and the San Diego Study (CCFF ¶ 932).

Response to Finding No. 956:

Complaint Counsel point to selected studies sponsored by Respondents in which allegedly no statistically significant differences in blood pressure were observed to show the Challenged Products are not effective. First, none of Respondent's subsequent studies examined blood pressure as a *primary endpoint* and, as a result, one cannot conclude that here was no effect of POM Juice or POMx on blood pressure. (RFF 1572-1573). In any clinical study, it is routine to take a blood pressure, pulse, body temperature, among other measurements, to make sure patients are healthy. (RFF 1570). Although blood pressure is measured in many studies, a specific claim on blood pressure requires a very specific study involving special equipment and personnel. (RFF 1571). Second, and as Dr. Sacks concedes, subsequent studies showing no statistically significant changes in systolic blood pressure cannot be construed to prove the opposite. (RFF 1455; 1513; 1553; Sacks, Tr. 1608-09; PX0361 (Sacks, Dep. at 230; 223-24); Heber, Tr. 1981)). Respondents incorporate by reference their responses to Complaint Counsel's proposed Finding Nos. 829, 858, 883, 915, and 932.

957. Nevertheless, POM ran the "Decompress" advertisement (which depicted a blood pressure cuff around a POM bottle), after it was aware of these five subsequent studies, which showed POM products had no effect on blood pressure. (CCFF ¶¶ 357-58; Tupper, Tr. 976). POM also continued to cite to the Aviram studies on its website until at least October 2009. (CX0473 (Oct. 2009, pomwonderful.com at 02:45-02:52)).

Response to Finding No. 957:

Respondents object to Complaint Counsel's proposed Finding No. 957 on the grounds that it misstates the record, lacks foundation, and assumes facts not in evidence. The body copy of the "Decompress" ad itself does not use the words "blood pressure" or say anything about "blood pressure." (RFF 2329; CX0103_0001; CX0459_0001). Viewing the "Decompress" ad as a whole, including the interaction of the words and visual imagery, the overall net impression of the ad is that POM Juice is healthy, healthy for your heart and good for cardiovascular health. (RFF 2331-2337; CX0103_0001; CX0459_0001). Complaint Counsel have presented no evidence that anyone who viewed the "Decompress" headline and imagery with the body copy quoted above would construe that POM Juice is "clinically proven" to prevent, treat or reduce the risk of heart disease by lowering blood pressure. (RFF 2342).

Respondents incorporate by reference their responses to Complaint Counsel's proposed Finding Nos. 357-358, and 956.

958. Mr. Resnick has admitted that Respondents do not have enough substantiation to support a claim that POM Juice lowers blood pressure. (CX1376 (S. Resnick, OS Dep. at 310-11)).

Response to Finding No. 958:

Respondents object to Complaint Counsel's proposed Finding No. 958 on the grounds that it is vague and ambiguous, lacks foundation, assumes facts not in evidence, and improperly attempts to convert lay opinion into expert legal and/or scientific testimony. Mr. Resnick's personal views do not amount to expert opinion on what constitutes competent and reliable scientific evidence for the purposes of the FTC Act.

d. Blood Flow Summary

959. Respondents frequently cited the Ornish MP Study (2005) in their advertising. (CCFF ¶¶ 415, 419). Respondents were aware, however, of significant problems with this study, including the lack of a statistical analysis in the protocol; the fact that the published

report reflected only three-month interim data; that only one out of three primary measures showed any benefit; and the fact that there were two separate instances of unblinding. (CCFF ¶¶ 830-38). Indeed, the published report itself acknowledged that the study was small and needed replication. (CCFF ¶ 828). In any event, myocardial perfusion measures are not recognized surrogate markers for the purpose of heart disease prevention and treatment studies. (CCFF ¶ 844).

Response to Finding No. 959:

Respondents object to Complaint Counsel's proposed Finding No. 959 on the grounds that it is vague, ambiguous, and overbroad, lacks foundation, assumes facts not in evidence, and misstates the record. The evidence cited by Complaint Counsel does not support the proposition that "Respondents were aware…of significant problems" with the Ornish MP Study (2005). Complaint Counsel's manufactured critiques of the Ornish MP Study (2005), which observed a 35% comparative benefit in subjects who consumed POM Juice daily for three months, lack merit. The Ornish MP Study (2005) constitutes competent and reliable scientific evidence that the consumption of the Challenged Products are beneficial to cardiovascular health by, among other things, improving blood flow. (RFF 1127-1138; 1303-1414; PX0023; PX0025-0011-0018; PX0192 -0037-0038, 0053; Ornish, Tr. 2354-55).

Respondents incorporate by reference their responses to proposed Finding Nos. 845 and 846. There is no admissible evidence in the record that supports the proposition that Respondents were purportedly on notice of the lack of a "statistical analysis plan." Respondents previously objected to Complaint Counsel's use of CX0576 (listed on Attachment B to JX2 as a conditionally admitted exhibit) on the grounds that it constitutes unreliable hearsay, lacking any exception. The document appears to be offered as proof for the truth of the matters stated therein. Respondents also objected to this exhibit on the grounds that it lacks foundation. Complaint Counsel has not cited to any deposition or trial testimony explaining and/or authenticating this document. For this reason, it should be stricken from the record.

Dr. Ornish's finding of statistically significant changes in the summed difference score (SDS) confirmed what the researchers were hoping to find (an improvement in blood flow to the heard when compared to rest and stress) and not in the summed rest score (SRS) or summed stress score (SSS) which measured infarcted or dead heart tissue. (RFF 1339-1358). The study was terminated after three months only because the Resnicks did not provide the funding previously committed, not because the p-value was statistically significant, and this does not undermine the confidence in the three-month findings, which stand on their own. (RFF 1402-1407).

As Dr. Ornish explained, with respect to blinding, the expectation that an intervention is beneficial has the potential for confounding the outcome of a study, but such an outcome was unlikely to have occurred in Ornish MP Study (2005). (RFF 1393; PX0025-0016). At the time that the study was conducted, there was not an awareness in the general population that pomegranate juice was beneficial or even that the subjects were drinking pomegranate juice (the study was entitled a "beverage study"). (RFF 1394; PX0025-0016; (CX1339 (Ornish, Dep. at 148-149)). At the time of the unblinding, people did not know that pomegranate juice might even be beneficial to them and if they found they were drinking Gatorade, there was a greater likelihood that that they would have thought that was the intervention. (RFF 1395; Ornish, Tr. 2345-46; (CX1339 (Ornish, Dep. at 148-149)). The real issue or reason studies are blinded is the expectation that something might have a positive benefit can sometimes be self-fulfilling, but in this case, there is no reason why the subjects would have necessarily thought that, even if they knew they were drinking pomegranate juice that was likely to provide them a benefit, because this was before people even knew what pomegranate juice was other than an exotic juice. (RFF 1396; Ornish, Tr. 2346; (CX1339 (Ornish, Dep. at 148-149)). It would be a stretch to say that subjects simply thinking they were getting something beneficial could affect blood flow to the heart, but even if one assumed that were true, they might just as well thought

that the Gatorade would be as beneficial as the pomegranate juice. (RFF 1397; Ornish, Tr. 2347).

Contrary to Complaint Counsel's assertions, myocardial perfusion (blood flow to the heard) is the "bottom line" in coronary heart disease; a better risk factor or surrogate than LDL cholesterol since it is more closely connected to how much blood the heart it getting; and superior than coronary angiography as a predictive test of cardiac events. (RFF 1305-1327; 1328-1338).

Finally, at trial, Dr. Ornish testified that the phrase "further research is needed" is common language in a study and in good science, a researcher is always trying to be his or her most intense critic. (Ornish, Tr. 2366).

e. Biomarkers

960. Many of Respondents' studies collected data on biomarkers related to heart health such as ACE, C-reactive protein, oxidized phospholipids, TBARS, and nitric oxide. (*See* CCFF ¶¶ 796-801 (Aviram ACE/BP Study (2001)), 912-919 (Davidson BART/FMD Study), 920-43 (Denver and San Diego studies), 944-49 (Heber/Hill and Rock Diabetes studies)). The heart-related biomarker data in Respondents' studies were on the whole, unsupportive of the proposition that the POM Products benefit heart health.

Response to Finding No. 960:

Respondents' object to Complaint Counsel's proposed Finding No. 960 on the grounds that is overbroad, vague, and ambiguous, lacks foundation, assumes facts not in evidence, and misstates the record.

The Aviram ACE/BP Study (2001) observed, in humans, after two weeks of pomegranate juice consumption, a 36% reduction in serum ACE activity and a 5% decrease in systolic blood pressure. A 31% decrease of ACE was observed also *in vitro*, thus confirming the effect of pomegranate juice. (RFF 1108; CX0005; CX1348 (Aviram, Dep. at 22-23)). The authors concluded: "the significant inhibitory effect of pomegranate juice on serum ACE activity and the minor attenuation in blood pressure in hypertensive patients, in

addition to its potent inhibitory effect on lipid peroxidation, suggests that pomegranate juice consumption can offer a wide protection against cardiovascular disease." (RFF 1109; CX0005_0003).

In the "Heber/Hill Study", which is comprised of the Denver and San Diego site studies, Dr. Heber and Dr. Hill, at the University of Colorado, examined the safety and antioxidant activity of POMx on overweight individuals with increased waist size. (RFF 1514; CX0934). At the San Diego site, where the authors conducted the safety part of the study, 64 overweight individuals received one or two POMx capsules per day for four weeks. (RFF 1515; CX0934). With respect to the safety of POMx, Dr. Heber found that "[t]here were no serious adverse events reported," "no qualitative or quantitative differences between treatment groups or by comparison placebo," "no apparent treatment-related changes of clinical significance, and no laboratory results were outside the normal range in any of the chemistry, hematology, or urinalysis laboratory testing." (RFF 1516; CX0934_0003). At the Denver site, where antioxidant activity was measured, 22 overweight subjects received two POMx capsules per day for four weeks. (RFF 1517; CX0934_0003). With respect to antioxidant activity, Dr. Hill found a statistically significant reduction in "TBARS" (thiobarbituric acid reactive substances), which is an important biomarker of oxidative stress in humans and strongly predictive of cardiovascular events in people with stable coronary artery disease, independent of traditional risk factors and inflammatory markers. (RFF 1518; CX0934_0003-0004).

Respondents' 15 published basic science studies constitute competent and reliable scientific evidence that the Challenged Products are beneficial to cardiovascular health by, among other things:

- reducing oxidation of LDL cholesterol;
- lessening the uptake of oxidized and native LDL cholesterol by macrophage foam cells;

- diminishing the size of atherosclerotic lesions and foam cells;
- inhibiting macrophage cholesterol biosynthesis;
- decreasing macrophage oxidative stress;
- protecting against cellular lipid peroxidation;
- reducing serum lipids and glucose levels;
- improving PON1;
- lessening of platelet aggregation;
- increasing and preserving levels of nitric oxide and decreasing expression of genes associated with stress and progression of atherosclerosis;
- reducing LDL oxidation, size of atherosclerotic plaques, and formation of foam cells;
- reversing effects of shear stress, which can damage the endothelial cells or thin layer of cells that line the interior of blood vessels;
- decreasing cellular production and release of oxygen radicals in the vascular wall;
- inhibiting activation of oxidation-sensitive genes; and
- improving biological activity of nitric oxide.

(RFF 1064-1088; PX0025; PX0192; PX0002, PX0007, PX0008, PX0009, PX0010, PX0015, CX0543, PX0017, PX0022, CX0053, PX0055, PX0056, PX0057, PX0058, PX0059).

Respondents' 10 published human clinical studies confirm and support the benefits found in the basic research and together, the totality of the evidence constitutes competent and reliable scientific evidence that pomegranate juice and/or its extracts promote cardiovascular health by, among other things, having the following beneficial benefits:

- decrease of LDL susceptibility to aggregation and retention;
- increase in PON1;
- protection against oxidation of LDL;
- reduction in the activity of ACE, an enzyme which produces "angiotensin II", a protein that causes blood vessels to constrict;

- lowering of systolic blood pressure;
- reduction in CIMT; and
- increase blood flow or myocardial perfusion.

(RFF 1089-1099; PX0025; PX0192; PX0004, PX0005, CX0611, PX0014, PX0020, PX0021, PX0023, PX0038, PX0127, CX0934).

Respondents incorporate by reference their previous responses to Complaint Counsel's proposed Finding Nos. 796-801, 912-949.

961. Nevertheless, Respondents touted the Aviram ACE/BP Study (2001) data until at least 2009 (*see, e.g.*, CCFF ¶¶ 455-56), even though the ACE data from the Davidson BART/FMD Study, which was an RCT, contradicted this result. (CCFF ¶ 917). Although the TBARS data from the uncontrolled Denver Study were positive (CCFF ¶ 926), there were no significant changes in the numerous antioxidant/inflammatory markers measured in the Davidson CIMT Study (2009), the San Diego Study, and the Heber Diabetes Study, all of which were RCTs. (CCFF ¶¶ 884, 933, 949).

Response to Finding No. 961:

Respondents object to Complaint Counsel's proposed Finding No. 961 on the grounds that it is overbroad, vague and ambiguous, compound, lacks foundation, assumes facts not in evidence, and misstates the record. Respondents incorporate by reference their previous responses to Complaint Counsel's proposed Finding Nos. 455 and 456. As Dr. Sacks concedes, just because the BART study does not show statistically significant changes with respect to blood pressure and ACE, among other measurements, that the absence of such evidence is proof there is no effect. (PX0361 (Sacks, Dep. at 230)).

No conclusions can be drawn from the absence of statistically significant changes of other markers in the Davidson CIMT Study (2009), San Diego Study, or Heber Diabetes Study, because such measurements were not primary endpoints and because the absence of proof does not prove the negative. (RFF 1455, 1513, 1553; PX0361 (Sacks, Dep. at 230, 238, 243)).

Respondents incorporate by reference their previous responses to Complaint Counsel's proposed Finding Nos. 884, 917, 933, 949).

f. Summary Analysis

962. In considering whether a product – whether a conventional food, drug, or dietary supplement – is likely to have an effect on the risk or treatment of a disease, it is important to first look at the individual items of evidence, to determine whether they are reliable and probative. Then, it is important to look at the evidence as a whole. (CX1291 (Sacks, Report at 0038)).

Response to Finding No. 962:

As explained by Respondents' experts, Dr. Miller, Dr. Ornish and Dr. Heber, the evidentiary standard for evaluating the efficacy of a natural food product is different than examining a pharmaceutical drug with potentially serious side effects. In the case at bar, *the totality of scientific evidence on pomegranates should be examined*, not just RCTs, given that: (1) pomegranate juice and its extracts are safe; (2) no one suggests that pomegranate juice or its extracts should be offered in lieu of conventional medical treatment or surgery; (3) the expense associated for conducting a FDA drug study for a non-patentable, natural food is exorbitant and prohibitive; and (4) the potential benefit or information to be gained by the public outweighs any plausible harm. (RFF 1184-1205).

As discussed in Respondents' Post-Trial Brief, Dr. Sacks conceded at trial and in deposition that: (1) in evaluating a natural food, RCTs are simply not necessary in all cases; (2) a lesser standard of evidence is appropriate for fruits and fruit juices as evidenced by his own DASH diet; (3) he has recommended (or would recommend) fish oil (Omega-3) or a reduction in sodium to patients with coronary heart disease even though no RCTs have been conducted; (4) RCTs are not feasible because of logistical, financial, and ethical considerations; and (5) he nevertheless concedes that we should weigh the risk that the product will do harm against the potential of keeping information from the public. (RFF 1214; 1221-22; 1227-48). Dr. Sacks' opinion on the appropriate

standard of evidence for evaluating cardiovascular science, therefore, should be disregarded.

Similarly, Professor Stampfer undermines Complaint Counsel's assertion that RCTs are required to demonstrate the efficacy of a whole fruit or juice. In his expert report, for instance, Dr. Stampfer agrees that it may be appropriate to communicate health recommendations in the absence of RCTs:

> I believe that it may be appropriate to use evidence short of randomized clinical trials for crafting public health recommendations regarding nutrient guidelines even when causality cannot be established, because everyone eats and the public should be given advice based on *the best evidence available*…*Long term trials of diet and disease outcomes are often unfeasible due to the financial and participant burden required to perform such studies*, but it is indisputable that the randomized clinical trial is the best study design that permits strong causal inference concerning the relationship between an administered agent (whether drug or nutrient) and any specific outcome.

(CX1293_0029-0030)(emphasis added).

Thus, based on these statements alone, Professor Stampfer concedes that the "*best evidence available*" should be considered, not RCTs as argued by Complaint Counsel, even when "causality cannot be established" because in his words, "everyone eats." (CX1293_0029-0030). Moreover, Professor Stampfer acknowledges that RCTs "are often infeasible" with respect to diet and disease outcomes. (CX1293_0030). At trial, Professor Stampfer disclosed that he has made public statements or recommendations that food and beverage products lower the risk of certain diseases, in the absence of RCTs and even when the product is not completely safe. (RFF 208-209).

It is a rather extreme position to state that only evidence from RCTs should be considered in evaluating the therapeutic efficacy. (RFF 1185; PX0025-0007). The research of Complaint Counsel's own expert, Dr. Frank Sacks, would not meet this RCT standard

and thus would not be clinically or scientifically relevant because most of his published studies have been epidemiological and observational in nature, rather than RCTs, and include relatively small numbers of patients. (RFF 1186; PX0025-0007). Much of what physicians provide patients in their clinical practices has not been proven to be beneficial in RCTs. (RFF 1187; PX0025-0007).

It is an extreme position to state that evidence from *in vitro* and animal studies should not be considered in determining the therapeutic value of an intervention. (RFF 1188; PX0025-0007). While there are limitations to extrapolating from *in vitro* and animal studies to human studies, it is false to say this research has no value in determining therapeutic efficacy. (RFF 1189; PX0025-0007). RCTs, even when conducted perfectly, do not control for all sources of bias and may inject new ones unique to RCTs. (RFF 1190; PX0025-0008).

A more thoughtful way of analyzing therapeutic efficacy is to carefully examine the totality of scientific evidence, including but not limited to RCTs that are perfectly conducted. (RFF 1191; PX0025-0008). It is an extreme position to state that the therapeutic efficacy of a fruit juice or extract of pomegranate juice should be held to the same standard of evidence as a new drug. (RFF 1192; PX0025-0008). The benefits of pomegranates have been described since Biblical times over thousands of years. (RFF 1193; PX0025-0008). Dr. Ornish is not aware of any studies showing any harmful effects of consuming pomegranates or pomegranate juice. (RFF 1194; PX0025-0008).

The study of pomegranates or pomegranate juice is different than studying a new drug, in which harmful side-effects, both short-term and long-term, are the rule rather than the exception. (RFF 1195; PX0025-0008). A new drug needs to be held to a higher standard than a juice that has been around for thousands of years. (RFF 1196; Ornish, Tr. 2340). Dr. Ornish understands that no one is suggesting that pomegranates, pomegranate

juice, or pomegranate extract be an alternative to conventional treatments of heart disease such as drugs and surgery. (RFF 1197; PX0025-0008). There is a world of difference between offering juice as a healthy lifestyle choice or as an *adjunct* to conventional treatments than offering it as a replacement for conventional medical care. (RFF 1198; PX0025-0008).

A beverage, which has been around since the Bible for thousands of years and whose side effects are good ones, should not be held to a drug standard, because then, in fact, no one can meet that standard, because drug companies spend literally billions of dollars to get a new drug approved. (RFF 1199; Ornish, Tr. 2324-25). Pfizer got four drugs approved in the last 10 years at an average cost of one to four billion dollars each. (RFF 1200; Ornish, Tr. 2325). No manufacturer would spend billions of dollars to test a fruit unless it is a drug like Lipitor, where you could make billions of dollars a year and it would be worthwhile to make such an investment. (RFF 1201; Ornish, Tr. 2325).

With all of the research done on pomegranates, if simple health claims cannot be made about the potential benefits, then no one will be able to make health claims except drug companies and that is to the detriment of the American people. (RFF 1202; Ornish, Tr. 2326). There are literally hundreds of thousands of protective substances in predominantly fruits, vegetables, whole grains, legumes, and soy products, and it is important for manufacturers to be able to share science-based information with the American people so that they can decide whether or not they want to purchase these products, not to overstate the claims and not say that these are a substitute for conventional approaches. It is important for the American people to know about these benefits so they can make their own choices and not have the Government do it for them. (RFF 1203; Ornish, Tr. 2326-27).

From a preventive standpoint, in cardiac studies since there is a preponderance of evidence from RCTs (even if not perfectly conducted) as well as other clinical trials, animal studies, and *in vitro* studies indicating that pomegranate juice is likely beneficial, it would be unfortunate to say that these benefits should not be communicated to the general public, including in advertising that is appropriately qualified, when the costs of pomegranate juice are relatively small (especially when compared to drugs) and the safety is clear. (RFF 1204; PX0025-0008). In examining the totality of the evidence, it is important to look at many elements from different studies, such as inflammation, oxidation and related biomarkers, which are interconnected. (RFF 1205; PX0353 (Heber, Dep. at 178)).

963. There is no reliable evidence that POM Juice reduces or delays the development of arterial plaque; reduces blood pressure; increases blood flow to the heart (or other blood vessels); or that it produces statistically significant reductions in LDL, HDL, triglycerides, or cholesterol. (CX1291 (Sacks, Report at 0038-39)). The current data do not support the claims for heart disease prevention or treatment. (CX1293 (Stampfer, Report at 0022)). Further, clinical studies, research and/or trials do not prove that drinking POM Juice, daily, prevents or reduces the risk of heart disease, including by decreasing arterial plaque, lowering blood pressure, and/or improving blood flow to the heart. (CX1291 (Sacks, Report at 0010); CX1293 (Stampfer, Report at 0017)).

Response to Finding No. 963:

Respondents object to Complaint Counsel's proposed finding No. 963 on the grounds that it is overbroad, vague, and ambiguous, compound, lacks foundation, assumes facts not in evidence, and misstates the record. Respondents dispute Complaint Counsel's allegations that the advertisements at issue suggest the Challenged Products can prevent, reduce the risk of, or treat heart disease.

To the extent the Commission finds that Respondents' advertisements convey the message that the Challenged Products can "reduce the risk" of heart disease, the totality of Respondents' scientific evidence supports the conclusion that the Challenged Products can "reduce the risk" of heart disease in the same manner that exercise and diet

do. Indeed, consuming the Challenged Products, which are 100% derived from a natural pomegranate fruit, is no different than eating broccoli or blueberries to "reduce the risk of" any disease. Dr. Ornish has stated in his expert report:

> Taken as a whole, the preponderance of the scientific evidence from basic scientific studies, animal research, and clinical trials in humans reveals that the pomegranate in its various forms (including POM Wonderful 100% Pomegranate Juice, POMx Pills, or POMx Liquid) is likely to be beneficial in maintaining cardiovascular health and is likely to ***help reduce the risk of cardiovascular disease***.

(RFF1206; PX0025-0005). In addition, both Dr. Ornish and Dr. Heber have testified that the Challenged Products are likely to help prevent or ***reduce the risk of heart disease*** by (1) decreasing arterial plaque; (2) lowering blood pressure, and/or (3) improving blood flow to the heart. (RFF 1210; PX0025-0005; Ornish, Tr. 2374-75; PX0355 (Ornish, Dep. at 42); PX0192-0045; PX0353 (Heber, Dep. at 76-80)).

Should Respondents' ads be construed by the Commission to suggest that the Challenged Products can "prevent" heart disease, then the totality of the scientific evidence also supports the conclusion that the Challenged Products "help prevent" heart disease in the same fashion as exercise and good diet can. In this sense, the Challenged Products do not "absolutely prevent" heart disease in all cases, like Lipitor, but rather help lower the overall incidence. Indeed, Dr. Ornish stated that pomegranate juice "actually improves the blood flow in people who already had heart disease" and if you can "begin to reverse a disease, it would only make sense that it would work even better to help ***prevent it in the first place***." (RFF 1211; Ornish, Tr. 2354-55) (emphasis added).

Finally, to the extent the Commission believes that the Respondents' advertisements convey the message that the Challenged Products can "treat" heart disease, then the totality of the scientific evidence supports the conclusion that the Challenged Products can "help treat" or ameliorate symptoms of an existing condition, not serve as substitute

or replacement for conventional medical care.[1] Dr. Ornish has explicitly stated "it is my expert opinion that clinical studies, research and trials, provide significant evidence that pomegranate juice is likely to *reduce blood pressure, improve blood flow, and reduce arterial plaque, period*." (RFF 1210; PX0025-0005; Ornish, Tr. 2374-75; PX0355 (Ornish, Dep. at 42)) (emphasis added). Similarly, Dr. Heber also concluded that "[t]here is credible scientific evidence that pomegranate juice and pomegranate extracts have significant health benefits for human cardiovascular systems, including: (1) *decreases in arterial plaque*; (2) *lowering of blood pressure*; and (3) *improvement of cardiac blood flow*…" (RFF 1209; PX0192-00045; PX0353 (Heber, Dep. at 76-80)) (emphasis added).

Respondents' 15 published basic science studies constitute competent and reliable scientific evidence that the Challenged Products are beneficial to cardiovascular health by, among other things:

- reducing oxidation of LDL cholesterol;
- lessening the uptake of oxidized and native LDL cholesterol by macrophage foam cells;
- diminishing the size of atherosclerotic lesions and foam cells;
- inhibiting macrophage cholesterol biosynthesis;
- decreasing macrophage oxidative stress;
- protecting against cellular lipid peroxidation;
- reducing serum lipids and glucose levels;
- improving PON1;
- lessening of platelet aggregation;

[1] Complaint Counsel's own expert, Dr. Sacks, acknowledges the role that diet or nutrition can play in "treating" or "preventing" heart disease. In counseling patients on cardiovascular health or disease, for instance, Dr. Sacks explains "my initial emphasis would be nutritional and other nondrug treatment like exercise, weight loss, improving the quality of the diet…" (RFF 1259; PX0361 (Sacks, Dep. at 23-24)) (emphasis added). According to Dr. Sacks, a nutritional emphasis is "the accepted sequence of treatment for prevention of cardiovascular disease…and prevention of recurrent disease." (RFF 1260; PX0361 (Sacks, Dep. at 25)) (emphasis added).

- increasing and preserving levels of nitric oxide and decreasing expression of genes associated with stress and progression of atherosclerosis;
- reducing LDL oxidation, size of atherosclerotic plaques, and formation of foam cells;
- reversing effects of shear stress, which can damage the endothelial cells or thin layer of cells that line the interior of blood vessels;
- decreasing cellular production and release of oxygen radicals in the vascular wall;
- inhibiting activation of oxidation-sensitive genes; and
- improving biological activity of nitric oxide.

(RFF 1064-1088; PX0025; PX0192; PX0002, PX0007, PX0008, PX0009, PX0010, PX0015, CX0543, PX0017, PX0022, CX0053, PX0055, PX0056, PX0057, PX0058, PX0059).

Respondents' 10 published human clinical studies confirm and support the benefits found in the basic research and together, the totality of the evidence constitutes competent and reliable scientific evidence that pomegranate juice and/or its extracts promote cardiovascular health by, among other things, having the following beneficial benefits:

- decrease of LDL susceptibility to aggregation and retention;
- increase in PON1;
- protection against oxidation of LDL;
- reduction in the activity of ACE, an enzyme which produces "angiotensin II", a protein that causes blood vessels to constrict;
- lowering of systolic blood pressure;
- reduction in CIMT; and
- increase blood flow or myocardial perfusion.

(RFF 1089-1099; PX0025; PX0192; PX0004, PX0005, CX0611, PX0014, PX0020, PX0021, PX0023, PX0038, PX0127, CX0934).

Respondents' human clinical studies confirm and support the benefits found in the basic and animal research and together, the totality of the evidence constitutes competent and reliable scientific evidence that pomegranate juice and/or its extracts promote cardiovascular health by, among other things, helping to reduce arterial plaque, lower blood pressure, and improve blood flow. (PX0004, PX0005, CX0611, PX0014, PX0020, PX0021, PX0023, PX0038, PX0127, CX0934, PX0002, PX0007, PX0008, PX0009, PX0010, PX0015, CX0543, PX0017, PX0022, CX0053, PX0055, PX0056, PX0057, PX0058, PX0059)). *See also* RFF 1206-1211.

The Aviram CIMT/BP Study (2004) and Davidson CIMT Study (2009) constitute competent and reliable scientific evidence that the consumption of the Challenged Products are beneficial to cardiovascular health by, among other things, reducing arterial plaque. (RFF 1111-1126; 1139-1146; 1288-1302; 1427-1504; PX0014; PX0611; PX0025-0009-0010; 0019-0022; PX0192-0036-0037, 0039; 0048, 005; Heber Tr. 1979-86; PX0014).

The Ornish MP Study (2005) constitutes competent and reliable scientific evidence that the consumption of the Challenged Products are beneficial to cardiovascular health by, among other things, improving blood flow. (RFF 1127-1138; 1303-1414; PX0023; PX0025-0011-0018; PX0192-0037-0038; 0053, Ornish, Tr. 2354-55).

The Aviram ACE/BP Study (2001) and Aviram CIMT/BP Study (2004) constitute competent and reliable scientific evidence that the consumption of the Challenged Products are beneficial to cardiovascular health by, among other things, improving blood pressure. (RFF 1107-1126; 1280-1302; CX0542; CX0611; PX0025-0009-0011; PX0192-0035-0037; 0052).

964. Further, Respondents' research provides no evidence that POMx Pills or POMx Liquid will treat, prevent, or reduce the risk of heart disease, through any mechanism. (CX1291 (Sacks, Report at 0038); CX1293 (Stampfer, Report at 0017)). Similarly, the establishment claims for POMx Pills and POMx Liquid are not supported. (CX1291 (Sacks, Report at 0010); CX1293 (Stampfer, Report at 0017)). POM Juice and POMx are not identical products. POM Juice contains anthocyanins and pomegranate sugars (PX0192 (Heber, Report at 0016) (POM Juice contains anthocyanins); CX1358 (Aviram, Dep. at 60-61) (POM Juice contains sugar)). The extract products do not. (CX1426_00042) (POMx contains no sugar); CX1352 (Heber, Dep. at 358 (anthocyanins are not part of any pomegranate extract)).

Response to Finding No. 964:

Complaint Counsel is wrong on all of this. Respondents' scientific research on cardiovascular health demonstrates that POM Juice, POMx Pills and POMx Liquid have beneficial effects on arterial plaque, blood pressure and blood flow. (RFF 1064-1146). With respect to POMx Pills and POMx Liquid in particular, Respondents detailed the findings of eight scientific studies that document the beneficial effects of POMx Pills and POMx Liquid on cardiovascular health. (CX0053; PX0057; PX0056; PX0008; PX0017; PX0038; PX0139; PX0127; RFF 831-840, 924, 930-957, 1100). Respondents dispute that they have made any establishment claims for POMx Pills and POMx Liquid.

Significantly, Respondents have never claimed that POM Juice and POMx are "*identical products*." Rather, Respondents have conveyed that these products provide nutritionally *equivalent benefits* to humans. (RFF 920, 921). Complaint Counsel may dispute the products' nutritional equivalency, *but they have provided no evidence of their own to do so*. Instead, they now rely on their own misleading inferences to suggest incorrectly that anthocyanins in the juice (from the red arils) contribute to the high antioxidant *activity* of POM Juice, and that, therefore, the lack of significant amounts of anthocyanins in the POMx must mean that they do not provide the same benefits as the juice. As creative an argument as this is, Complaint Counsel know better. Dr. Heber testified unambiguously that there exists no significant correlation between anthocyanin levels and antioxidant *activity*. (RFF 796). Instead, the ellagitanin polyphenols of the pomegranate, not

anthocyanins, contribute significantly to the antioxidant *activity* of pomegranate products. (RFF 794-796, 1061-1062). Because both the 100% Juice and POMx contain ellagitannins that do contribute to the antioxidant *activity* of the products (and because both are bioavailable (absorbed) in humans), there is no difference in the antioxidant *effect* between POM Juice and POMx products in laboratory studies. Dr. Heber, the only expert who opined on this entire subject at trial, and who opined on this non-rebutted subject in his expert witness report, found no difference in the antioxidant *effect* between POM Juice and POMx products in laboratory studies he conducted. (RFF 925). Complaint Counsel presented absolutely no evidence contrary, and Professor Stampfer did not dispute Dr. Heber's conclusions. (RFF 215-216, 818-819). The Respondents have provided ample evidence to demonstrate that POMx Pills and POMx Liquid are bioequivalent to POM Juice and that POMx Pills and POMx Liquid provide similar health benefits as POM Juice provides. (RFF 915-951).

965. Research by Dr. Heber showed that POM Juice has greater antioxidant activity than the extracts (Heber, Tr. 2187), and he testified that the anthocyanins in POM Juice "undoubtedly" contribute to its antioxidant activity. (PX0192 (Heber, Report at 0017); *see also* CX1352 (Heber, Dep. at 273-74 (antioxidant components of pomegranate juice due in part to anthocyanins)). Dr. Aviram attributes the benefits of POM Juice in part to its sugars. (CX1358 (Aviram, Dep. at 60-61)). Dr. Aviram testified that much less research has been done on POMx and that he is not confident that POMx will work in the same manner as POM Juice. (CX1358 (Aviram, Dep. at 48)). Respondents' own internal documents recognize that research on POM Juice cannot be used to support claims for POMx. (CX0266_0003).

Response to Finding No. 965:

Incorrect and a surprisingly misleading from government counsel. Dr. Heber never testified that the anthocyanins in POM Juice contribute to its antioxidant *activity*. Instead, in his report he states that testified that the anthocyanins in POM Juice "undoubtedly" contribute to the antioxidant *capacity* of pomegranates" (PX0192 (Heber, Report at 0017), referring solely to the *amount* of antioxidants in pomegranates. Significantly, Respondents have never claimed that POM Juice and

POMx are "*identical products*." Rather, Respondents have conveyed that these products provide nutritionally *equivalent benefits* to humans. (RFF 920, 921). Complaint Counsel may dispute the products' nutritional equivalency, *but they have provided no evidence of their own to do so*. Instead, they now rely on their own misleading inferences to suggest incorrectly that anthocyanins in the juice (from the red arils) contribute to the high antioxidant *activity* of POM Juice, and that, therefore, the lack of significant amounts of anthocyanins in the POMx must mean that they do not provide the same benefits as the juice. As creative an argument as this is, Complaint Counsel know better. Dr. Heber testified unambiguously that there exists no significant correlation between anthocyanin levels and antioxidant *activity*. (RFF 796). Instead, the ellagitanin polyphenols of the pomegranate, not anthocyanins, contribute significantly to the antioxidant *activity* of pomegranate products. (RFF 794-796, 1061-1062). Because both the 100% Juice and POMx contain ellagitannins that do contribute to the antioxidant *activity* of the products (and because both are bioavailable (absorbed) in humans), there is no difference in the antioxidant *effect* between POM Juice and POMx products in laboratory studies. Dr. Heber, the only expert who opined on this entire subject at trial, and who opined on this non-rebutted subject in his expert witness report, found no difference in the antioxidant *effect* between POM Juice and POMx products in laboratory studies he conducted. (RFF 925). Complaint Counsel presented absolutely no evidence contrary, and Professor Stampfer did not dispute Dr. Heber's conclusions. (RFF 215-216, 818-819). The Respondents have provided ample evidence to demonstrate that POMx Pills and POMx Liquid are bioequivalent to POM Juice and that POMx Pills and POMx Liquid provide similar health benefits as POM Juice provides. (RFF 915-951).

g. Respondents' Awareness of Inadequate Evidence

966. In January 2009, Mr. Tupper and Dr. Dreher prepared a medical research portfolio review. These portfolio reviews were updated from time to time and used during meetings with Mr. Resnick and other scientific advisors when discussing POM's current research and making decisions on future research. (Tupper, Tr. 941-42; CX1029).

Response to Finding No. 966:

Complaint Counsel mischaracterizes both the nature of the January 2009 Medical Research Portfolio Review as well as Mr. Tupper's testimony.

Mr. Tupper testified that, as part of their internal preparation to potentially submit an application to the FDA for drug approval, Respondents conducted candid reviews of POM's entire science portfolio to examine whether and to what extent their research would meet the requirements of the FDA, with its current limited recognition of surrogate markers used in POM's research. (Tupper, Tr. 3011)

One of these summaries entitled "Medical Research Portfolio Review" was prepared by Respondent Matt Tupper and Mark Dreher for an internal meeting with POM's advisors, including Mr. Tupper, Mark Dreher, Dr. Harley Liker, Dr. Kavid Kessler, and Dr. David Heber, and Mr. Resnick. (Tupper, Tr. 3011; CX1029).

The assessment of POM's research science in the Medical Research Portfolio Review, as part of that internal preparation, was done from a "drug perspective" or through the lens of FDA approval, and not as Complaint Counsel alleges, for a general assessment of POM's current research in connection with a whole food. (Dreher, Tr. 564; Tupper, Tr. 3009-3010; CX1029).

967. POM's January 2009 Medical Research Portfolio Review summarized POM's medical research to that point on various conditions (including heart disease, prostate cancer, and erectile dysfunction/sexual function). It also contained a section meant to facilitate a discussion about options looking forward, including end game scenarios and assessments. (CX1029_0003-04, 0013; Tupper, Tr. 951, 976-77).

Response to Finding No. 967:

Complaint Counsel again mischaracterizes both the nature of the January 2009 Medical Research Portfolio Review as well as Mr. Tupper's testimony.

Mr. Tupper testified that, as part of their internal preparation to potentially submit an application to the FDA for drug approval, Respondents conducted candid reviews of POM's entire science portfolio to examine whether and to what extent their research would meet the requirements of the FDA, with its current limited recognition of surrogate markers used in POM's research. (Tupper, Tr. 3011)

The "Medical Research Portfolio Review", as part of that internal preparation, was prepared by Respondent Matt Tupper and Mark Dreher for an internal meeting with POM's advisors, including Mr. Tupper, Mark Dreher, Dr. Harley Liker, Dr. Kavid Kessler, and Dr. David Heber, and Mr. Resnick. (Tupper, Tr. 3011; CX1029). Indeed, POM's chief science officers, Brad Gillespie and Mark Dreher, were regularly asked to provide research summaries that included the FDA perspective as part of at the candid assessment to establish the viability of obtaining FDA drug approval. (Tupper, Tr. 3014)

The summary of POM's research science in the Medical Research Portfolio Review was done from a "drug perspective" or through the lens of FDA approval, and not as Complaint Counsel alleges, for a general assessment of POM's current research without respect to the strict FDA requirements. (Dreher, Tr. 564; Tupper, Tr. 3009-3010; CX1029).

968. The heart disease summary clearly shows that respondents knew they did not have enough science to make treat, prevent, or reduce the risk of heart disease claims, including claims about lowering blood pressure. (CX1029_0003).

Response to Finding No. 968:

Complaint Counsel mischaracterizes the January 2009 Medical Research Portfolio Review.

Mr. Tupper testified that, as part of their internal preparation to potentially submit an application to the FDA for drug approval, Respondents conducted candid reviews of

POM's entire science portfolio to examine whether and to what extent their research would meet the requirements of the FDA, with its current limited recognition of surrogate markers used in POM's research. (Tupper, Tr. 3011)

The summary of POM's research science in the Medical Research Portfolio Review, as part of that internal preparation, was done from a "drug perspective" or through the lens of FDA approval, and not as Complaint Counsel alleges, as an assessment of what claims can or cannot be made outside of the FDA approval process pertinent to a drug approval. (Dreher, Tr. 564; Tupper, Tr. 3009-3010; CX1029_003).

Thus, the Medical Research Portfolio Review relating to heart disease was specifically targeted at the requirements for FDA drug approval, and do not address (and are not relevant to) the legal standard that Respondents' science should be held to in order to meet the FTC's substantiation requirements in connection with a whole food. (Tupper, Tr. 3009-3011; Dreher, Tr. 564).

For example, POM assessed in the Medical Research Portfolio Review that the required action for a botanical drug in connection with heart disease claims would be two studies with 1000 patients. (CX1029_003). That observation was made due to the fact that the FDA does not yet recognize IMT as an end-point for drug approval, but instead presently requires that heart attack data or death data be used as the end point. (Tupper, Tr. 983-984; CX1029_003).

The FDA's standard for drug approval is not the legal standard by which Respondents' science should be held to in order to meet the FTC's substantiation requirements. (Tupper, Tr. 3009-3011; Dreher, Tr. 564). Indeed, POM has pursued using different endpoints than those used by the FDA to approve a drug for heart disease, which nonetheless substantiate the claims made in its advertisements. (Tupper, Tr. 3011).

969. For example, the summary noted that claims of "prevent heart disease" or "lower blood pressure" must be based on death/heart attack data and systolic BP data, respectively, for the pills. POM deemed the claims "too expensive and too risky" since such claims would require FDA approval. (CX1029_0003).

Response to Finding No. 969:

Complaint Counsel mischaracterizes the January 2009 Medical Research Portfolio Review.

Mr. Tupper testified that, as part of their internal preparation to potentially submit an application to the FDA for drug approval, Respondents conducted candid reviews of POM's entire science portfolio to examine whether and to what extent their research would meet the requirements of the FDA, with its current limited recognition of surrogate markers used in POM's research. (Tupper, Tr. 3011)

The summary of POM's research science in the Medical Research Portfolio Review, as part of that internal preparation, was done from a "drug perspective" or through the lens of FDA approval, and not as Complaint Counsel alleges, as an assessment of the substantiation for the claims made in Respondents' advertisements in connection with a whole food. (Dreher, Tr. 564; Tupper, Tr. 3009-3010; CX1029_003).

Thus, the Medical Research Portfolio Review relating to heart disease was specifically targeted at the requirements for FDA drug approval, and do not address (and are not relevant to) the legal standard that Respondents' science should be held to in order to meet the FTC's substantiation requirements. (Tupper, Tr. 3009-3011; Dreher, Tr. 564)

For example, POM assessed in the Medical Research Portfolio Review that the required action for a botanical drug in connection with heart disease claims would be two studies with 1000 patients. (CX1029_003). That observation was made due to the fact that the FDA does not yet recognize IMT as an end-point for drug approval, but instead presently

requires that heart attack data or death data be used as the end point. (Tupper, Tr. 983-984; CX1029_003).

The FDA's standard for drug approval is not the legal standard by which Respondents' science should be held to in order to meet the FTC's substantiation requirements. (Tupper, Tr. 3009-3011; Dreher, Tr. 564). Indeed, POM has pursued using different endpoints than those used by the FDA to approve a drug for heart disease, which nonetheless substantiate the claims made in its advertisements relating to its whole-food products. (Tupper, Tr. 3011).

970. POM further deemed the idea of seeking FDA approval for a health claim for juice or pills (*e.g.*, "reduced risk of heart disease" or "reduced risk of hypertension") as "[p]robably not worth pursuing" because, in part, its heart disease (CIMT) and blood pressure data may not have been strong enough. (CX1029_0003).

Response to Finding No. 970:

Complaint Counsel mischaracterizes the January 2009 Medical Research Portfolio Review.

Mr. Tupper testified that, as part of their internal preparation to potentially submit an application to the FDA for drug approval, Respondents conducted candid reviews of POM's entire science portfolio to examine whether and to what extent their research would meet the requirements of the FDA, with its current limited recognition of surrogate markers used in POM's research. (Tupper, Tr. 3011)

The summary of POM's research science in the Medical Research Portfolio Review, as part of that internal preparation, was done from a "drug perspective" or through the lens of FDA approval, and not as Complaint Counsel alleges, as an assessment of the substantiation for the claims made in Respondents' advertisements in connection with a whole food. (Dreher, Tr. 564; Tupper, Tr. 3009-3010; CX1029_003).

Thus, the Medical Research Portfolio Review relating to heart disease was specifically targeted at the requirements for FDA drug approval, and do not address (and are not relevant to) the legal standard that Respondents' science should be held to in order to meet the FTC's substantiation requirements. (Tupper, Tr. 3009-3011; Dreher, Tr. 564).

For example, POM assessed in the Medical Research Portfolio Review that the required action for a botanical drug in connection with heart disease claims would be two studies with 1000 patients. (CX1029_003). That observation was made due to the fact that the FDA does not yet recognize IMT as an end-point for drug approval, but instead presently requires that heart attack data or death data be used as the end point. (Tupper, Tr. 983-984; CX1029_003). Thus, Respondents' statement that it was "[p]robably not worth pursuing" FDA drug approval for specified health benefit claims was merely a reflection of the fact that the FDA drug approval process did not currently utilize the end points (such as IMT) that POM's research had pursued. (Tupper, Tr. 983-984; CX1029_003).

The FDA's standard for drug approval is not the legal standard by which Respondents' science should be held to in order to meet the FTC's substantiation requirements. (Tupper, Tr. 3009-3011; Dreher, Tr. 564). Indeed, POM has pursued using different endpoints than those used by the FDA to approve a drug for heart disease, which nonetheless substantiate the claims made in its advertisements relating to its whole-food products. (Tupper, Tr. 3011).

971. POM's summary assessment at the time noted that its heart disease research "has holes" and that its "current body of research [was] only viewed as a '3' on a scale of 1-10 by MDs[.]" (CX1029_0003). Respondents' "End Game Scenarios" listed for heart disease research, as well as for other research areas, included doing "[a]dditional, targeted research for Marketing/PR/Medical Outreach purposes" or "[n]o more clinical research – publicize what we already have[.]" (CX1029_0003; *see also* CX1029_0004).

Response to Finding No. 971:

Complaint Counsel mischaracterizes the January 2009 Medical Research Portfolio Review.

Mr. Tupper testified that, as part of their internal preparation to potentially submit an application to the FDA for drug approval, Respondents conducted candid reviews of POM's entire science portfolio to examine whether and to what extent their research would meet the requirements of the FDA, with its current limited recognition of surrogate markers used in POM's research. (Tupper, Tr. 3011)

The summary of POM's research science in the Medical Research Portfolio Review, as part of that internal preparation, was done from a "drug perspective" or through the lens of what would be required for FDA approval, and not as Complaint Counsel alleges, as an assessment of the substantiation for the claims made in Respondents' advertisements in connection with a whole food. (Dreher, Tr. 564; Tupper, Tr. 3009-3010; CX1029_003).

Thus, the Medical Research Portfolio Review relating to heart disease was specifically targeted at the requirements for FDA drug approval, and do not address (and are not relevant to) the legal standard that Respondents' science should be held to in order to meet the FTC's substantiation requirements for advertisements of whole foods. (Tupper, Tr. 3009-3011; Dreher, Tr. 564). Thus, the reference to "doctors" or "MDs" in the review was a reference to those subset of doctors or researchers in the FDA drug approval realm, not practicing clinicians focused on what makes sense for their patients. (Tupper, Tr. 986-87; Dreher, Tr. 561-62).

For example, POM assessed in the Medical Research Portfolio Review that the required action for a botanical drug in connection with heart disease claims would be two studies

with 1000 patients. (CX1029_003). That observation was made due to the fact that the FDA does not yet recognize IMT as an end-point for drug approval, but instead presently requires that heart attack data or death data be used as the end point. (Tupper, Tr. 983-984; CX1029_003).

The statement in the Medical Research Portfolio Review that Respondents' research "has holes" was solely in reference to the fact that, **with respect to FDA drug approval**, POM's research had pursued different end points (such as IMT) that the FDA drug approval process does not currently utilize. (Tupper, Tr. 985-986). Similarly, the rationale for ranking Respondents' science as a three on a scale of ten was specifically in reference to an assessment given by doctors oriented to FDA drug approval and because POM has pursued endpoints, like IMT, that are not currently used by the FDA to approve a pharmaceutical drug for heart disease. (Tupper, Tr. 3001, 3011; CX1029_003)

Putting aside the strict FDA requirements and FDA lens, Respondent Matt Tupper personally ranks POM's body of cardiovascular science as an eight on a scale of ten. (Tupper, Tr. 3012).

The FDA's standard for drug approval is not the legal standard by which Respondents' science should be held to in order to meet the FTC's substantiation requirements. (Tupper, Tr. 3009-3011; Dreher, Tr. 564). Indeed, POM has pursued using different endpoints than those used by the FDA to approve a drug for heart disease, which nonetheless substantiate the claims made in its advertisements relating to its whole-food products. (Tupper, Tr. 3011).

972. Despite POM's own assessment in January 2009 that doctors would consider POM's cardiovascular science as three out of ten, Mr. Tupper testified at trial that he would grade POM's cardiovascular science an eight out of ten. (Tupper, Tr. 3011-12).

Response to Finding No. 972:

Complaint Counsel mischaracterizes the January 2009 Medical Research Portfolio Review as well as Mr. Tupper's testimony.

Mr. Tupper testified that, as part of their internal preparation to potentially submit an application to the FDA for drug approval, Respondents conducted candid reviews of POM's entire science portfolio to examine whether and to what extent their research would meet the requirements of the FDA, with its current limited recognition of surrogate markers used in POM's research. (Tupper, Tr. 3011)

The summary of POM's research science in the Medical Research Portfolio Review, as part of that internal preparation, was done from a "drug perspective" or through the lens of what would be required for FDA approval, and not as Complaint Counsel alleges, as an assessment of the substantiation for the claims made in Respondents' advertisements in connection with a whole food. (Dreher, Tr. 564; Tupper, Tr. 3009-3010; CX1029_003). Thus, the reference to "doctors" or MDs" in the Review was a reference to those subset of doctors or researchers in the FDA drug approval realm, not practicing clinicians focused on what makes sense for their patients. (Tupper, Tr. 986-87; Dreher, Tr. 561-62).

The rationale for ranking Respondents' science as a three on a scale of ten was because such rankings were given **in the context of FDA drug approval** and specifically in reference to an assessment given by doctors oriented to FDA drug approval and because POM has pursued endpoints, like IMT, that are not currently used by the FDA to approve a pharmaceutical drug for heart disease. (Tupper, Tr. 3001, 3011; CX1029_003)

Putting aside the strict FDA requirements and FDA lens, Respondent Matt Tupper personally ranks POM's body of cardiovascular science as an eight on a scale of ten. (Tupper, Tr. 3012).

The FDA's standard for drug approval is not the legal standard by which Respondents' science should be held to in order to meet the FTC's substantiation requirements. (Tupper, Tr. 3009-3011; Dreher, Tr. 564). Indeed, POM has pursued using different endpoints than those used by the FDA to approve a drug for heart disease, which nonetheless substantiate the claims made in its advertisements relating to its whole-food products. (Tupper, Tr. 3011).

973. Dr. Heber testified that he did not tell Mr. Resnick or Mr. Tupper that there was scientific agreement that POM Juice or POMx could prevent or treat cardiovascular disease. (CX1352 (Heber, Dep. at 244-45)).

Response to Finding No. 973:

Respondents object to the proposed finding to the extent that Complaint Counsel construe this testimony to bolster their argument that Respondents intended to convey to consumers the claim that the Challenged Products prevent or treat coronary heart disease. Although Respondents believe that pomegranate juice is beneficial to cardiovascular health and that POM's research supports this belief (RFF 506, 510, 519-20), they dispute that Respondents ever intended to convey or that the Challenged Ads do convey the claim that the Challenged Products treat, prevent or reduce the risk of heart disease, or that they are "clinically proven" to do so. (RFF 496, 535, 538, 540, 547, 549, 2209-11, 2279-80; CX1375 (L. Resnick, Trop., Dep. at 79-81). Moreover, competent and reliable scientific evidence exists supporting the conclusion that the consumption of the Challenged Products have beneficial effects cardiovascular health. (RFF 1077, 1087-88, 1099-1106, 1209-10, 1297).

D. Analysis of Respondents' Research Related to Prostate Cancer

1. Background Information

974. To substantiate a claim that a food or a diet supplement is effective in preventing or reducing the risk of prostate cancer, experts in the field of prostate cancer would require at least one well-designed, randomized, double-blind, placebo-controlled clinical trial (RCT) involving an appropriate sample population and endpoint. (CX1287 (Eastham, Report at 0012-15); CX1293 (Stampfer, Report at 0009-10); CCFF ¶ 771).

Response to Finding No. 974:

Respondents dispute this proposed finding as contrary to the evidence in the record. Experts in the field of prostate cancer would not require a RCT to substantiate a claim that a food or a diet supplement is effective in preventing or reducing the risk of prostate cancer. Dr. deKernion, one of the foremost experts in the field of prostate cancer, testified that in the case of fruit juice such as POM Juice, that has low or no toxicity, it is not necessary to have a RCT, placebo-controlled test. (deKernion, Tr. 3060). Dr. Miller opined that a double-blind, placebo controlled trial evaluating the Challenged Products as a prostate cancer protective agent would take decades and thousands of patients and would have to control for other naturally occurring dietary antioxidants, anti-inflammatory, and anticancer agents as well as life-style activities (e.g., exercise, smoking, alcohol use), genetic predisposition, racial and ethnic factors, benign prostatic hypertrophy, and other factors that might have an effect on carcinogenesis of prostate cancer. (PX0206-0014). Dr. Miller testified that if a claim was made that a fruit juice prevents prostate cancer and there was reliable scientific data to support such a claim, the claim could be made without a RCT. (Miller, Tr. 2201). Dr. Heber testified in that dealing with nutrients, RCTs are often infeasible and too expensive to conduct. (Heber, Tr. 1950). As a practicing clinician, Dr. Pantuck believed that the level of certainty required of a study before he relies on it for clinical practice, is not necessarily based on RCTs, but based on a clinical judgment of what the risks and benefits and level of evidence are to suggest that some treatment might be good for some patient. (CX1341

(Pantuck, Dep. at 26)). Dr. Pantuck further testified that there is no study to show that radiation and surgery are equivalent in terms of a cure for prostate cancer but nonetheless, every week he makes recommendations to patients about whether they should have radiation or surgery. (CX1341 (Pantuck, Dep. at 267-268)). In clinical practice Dr. Pantuck estimated that significantly less than 50 percent of his clinical decisions are based on results of RCTs as there are very few RCTs in urology that have been done. (CX1341 (Pantuck, Dep. at 276)).]

975. Prostate cancer prevention clinical trials study the effect of a product in a healthy population to determine whether the product will prevent disease occurrence in the future. (Eastham, Tr. 1270; CX1287 (Eastham, Report at 0012)). In a prostate cancer prevention trial, prevalence or the incidence of prostate cancer in the population studied is the endpoint generally accepted by experts in the field. (Eastham, Tr. 1273; CX1287 (Eastham, Report at 0014)).

Response to Finding No. 975:

Respondents add the following explanatory facts to this proposed finding: Dr. Miller opined that a double-blind, placebo controlled trial evaluating the Challenged Products as a prostate cancer protective agent would take decades and thousands of patients and would have to control for other naturally occurring dietary antioxidants, anti-inflammatory, and anticancer agents as well as life-style activities (e.g., exercise, smoking, alcohol use), genetic predisposition, racial and ethnic factors, benign prostatic hypertrophy, and other factors that might have an effect on carcinogenesis of prostate cancer. (PX0206-0014). Dr. Eastham testified that studies of disease prevention should involve 10,000 to 30,000 men and that such studies are "incredibly expensive" and in the range of $600 million. (Eastham, Tr. 1328).

976. PSADT (PSA doubling time) is not a relevant surrogate marker for prostate cancer prevention trials because it is not used by urologists to predict whether or not a healthy patient will end up getting prostate cancer, nor is it used as a screening tool for prostate cancer. (*See generally* CX1287 (Eastham, Report at 0006-08) (explaining the use of PSA in screening for prostate cancer)). In fact, Dr. Heber noted that PSA is "an imperfect surrogate marker when the prostate is intact." (PX0192 (Heber, Report at 0026)).

Response to Finding No. 976:

Respondents dispute portions of this finding of fact as contrary to the evidence in the record and add the following facts: Dr. deKernion testified that urologists do use PSA velocity in people who have their prostates. (deKernion, Tr. 3050-51). Urologists use a change in PSA velocity to determine the greater or lesser probability of a patient having cancer cells that are growing. (deKernion, Tr. 3050-51).

Dr. deKernion testified that in order to show an effect of POM on cancer, the best way to do that research is on patients whose prostate had been removed because the presence of PSA elevation is almost always indication of remaining cancer. This is how the Pantuck and Carducci studies were conducted. (RFF 1761).

Dr. deKernion testified that the study population of Dr. Pantuck and Dr. Carducci's study were people who should have been cured of prostate cancer except their PSA was detectable, which indicated they had microscopic cancer. (RFF 1762). In each of the studies, they then treated the subjects with POM Juice (Pantuck study) or POMx (Carducci study), and showed that it slowed down the growth of the tumor cells as expressed by the longer time it took for those tumor cells to double. (RFF 1763). Dr. deKernion opined that, while such things could never be subject to 100% proof, the same mechanism shown in the *in vitro* and animal studies and in the Pantuck and Carducci human studies also showed, with a "high degree of probability" that POM and POMx would inhibit the clinical development of prostate cancer in men who have not been diagnosed with that disease. (deKernion, Tr. 3119-20).

977. To substantiate a claim that a food or dietary supplement is an effective treatment for prostate cancer, experts in the field would require a similar RCT trial with an appropriate sample population of patients with the stage of the disease targeted by the study, and measuring a proper endpoint. (CX1287 (Eastham, Report at 0015)). In a prostate cancer treatment trial, overall survival or prostate cancer-specific mortality is the endpoint generally accepted by experts in the field. (Eastham, Tr. 1280; CX1287 (Eastham, Report at 0009); CX1293 (Stampfer, Report at 0025)).

Response to Finding No. 977:

Respondents dispute portions of this proposed finding as contrary to the evidence in the record. Experts in the field of prostate cancer would not require a RCT to substantiate a claim that a food or a diet supplement is effective treatment for prostate cancer. Dr. deKernion, one of the foremost experts in the field of prostate cancer, testified that in the case of fruit juice such as POM Juice, that has low or no toxicity, it is not necessary to have a RCT, placebo-controlled test. (deKernion, Tr. 3060). Dr. Miller opined that a double-blind, placebo controlled trial evaluating the Challenged Products as a prostate cancer protective agent would take decades and thousands of patients and would have to control for other naturally occurring dietary antioxidants, anti-inflammatory, and anticancer agents as well as life-style activities (e.g. exercise, smoking, alcohol use), genetic predisposition, racial and ethnic factors, benign prostatic hypertrophy, and other factors that might have an effect on carcinogenesis of prostate cancer. (PX0206-0014). Dr. Heber testified that in dealing with nutrients, RCTs are often infeasible and too expensive to conduct. (Heber, Tr. 1950). As a practicing clinician, Dr. Pantuck believed, that the level of certainty required of a study before he relies on it for clinical practice, is not necessarily based on Phase III placebo controlled studies, but based on a clinical judgment of what the risks and benefits and level of evidence are to suggest that some treatment might be good for some patient. (CX1341 (Pantuck, Dep. at 26)). Dr. Pantuck further testified that there is no study to show that radiation and surgery are equivalent in terms of a cure for prostate cancer but every week nonetheless, he makes recommendations to patients about whether they should have radiation or surgery. (CX1341 (Pantuck, Dep. at 267-268)). In clinical practice Dr. Pantuck estimated that significantly less than 50 percent of his clinical decisions are based on results of RCTs as there are very few in urology that have been done. (CX1341 (Pantuck, Dep. At 276)).

Complaint Counsel's expert Professor Stampfer also agreed that RCTs have certain limitations in a nutritional context, such as the length of time required and the number of participants, and also because RCTs are a "huge expense," even simple ones are "very expensive". (Stampfer, Tr. 823-26). Professor Stampfer also agreed that where the risk of harm is slight and a potential benefit exists, he is a strong advocate of giving that information to the public. (Stampfer, Tr. 827-29). He also conceded that it is appropriate to rely on evidence short of RCTs, and *in vitro* and animal research can both provide useful information. (Stampfer, Tr. 830, 840).

Additionally, Complaint Counsel's expert, Dr. Sacks, concedes that a causal influence can be demonstrated between an agent and its effect on humans without the use of RCTs. (RFF 647; PX0361 (Sacks, Dep. at 134-135)). Dr. Sacks testified that you do not need RCT trials to test the benefit of food categories that are included in a diet already tested, like the DASH diet, which includes pomegranates. (RFF 648; Sacks, Tr. 1545-46).

978. Experts in the field of prostate cancer agree that PSADT is not an accepted surrogate endpoint for survival or prostate cancer-specific mortality in prostate cancer treatment clinical trials. (Eastham, Tr. 1297; Stampfer, Tr. 782-83; deKernion, Tr. 3096; CX1287 (Eastham, Report at 0010); CX1293 (Stampfer, Report at 0025); CX1340 (Carducci, Dep. at 88-90); CX1341 (Pantuck, Dep. at 253-54)). Many men with increases in PSA after initial therapy do not die of prostate cancer. (Stampfer, Tr. 783; Eastham, Tr. 1258; deKernion, Tr. 3088). On the other hand, some men succumb to prostate cancer without an increase in PSA. (Stampfer, Tr. 783).

Response to Finding No. 978:

Respondents dispute portions of this finding of fact as contrary to the evidence in the record. First, Complaint Counsel's citation to Dr. deKernion is unsupported. Dr. deKernion states in the citation noted that he was referring to "chemotherapy trials" not all prostate cancer treatment clinical trials as the proposed finding would suggest. (deKernion, Tr. 3096). Secondly, many published studies have demonstrated the now widespread acceptance of PSAD Time as a valid surrogate and predictor of disease and

death. (*See* generally RFF 1841-1855 "Prostate-specific antigen doubling time is an independent predictor of clinical disease recurrence and mortality after surgical biochemical failure." (PX0166)). PSADT can help risk stratify patients for prostate cancer-specific mortality following biochemical recurrence after radical prostatectomy. (PX0165).

Further, Complaint Counsel's own expert has acknowledged PSADT as a legitimate surrogate marker for prostate cancer specific death. Specifically, Complaint Counsel's expert Dr. Eastham admitted in his article, "Prostate-specific antigen doubling time as a prognostic marker in prostate cancer": "PSA doubling time has emerged as an important factor in the evaluation of men with newly diagnosed prostate cancer or prostate cancer that recurs after treatment. PSA doubling time can be used as a surrogate marker for prostate cancer specific death." (PX0178). Dr. Eastham cites studies showing that "only PSADT was a significant predictor of either systematic progression or local recurrence" of disease, that "PSADT was the strongest predictor of eventual clinical recurrence" and that authors, "suggest that PSADT might serve as a possible surrogate for prostate-cancer-specific death." (PX0178-0006-0008). In his article, Dr. Eastham concludes that "PSADT is an important prognostic marker in men with biochemical failure after local therapy for prostate cancer, and it predicts the probable response to salvage radiotherapy, progression to metastatic disease and prostate cancer specific death." (PX0178-0009).

979. Prostate specific antigen or PSA is a protein produced exclusively by the prostate gland, which is used as a biomarker for detecting prostate cancer incidence and recurrence. After initial treatment for prostate cancer, PSA values fall to zero or near zero. (CX1293 (Stampfer, Report at 0025); CX1287 (Eastham, Report at 0008)). If PSA rises rapidly after initial treatment, it is a sign that the cancer may not have been sufficiently eliminated by treatment or that it had spread to other organs prior to surgical removal of the prostate. (CX1293 (Stampfer, Report at 0025); CX1287 (Eastham, Report at 0008)). A rise in PSA after treatment is called a "biochemical recurrence." (Eastham, Tr. 1257-58; deKernion, Tr. 3053-54). For example, approximately, one-third of prostate cancer patients treated by radical prostatectomy will develop a biochemical recurrence. (CX0815_0001; Eastham, Tr. 1257-58; PX0163-0002).

Response to Finding No. 979:

Respondents have no specific response.

980. PSADT is used by clinicians as a prognostic tool at the time of biochemical recurrence of prostate cancer to predict the odds of clinical progression of the disease in prostate cancer patients who have undergone initial treatment. (Eastham, Tr. 1260; PX0351 (deKernion, Dep. at 93)). PSADT is a mathematical calculation of how rapidly PSA is increasing. (Eastham, Tr. 1259-60; CX1340 (Carducci, Dep. at 57); CX1341 (Pantuck, Dep. at 75); deKernion, Tr. 3050)).

Response to Finding No. 980:

Respondents have no specific response other than that PSADT is not only used as a prognostic tool at the time of biochemical recurrence but throughout disease progression. (RFF 1743-1759; 1841-1851).

981. As a prognostic tool, the most clinically meaningful PSADT value is a doubling time of less than three months. (Eastham, Tr. 1262; CX1287 (Eastham, Report at 0008); CX1293 (Stampfer, Report at 0026)). The vast majority of men with a PSADT of less than 3 months after being treated with radiation and/or surgery will develop metastatic disease and ultimately die of prostate cancer. (Eastham, Tr. 1262; CX1293 (Stampfer, Report at 0026); deKernion, Tr. 3084)).

Response to Finding No. 981:

Respondents dispute this proposed finding to the extent it suggests that a PSADT value of greater than three months is not clinically meaningful or corresponds with certain risk with disease progression or mortality. (PX0161-0004).

982. In contrast, men with a long PSADT of 15 months after having been treated with radiation and/or surgery will have a lower risk of clinical progression. (Eastham, Tr. 1263; deKernion, Tr. 3085; Stampfer, Tr. 784). Few prostate cancer deaths occur in men with long PSADT. (deKernion, Tr. 3085).

Response to Finding No. 982:

Respondents dispute portions of this finding of fact as contrary to the evidence in the record as Dr. deKernion testified although few deaths occur in men with long PSADT, the number is "not zero." (deKernion, Tr. 3085). Dr. deKernion also opined that, "even a

slow-growing cancer can occasionally become clinically significant, and prompt toxic intervention such as hormonal or chemotherapy. Further, knowledge that one's tumor is growing has significant impact on quality of life. Given that return of measurable PSA after expected curative treatment does indeed mean the return of cancer (and that has never been disputed) and that changes in the PSA do indeed reflect growth of the tumor, citizens with this problem appreciate the opportunity to have access to low-toxicity, non-traditional methods of treatment." (PX0161-0010).

983. There are no studies demonstrating that modulating PSADT (*i.e.*, changing the rate of the PSA doubling time) changes the natural history of prostate cancer by delaying the development of metastases or death from the disease. (Eastham, Tr. 1261; CX1287 (Eastham, Report at 0011, 0019); PX0161 (deKernion, Report at 0004); PX0351 (deKernion, Dep. at 52-53)).

Response to Finding No. 983:

Respondents dispute portions of this proposed finding as contrary to the evidence in the record. Dr. deKernion opined that although there are no studies that have been performed for sufficient length to prove an impact on survival it is the best marker available and the one primarily used by prostate cancer physicians and researchers alike. (RFF 1743-1749). As Dr. deKernion explained in his expert report, in deposition and on the stand, the reason for this is at least two-fold: (1) prostate cancer is typically a slow growing cancer that often does not clinically recur or kill the patient and (2) prostate cancer usually occurs in older men that typically die from other age-related causes before the prostate cancer can kill them. Because of this, large, lengthy and extremely expensive studies would be required to prove (if even possible) absolutely that PSADT is surrogate marker for clinical recurrence and death. This has yet to be done (PX0161).

984. Respondents have been researching prostate cancer since 1999 and spent approximately $12 million, or one third of their research dollars, in this area. (*See* CX1263) (calculating this amount by adding the prostate cancer expenditures by the 1988 Trust and POM for the years 1999 through 2010 listed on pages CX1263_ 0003-06).

Response to Finding No. 984:

Respondents have no specific response.

985. Respondents, however, have just one human study completed and published. It is not an RCT. Respondents also conducted four *in vitro* studies and four animal studies relating to prostate cancer, according to their January 13, 2009 summary of their prostate cancer research to date. (CX1029_0004). Complaint Counsel's experts reviewed the available *in vitro* and animal research, and concluded that RCTs with proper endpoints are needed to confirm the potential antioxidant effect on prostate cancer observed in a test tube or laboratory setting. (CX1293 (Stampfer, Report at 0022); CX1287 (Eastham, Report at 0021)). Thus, Respondents do not have support for their prostate cancer advertising claims, as further explained below.

Response to Finding No. 985:

Respondents dispute this finding of fact as contrary to the evidence in the record. Experts in the field of prostate cancer would not require an RCT to substantiate a claim that a food or diet supplement is effective in preventing or reducing the risk of prostate cancer. Dr. deKernion, one of the foremost experts in the prostate cancer field, testified that in the case of fruit juice, such as POM Juice, that has low or no toxicity, it is not necessary to have an RCT, placebo-controlled test. (deKernion, Tr. 3060). Dr. Miller opined that a double-blind, placebo controlled trial evaluating the Challenged Products as a prostate cancer protective agent would take decades, thousands of patients, and would have to control for other naturally occurring variables, such as dietary antioxidants, anti-inflammatory, and anticancer agents as well as life-style activities (e.g., exercise, smoking, alcohol use, etc.) genetic predisposition, racial and ethnic factors, benign prostatic hypertrophy, and other factors that might have an effect on carcinogenesis of prostate cancer. Dr. Miller testified that if a claim was made that a fruit juice prevents prostate cancer and there was reliable scientific data to support such a claim, the claim could be made without a RCT. (Miller, Tr. 2201). Dr. Heber testified that in dealing with nutrients, RCTs are often infeasible and too expensive to conduct. (Heber, Tr. 1950). As a practicing clinician, Dr. Pantuck believed, that the level of certainty required

of a study before he relies on it for clinical practice, is not necessarily based on RCTs but based on a clinical judgment of what the risks and benefits and the level of evidence are to suggest that some treatment might be good for some patient. (CX1341 (Pantuck, Dep. at 26)). Dr. Pantuck further testified that there is no study to show that radiation and surgery are equivalent in terms of a cure for prostate cancer but nonetheless, every week he makes recommendations to patients about whether they should have radiation or surgery. (CX1341 (Pantuck, Dep. at 267-268)). In clinical practice, Dr. Pantuck estimated that significantly less than 50% of his clinical decisions are based on the results of RCTs as there are very few RCTs in urology that have been done. (CX1341 (Pantuck, Dep. at 276)).

Complaint Counsel's expert Professor Stampfer also agreed that RCTs have certain limitations in a nutritional context, such as the length of time required and the number of participants, and also because RCTs are a "huge expense," even simple ones are "very expensive". (Stampfer, Tr. 823-26). Professor Stampfer also agreed that where the risk of harm is slight and a potential benefit exists, he is a strong advocate of giving that information to the public. (Stampfer, Tr. 827-29). He also conceded that it is appropriate to rely on evidence short of RCTs, and *in vitro* and animal research can both provide useful information. (Stampfer, Tr. 830, 840).

Additionally, Complaint Counsel's expert, Dr. Sacks, concedes that a causal influence can be demonstrated between an agent and its effect on humans without the use of RCTs. (RFF 647; PX0361 (Sacks, Dep. at 134-135)). Dr. Sacks testified that you do not need RCT trials to test the benefit of food categories that are included in a diet already tested, like the DASH diet, which includes pomegranates. (RFF 648; Sacks, Tr. 1545-46).

Respondents object to Complaint Counsel's phrase "their prostate cancer advertising claims" on the basis that this phrase is vague and ambiguous. Respondents deny Complaint Counsel's allegations that their advertising and promotional materials make the claim that (1) Respondents' clinical studies, research, and/or trials prove that drinking eight ounces of POM Juice, or taking one POMx Pill or one teaspoon of POMx Liquid daily, prevents or reduced the risk of prostate cancer and (2) treats prostate cancer. (RFF 1581). Further, Respondents aver that competent and reliable scientific evidence supports the conclusion that the consumption of pomegranate juice and pomegranate extract supports prostrate health and the conclusion that the same mechanism in the *in vitro* studies, the animal studies and in the Pantuck and Carducci human studies also showed with a high degree of probability that the Challenged Products inhibit the clinical development of prostate cancer cells in men who have not been diagnosed with prostate cancer. (RFF 1577-1578).

2. Prostate Cancer Studies

a. Pantuck Phase II Prostate Cancer Study (2006)

(3) About the Study

986. Dr. Allan J. Pantuck is a urologist in the Department of Urology at the UCLA Medical Center in Los Angeles, California and, at the time of the study, reported to Respondent's expert, Dr. deKernion, Chairman of the Department. (deKernion, Tr. 3114; CX1090_0004).

Response to Finding No. 986:

Respondents have no specific response.

987. The *Phase II Study of Pomegranate Juice for Men with Rising Prostate-Specific Antigen following Surgery or Radiation for Prostate Cancer* ("Pantuck Phase II Prostate Cancer Study (2006)") involving POM Juice and men with prostate cancer. (CX1379_0019, *in camera*). Dr. Pantuck conducted the study for, and it was sponsored by, Respondents. (CX0815_0001; CX1128_0001). The Pantuck Phase II Prostate Cancer Study (2006) cost $479,236.50. (CX1128_0001).

Response to Finding No. 987:

Respondents have no specific response other than the exhibits cited in this proposed finding of fact speak for themselves.

988. In 2001, Dr. Allan J. Pantuck wrote a letter to Dr. Dornfeld and Dr. Liker (Respondents' scientific advisors) setting forth his protocol concepts for two clinical studies studying the benefits of pomegranate juice in populations of men with prostate cancer. (CX0544_0001). According to the letter, "these pilot studies are designed to provide preliminary data to justify further development of pomegranate juice as a chemopreventative agent for prostate cancer." (CX0544_0001). One of the two proposed protocol concepts became the Pantuck Phase II Prostate Cancer Study (2006). (CX1341 (Pantuck, Dep. at 57)).

Response to Finding No. 988:

Respondents have no specific response other than the exhibits cited in this proposed finding of fact speak for themselves.

989. The Pantuck Phase II Prostate Cancer Study (2006) commenced in 2003. (CX1128_0001). According to the protocol, the study was a single-center, three-year study in which approximately 40 patients with prostate cancer treated by radical prostatectomy or radiotherapy with a rising PSA would receive eight ounces of pomegranate juice daily. (CX0666_0004-05).

Response to Finding No. 989:

Respondents have no specific response other than to state the exhibits cited in this proposed finding of fact speak for themselves.

990. By 2006, the Pantuck Phase II Prostate Cancer Study (2006) was complete and ready for publication. Dr. Pantuck first submitted the manuscript for the study to the *Journal of Clinical Oncology*. (CX1341 (Pantuck, Dep. at 107)). It was rejected. (CX1341 (Pantuck, Dep. at 107)). He subsequently submitted it to *Clinical Cancer Research*. (CX1341 (Pantuck, Dep. at 107)). One peer reviewer called the manuscript "excessively advocatory of pomegranate juice as a treatment for prostate cancer." (CX0790_0001). Dr. Pantuck addressed this concern and other comments by making various changes to the manuscript. (CX0790; CX0786). The results of the Pantuck Phase II Prostate Cancer Study (2006) were published in the journal *Clinical Cancer Research* in July 2006. (CX0815).

Response to Finding No. 990:

Respondents add the following explanatory facts to this proposed finding: As Complaint Counsel's own expert, Dr. Eastham, testified, as part of the publishing process, sometimes studies are rejected by journals, comments are considered and edits are made for resubmission to another journal. In fact, Dr. Eastham has had articles he submitted rejected by journals. (Eastham, Dep. at 67-70). Further, the fact that Dr. Pantuck's study was published and survived the rigorous peer review process is significant evidence that the research was scientifically valid. (RFF 1760).

991. Dr. Liker, an author of the Pantuck Phase II Prostate Cancer Study (2006), indicated his academic affiliation with UCLA in the published study article, but did not disclose his affiliation as the Medical Director for Respondents. (Liker, Tr. 1931).

Response to Finding No. 991:

Respondents object to the extent Complaint Counsel insinuate that Dr. Liker's affiliation as the Medical Director for Respondents somehow suggests he is biased or that the study is not a well done, peer-reviewed and published study. Dr. Liker, like every author on the Pantuck Phase II Prostate Cancer Study listed only his academic affiliations as is the common practice. (CX1350 (Liker, Dep. at. 98)).

992. According to the published study report, the Pantuck Phase II Prostate Cancer Study (2006) was "an open-label, single-arm clinical trial," meaning it was not a RCT and did not have a placebo group. (CX0815_0002). The Pantuck Phase II Prostate Cancer Study (2006) included 46 patients who were evaluated for a treatment response. (CX0815_0003). All the patients in the Pantuck Phase II Prostate Cancer Study (2006) had been diagnosed with prostate cancer. (*See* CX0815_0001). The majority of the patients (68%) in the Pantuck Phase II Prostate Cancer Study (2006) had been previously treated for prostate cancer by undergoing radical prostatectomy. (CX0815_0003). The remainder had been treated by radiation (10%), brachytherapy (10%), a combination of surgery and radiation (7%), or cryotherapy (5%). (CX0815_0003).

Response to Finding No. 992:

Respondents have no specific response.

993. All 46 patients drank eight ounces of pomegranate juice daily until meeting disease progression endpoints. (CX0815_0002). Patients had their blood drawn every three months to have their PSA determined. (CX0815_0002). Disease progression was defined as either a greater than 100% increase in PSA (with a minimum value of 1.0 ng/mL) compared with the best response observed or any documentation of metastatic or recurrent disease. (CX0815_0002). The primary endpoint for the Pantuck Phase II Prostate Cancer Study (2006) was the effect on PSA variables, such as change in PSADT. (CX0815_0002). The average pretreatment PSADT before intervention was approximately 15 months, and after 33 months, the average post-treatment PSADT was 54 months. (CX0815_0004).

Response to Finding No. 993:

Respondents have no specific response.

994. The men treated with POM Juice in the study experienced a significant statistical increase in PSADT when compared to their own baseline pre-treatment PSADT. Dr. Pantuck stated in the published report that "[i]t remains controversial whether modulation of PSA levels represents an equally valid clinical endpoint." (CX0815_0008). According to Dr. Pantuck, "PSA has not been validated prospectively as a surrogate endpoint for a meaningful prostate cancer outcome." (CX1080_0001). Dr. Pantuck has stated that "although PSA changes are thought to be prognostically important, it is based on level 2 evidence, and nobody had ever shown conclusively that changes in PSA kinetics arising from therapeutic intervention is meaningful." (CX1080_0001).

Response to Finding No. 994:

Respondents add the following explanatory facts: Dr. Pantuck testified that his study showed evidence that the growth of the cancer had been altered by POM Juice. (CX1341 (Pantuck, Dep. at 119)). Dr. Pantuck's study showed that POM Juice slowed down the growth of prostate tumor cells as expressed by the longer time it took for those tumor cells to double. (deKernion, Tr. 3057). Complaint Counsel's expert, Dr. Meir Stampfer opined that PSADT was a "predictor of disease and mortality" and that, if the extension of PSADT is true, it would substantially prolong lives. (Stampfer, Tr. 869, 873). Complaint Counsel's expert, Dr. Sacks, also testified that if something is considered a surrogate for a particular illness or death (as is PSADT), it necessarily follow that changes in that surrogate predict the likelihood of illness or death. (Sacks, Tr. 1613). Complaint Counsel's expert Dr. Eastham wrote in his article, "Prostate-specific antigen doubling time as a prognostic marker in prostate cancer" that, "PSA doubling time has

emerged as an important factor in the evaluation of men with newly diagnosed prostate cancer or prostate cancer that recurs after treatment. PSA doubling time can be used as a surrogate marker for prostate cancer specific death." (PX0178). Dr. Eastham cites studies showing that "only PSADT was a significant predictor of either systematic progression or local recurrence" of disease, that "PSADT was the strongest predictor of eventual clinical recurrence" and that authors, "suggest that PSADT might serve as a possible surrogate for prostate-cancer-specific death." (PX0178 -0006-0008). In his article, Dr. Eastham concludes that "PSADT is an important prognostic marker in men with biochemical failure after local therapy for prostate cancer, and it predicts the probable response to salvage radiotherapy, progression to metastatic disease and prostate cancer specific death." (PX0178-0009). Dr. deKernion stated that PSA doubling time is used to determine success or failure of prostate cancer treatment and that multiple studies have associated PSA doubling time with not only the risk of clinical recurrence but also death. (PX0161-0004, 0007; deKernion, Tr. 3050-58). Dr. deKernion stated that because PSA doubling time is used as predictive of risk of clinical recurrence and death, it is simply illogical that radical changes to PSADT due to intervention would not be informative of the intervention's effectiveness—particularly when you see such large and statistically significant changes in PSADT following consumption of POM Juice. (PX0161-0007, 0011-0012). Dr. Heber also opined that, "PSA doubling time is an accepted variable by the vast majority of the urological community, including members of the American Urological Association and all the leading experts in prostate cancer research in the United States. This is not in dispute." (Heber, Tr. 2151).

995. Dr. Pantuck stated in the published report that "further research is needed to . . . determine whether improvements in such biomarkers [including PSADT] are likely to serve as surrogates for clinical benefit." (CX0815_0008). He also indicated in the published report that the results of the Pantuck Phase II Prostate Cancer Study (2006) need to be tested further in a randomized, double-blind, placebo-controlled study, in which the ability of pomegranate juice to produce an alteration in PSA kinetics is compared with the change observed in a control group. (CX0815_0008).

Response to Finding No. 995:

Respondents add the following explanatory facts: Dr. Pantuck testified that his study showed evidence that the growth of the cancer had been altered by POM Juice. (CX1341 (Pantuck, Dep. at 119)). Dr. Pantuck's study showed that POM Juice slowed down the growth of prostate tumor cells as expressed by the longer time it took for those tumor cells to double. (deKernion, Tr. 3057). Dr. deKernion stated that it is standard practice among researchers to qualify studies with language such as "further studies are required" regardless of how exciting or ground breaking the results may be. (deKernion, Tr. 3103-04).

996. Dr. Pantuck testified that the greatest limitation of the Pantuck Phase II Prostate Cancer Study (2006) was the lack of a blinded control arm. (CX1341 (Pantuck, Dep. at 110)). In the published study report, Dr. Pantuck specifically pointed to the published study *Rosiglitizone versus Placebo for Men with Prostate Carcinoma and a Rising Serum Prostate-Specific Antigen Level after Radical Prostatectomy and/or Radiation Therapy*, Cancer 2004: 101:1569-74 ("Rosiglitizone Study") as a reason for the need of confirmatory study with a blinded control arm. (CX0815_0008).

Response to Finding No. 996:

Respondents dispute the characterization of portions of this proposed finding. Dr. deKernion testified that the use of a placebo group is more important when you have a subjective reporting as opposed to an objective reporting. (deKernion, Tr. 3059). A control arm is not necessary for an objective Phase II study which is exploratory in nature. (PX0161- 0009). Many studies on food and many other categories in science are observational type studies without use of a control—a control is important when there is a high risk that the observed effect could be attributed to something other than the substance being tested. (deKernion, Tr. 3059-60; PX0351 (deKernion, Dep. at 97-99); PX0161- 0007). A control is often used to control for the placebo effect—in POM's clinical studies on prostate health, the researchers are looking and testing objective blood results—there is no evidence to suggest the placebo effect plays any role in modulating

the PSADT of the subject. (deKernion, Tr. 3059-3060; PX0351 (deKernion, Dep. at 97-99). Dr. Pantuck's study was a Phase II study. Dr. Eastham, Complaint Counsel's own expert, agreed that the Pantuck study as a Phase II study could not be blinded and that blinding was not important in such a study. (Eastham, Tr. 1327).

997. The Rosiglitazone Study was a randomized, double-blind placebo-controlled study examining the effect of rosiglitazone in a population of men similar to the patients studied in the Pantuck Phase II Prostate Cancer Study (2006), namely men who had been treated by radical prostatectomy or radiation with a rising PSA. (PX0172-0001; CX0815_0001; deKernion, Tr. 3069). The Rosiglitazone Study found that 40% of the placebo group and 38% of the treatment group experienced a prolongation in PSADT. (PX0172-0001; deKernion, Tr. 3071). Although the patients in the Rosiglitizone Study had a higher risk of clinical progression than the patients in the Pantuck Phase II Prostate Cancer Study (2006), they still experienced improvement in their PSADT. (deKernion, Tr. 3072-73; PX0172-0004).

Response to Finding No. 997:

Respondents dispute the characterization of the Rosiglitizone study and its comparison with the Pantuck Phase II Prostate Cancer Study (2006). Complaint Counsel's use of the Rosiglitizone study in attempt to argue that there may be a placebo effect in the Pantuck Study is not persuasive. As the authors of the Rosiglitizone study noted, their study had "limitations." The authors state that "baseline PSADT was calculated using PSA values that were determined at irregular intervals, whereas post treatment PSADT was calculated using monthly PSA values. For most patients, baseline PSADT was calculate[ed] using fewer PSA values than the posttreatment PSADT. Differences in the intervals between PSA measurements and the number of PSA values may have contributed to the variability between baseline and post treatment PSADT in the placebo group." Irregular intervals of PSA calculations was not how the Pantuck study was conducted. In the Pantuck Phase II study, "patients were followed in 3-month intervals for serum PSA". (PX00060-0002).

998. The Rosiglitizone Study authors -- including Dr. Kantoff (with whom Respondents consulted and who testified as a rebuttal witness for Complaint Counsel) -- stated that "[t]he discordance between baseline and posttreatment PSADT in our placebo group suggests caution is required when using changes in PSADT as an outcome in

uncontrolled trials and reinforces the value of randomized, placebo-controlled trials in this setting." (PX0172-0006). Dr. Pantuck stated that the Rosiglitazone Study "highlights the potential limitations of PSA variables in monitoring patients and the need for confirmatory prospective studies using a blinded control arm." (CX0815_0008).

Response to Finding No. 998:

Respondents dispute portions of this proposed finding of fact as it mischaracterizes the evidence in the record. Complaint Counsel fail to note that the Rosiglitazone Study authors conclude that, "the current results do not diminish the potential value of changes in PSADT as an outcome variable for the early evaluation of novel therapeutic agents. In randomized studies of similar design, more active agents may demonstrate the value of PSA kinetics as a screen for biologic activity." (PX0172-0006).

It is also notable that Complaint Counsel cite a study that uses PSA doubling time as a surrogate marker in a treatment trial in support of this proposed finding but asserts in other proposed findings that Respondents' science is not competent and reliable in part because of the use of PSA doubling time as a surrogate marker.

999. When the Pantuck Phase II Prostate Cancer Study (2006) report was released in 2006, Dr. Pantuck stated "[w]e don't believe we are curing anyone from prostate cancer." (CX0816_0002). He pointed out that "although a third of patients experienced a decrease in PSA during the study, nobody's PSA went to zero." (CX0816_0002).

Response to Finding No. 999:

Respondents object to this finding of fact as it contains an incomplete quote from Dr. Pantuck. Complaint Counsel neglected to include the remainder of the statement Dr. Pantuck made that was quoted in the American Association for Cancer Research press release, in which he stated: "The PSA doubling time, however, was longer. For many men, this may extend the years after surgery or radiation that they remain recurrence free and their life expectancy is extended. They may be able to prevent the need to undergo additional therapies, such as radiation, hormonal or chemotherapies." (CX0816_0002).

1000. Dr. Pantuck testified that the Pantuck Phase II Prostate Cancer Study (2006) did not prove that pomegranate juice prevents or reduces the risk of prostate cancer. (CX1341 (Pantuck, Dep. at 108)). He also refused to state that the Pantuck Phase II Prostate Cancer Study (2006) proved that pomegranate juice treats prostate cancer. (CX1341 (Pantuck, Dep. at 108)). Instead, Dr. Pantuck summarized the findings of the Pantuck Phase II Prostate Cancer Study (2006) as follows: "pomegranate juice was given to men with prostate cancer, to measure . . . how their PSA levels were affected" and "what [the study] showed is that the doubling time was prolonged." (CX1341 (Pantuck, Dep. at 108)).

Response to Finding No. 1000:

Complaint Counsel's assertion in this proposed finding that Dr. Pantuck "refused to state" whether pomegranate juice treats prostate cancer, is without merit, argumentative, unsupported by the evidence in the record and mischaracterizes Dr. Pantuck's testimony. Dr. Pantuck supported the findings of his study that PSA doubling time was prolonged for men with prostate cancer when they were given pomegranate juice. (CX1341 (Pantuck Dep. at 108)). Dr. Pantuck testified that the study showed evidence that the growth of the cancer had been altered by POM Juice. (CX1341 (Pantuck, Dep. at 119)). Dr. Pantuck's study showed that POM Juice slowed down the growth of prostate tumor cells as expressed by the longer time it took for those tumor cells to double. (deKernion, Tr. 3057). Dr. Pantuck stated that the feedback from the scientific community with regard to the peer-reviewed published Phase II study has primarily been favorable, and that some doctors have discussed the findings with patients. (CX1341 (Pantuck, Dep. at 268)). Dr. Pantuck also stated that there are categories of patients with whom he has discussed the benefits of pomegranate juice. (CX1341 (Pantuck, Dep. at 270-271)). Dr. Pantuck publicly commented, "In older men 65 to 70, who have been treated for prostate cancer, we can give them pomegranate juice and it may be possible for them to outlive their risk of dying from their cancer." He also commented, "The juice seems to be working." (RFF 1918).

1001. In 2008, Dr. Pantuck released the following abstract: Pantuck, AJ, *et al*., *Long term follow up of pomegranate juice for men with prostate cancer and rising PSA shows durable improvement in PSA doubling times*, American Society of Clinical Oncology (2008 Genitourinary Cancers Symposium) ("Pantuck Phase II Follow-Up Results").

(CX0955). The abstract summarized follow-up results for the Pantuck Phase II Prostate Cancer Study (2006). (CX0955). According to the abstract, the mean post-treatment PSADT of the active group (17 men) increased to 68.57 months and in the non-active group to 51.2 months. (CX0955). All of the men who had dropped out of the study did so because their PSA had increased. (CX0918_0001). As of June 2010, only 12 patients remained active in the study. (CX1128_0001).

Response to Finding No. 1001:

Respondents add the following facts to this proposed finding: According to Dr. Pantuck of the men who dropped out not because they met the disease progression criteria but because they decided "to try something else" such as cryotherapy (CX0918_0001).

(4) Expert Analysis

1002. Complaint Counsel's experts testified that the Pantuck Phase II Prostate Cancer Study (2006) fails to provide support for prostate cancer treatment claims for two major reasons: the lack of a placebo control group and the lack of an accepted endpoint marker. (Eastham, Tr. 1295-97; CX1287 (Eastham, Report at 0018-19); CX1293 (Stampfer, Report at 0024-25); Stampfer, Tr. 782-83).

Response to Finding No. 1002:

Complaint Counsel expert's conclusions noted in this proposed finding is without merit and not supported by the evidence in the record. Respondents object to Complaint Counsel's phrase "prostate cancer treatment claims" on the basis that this phrase is vague and ambiguous.

Respondents aver that competent and reliable scientific evidence supports the conclusion that the consumption of pomegranate juice and pomegranate extract supports prostate health, including by prolonging PSA doubling time in men with rising PSA after primary treatment for prostate cancer. Additionally, competent and reliable scientific evidence supports the conclusion that the consumption of pomegranate juice and pomegranate extract supports prostrate health and the conclusion that the same mechanism in the *in vitro* studies, the animal studies and in the Pantuck and Carducci human studies also showed with a high degree of probability that the Challenged Products inhibit the clinical

development of prostate cancer cells in men who have not been diagnosed with prostate cancer. (RFF 1577-1578; 1740-1783; 1919-1922).

1003. According to Dr. Stampfer, without a placebo control group in the Pantuck Phase II Prostate Cancer Study (2006), it is not possible to know whether the same change in PSADT would have been observed in this patient group if they had never received POM Juice. (Stampfer, Tr. 870; CX1293 (Stampfer, Report at 0024)).

Response to Finding No. 1003:

Respondents dispute this proposed finding as contrary to the evidence in the record. Dr. deKernion opines that all "evidence supports that PSA changes including doubling time after failure of definitive therapy truly reflect a change in the tumor cell growth, no evidence exists to suggest that a biochemical effect on PSA measurement can account for changes; and no evidence exists that PSA doubling time significantly and spontaneously lengthens in a patient with known biochemical or clinical cancer." (PX0161-0008). Therefore, in the Pantuck Phase II Prostate Cancer Study it is only logical to conclude that the agent causing the change in PSA doubling time is POM Juice especially given the pre-clinical evidence of the effect of the Challenged Products on prostate cancer, "and the results of these studies could not be explained otherwise." (PX0161-0011-0012).

1004. According to Dr. Eastham, if the Pantuck study had included a control group, it is possible that *no* statistical difference between groups would have been observed. (Eastham, Tr. 1295-97; CX1287 (Eastham, Report at 0018)). Without a placebo, there is no way to eliminate confounding factors that may have impacted PSADT -- such as changes in diet, exercise, or the reduction of stress. (Eastham, Tr. 1295-96).

Response to Finding No. 1004:

Respondents refer to RRFF 1003; RFF 1760-1776.

1005. Respondents' expert, Dr. deKernion, acknowledged during his testimony that the purpose of a placebo control group is to limit confounding factors. (deKernion, Tr. 3066-67). Dr. deKernion agreed with Dr. Eastham that there are variables such as exercise and a low-fat diet which may affect prostate cancer growth and that without a placebo control arm in a clinical study it is impossible to control for confounding factors. (*See* deKernion, Tr. 3067).

Response to Finding No. 1005:

Complaint Counsel mischaracterizes Dr. deKernion's testimony. Dr. deKernion testified that one purpose of a placebo control group is to limit confounding factors. (deKernion, Tr. 3066-67). Dr. deKernion testified that there is evidence that some things affect PSA in patients and the extrapolation is that it affects tumor growth; exercise has been shown to change PSADT in some patients and some research indicates that a low-fat diet can reduce the growth of prostate cancer cells. (deKernion, Tr. 3067). Regarding placebo control arms in clinical studies, Dr. deKernion's position is that a control arm is unnecessary for an objective Phase II study which is exploratory in nature. (RFF 1768). As Dr. deKernion explained, a control is often used to control for the placebo effect, however, in POM's clinical studies on prostate health, the researchers are looking and testing objective blood results and there is no evidence to suggest that the placebo effect plays any role in modulating the subjects' PSADT. (RFF 1767-1770). Dr. deKernion specifically testified that a placebo control arm is not needed when PSADT is the study endpoint to assess the efficacy of the product or therapy being studied. (deKernion, Tr. at 3081).

1006. Dr. deKernion believes that a placebo arm is a good thing for a study when it is feasible. (*See* deKernion, Tr. 3081). He agreed with Dr. Stampfer that it would have been ethical to use a placebo in the Pantuck Phase II Prostate Cancer Study (2006), because there is no "standard of care" for men of the type studied in the Pantuck Phase II Prostate Cancer Study (2006). (Stampfer, Tr. 872; deKernion, Tr. 3083).

Response to Finding No. 1006:

Complaint Counsel mischaracterizes Dr. deKernion's testimony. Dr. deKernion testified that he believes that a blinded control arm is good for any study when it is necessary and/or feasible. (deKernion, Tr. 3081). Dr. deKernion testified that there was no "standard of care" for the population that Dr. Pantuck studied. He also testified that it would be acceptable to give this population a placebo but that providing a placebo in this

type of study can be problematic as patients in the placebo group often want and sometimes seek the treatment that is being tested. (DeKernion, Tr. 3082-83). Dr. Heber also testified similarly; he explained that one of the reasons there was no placebo group in the Pantuck Phase II study was because it is difficult to recruit prostate cancer patients for a placebo arm once they are aware of the benefits of pomegranate juice. (RFF 1771).

1007. Dr. Eastham testified that there is evidence in the scientific literature showing that a patient's PSADT can be prolonged even without treatment. (Eastham, Tr. 1300). Dr. Eastham and Dr. deKernion testified that both the treatment and placebo groups in the Rosiglitazone Study (CCFF ¶¶ 997-98) experienced a lengthening of PSADT. (Eastham, Tr. 1299-1300; CX1287 (Eastham, Report at 0018); deKernion, Tr. 3071). Dr. Eastham and Dr. deKernion testified that another randomized, double-blind, placebo-controlled study examining the effect of celecoxib (an anti-inflammatory drug) on prostate cancer in a patient population similar to that of the Pantuck Phase II Prostate Cancer Study (2006) also found that men in both the treatment and placebo groups experienced a lengthening in PSADT. (Eastham, Tr. 1300; deKernion, Tr. 3071).

Response to Finding No. 1007:

Respondents dispute portions of this proposed findings as unsupported by the evidence. Dr. deKernion stated that, "no evidence exists to suggest that a biochemical effect on PSA measurement can account for changes; and no evidence exists that PSA doubling time significantly and spontaneously lengthens in a patient with known biochemical or clinical cancer." (PX0161-0008).

1008. At trial, Dr. Heber argued that it is not possible to conduct a placebo-controlled study because PSA is so variable. (Heber, Tr. 2150-51). However, Dr. Heber is not an expert in the clinical treatment of prostate cancer. (Heber, Tr. 2034-35). His view strains credulity because he co-authored the Pantuck Phase II Prostate Cancer Study (2006) report, which stated that a confirmatory study with a blinded control arm was needed. (CX0815_0008). In addition, Dr. Pantuck consulted with Dr. Heber when designing the protocol for the Pantuck Phase III Study (*see* CCFF ¶ 3.1026), which includes a placebo control group. (CX1341 (Pantuck, Dep. at 44-46); *see also* CX0740).

Response to Finding No. 1008:

Respondents object to this finding of fact on the basis that it is argumentative and conclusory and mischaracterizes Dr. Heber's testimony. Dr. Heber testified that he could not speculate on what would have happened to the PSA levels in a placebo group if such

a group had been used in the Pantuck Study because the level of rate of rise in patients with prostate cancer of their PSA after primary treatment is highly variable, and it would have been impossible to recruit matched groups for a placebo and control; therefore, in this study, each patient established a rate of rise of PSA prior to recruitment into the study, and then that individual's course of rise of PSA was subsequently followed. (Heber, Tr. 2150-51). Dr. Heber also testified that this methodology is standard in urological research, and that PSADT is an accepted variable by the vast majority of the urological community. (Heber, Tr. 2150-51). Dr. deKernion testified that the use of a placebo group is more important when you have a subjective reporting as opposed to an objective reporting. (RFF 1767) (deKernion, Tr. 3059). A control arm is not necessary for an objective Phase II study which is exploratory in nature. Many studies on food and many other categories in science are observational type studies without use of a control—a control is important when there is a high risk that the observed effect could be attributed to something other than the substance being tested. (RFF 1768). A control is often used to control for the placebo effect—in POM's clinical studies on prostate health, the researchers are looking and testing objective blood results—there is no evidence to suggest the placebo effect plays any role in modulating the PSADT of the subject. (RFF 1769).

Furthermore, even Dr. Eastham agreed that the Pantuck study as a Phase II study could not be blinded and that blinding would not even be important in such a study. (RFF 1828).

1009. Another issue in weighing the assessment of benefit for POM Juice observed in the Pantuck Phase II Prostate Cancer Study (2006) is the patient population studied. The average pretreatment PSADT for the study participants in the Pantuck Phase II Prostate Cancer Study (2006) was 15 months. (CX0815_0001). These patients are considered to have a far lower risk of clinical progression and thus, it is unclear whether the increase in PSADT observed in the Pantuck Phase II Prostate Cancer Study (2006) is clinically significant. (Eastham, Tr. 1297-98; Stampfer, Tr. 785; *see also* CX1287 (Eastham, Report at 0019); CX1293 (Stampfer, Report at 0026); PX0351 (deKernion, Dep. at 94)).

Response to Finding No. 1009:

Respondents dispute portions of this proposed finding as it its contrary to the evidence in the record. From a patient and patient care standpoint, PSADT is clinically significant. The presence of detectable PSA after radical prostatectomy or other radical treatment usually indicates cancer is present. (deKernion, Tr. 3051). PSADT provides an expression of how those tumor cells are going to behave. (deKernion, Tr. 3051-52). The longer the PSADT, the less dangerous the growth of the cancer. (deKernion, Tr. 3052). Dr. deKernion opined that, "even a slow-growing cancer can occasionally become clinically significant, and prompt toxic intervention such as hormonal or chemotherapy. Further, knowledge that one's tumor is growing has significant impact on quality of life. Given that return of measurable PSA after expected curative treatment does indeed mean the return of cancer (and that has never been disputed) and that changes in the PSA do indeed reflect growth of the tumor, citizens with this problem appreciate the opportunity to have access to low-toxicity, non-traditional methods of treatment." (PX0161-0010). Dr. deKernion stated that level of comfort, quality of life, avoidance of more drastic invasive and potentially complicated treatments, all are very important and PSADT serves as a good marker in addressing these issues. (PX0161-0010; deKernion Tr. 3065). Dr. Pantuck stated that PSADT is clinically important for prostate cancer treatment and one of the most important variables that characterizes a prostate cancer patient. (CX1341 (Pantuck, Dep. at 254-255)). Dr. Pantuck stated that from a patient care standpoint, PSA doubling time is extremely important. (CX1341 (Pantuck, Dep. at 255)). Dr. Carducci testified that the potential benefits from a clinical or patient point of view of extending PSADT include delaying more aggressive therapy and living longer. (CX1340 (Carducci, Dep. at 182)).

1010. Also, the Pantuck Phase II Prostate Cancer Study (2006) was designed as a treatment study (*i.e.*, study was conducted in men with prostate cancer) and does not provide any evidence that POM Juice is a prostate cancer preventative. (CX1293 (Stampfer, Report at 0025); Eastham, Tr. 1294-99). Complaint Counsel's and Respondents' experts agree

that Respondents have not conducted a prevention clinical study on prostate cancer. (CX1287 (Eastham, Report at 0025); CX1293 (Stampfer, Report at 0025); *see also* deKernion, Tr. 3062-63). More importantly, Respondents acknowledge that they have "no data on prostate cancer prevention, prior to radiation or prostatectomy." (CX1029_ 0004).

Response to Finding No. 1010:

Complaint Counsel misrepresent evidence and mischaracterize testimony in portions of this proposed finding. Dr. deKernion testified that in order to show an effect of POM Juice and POMx on cancer, the best way to do that research is on patients whose prostate had been removed because the presence of PSA elevation is almost always indication of remaining cancer. This is how the Pantuck and Carducci studies were conducted. (deKernion, Tr. 3057). Dr. deKernion testified that the study population of Dr. Pantuck and Dr. Carducci's studies were people who should have been cured of prostate cancer except their PSA was detectable, which indicated they had microscopic cancer. (deKernion, Tr. 3057). In each of the studies, they then treated the subjects with POM Juice (Pantuck study) or POMx (Carducci study), and showed that it slowed down the growth of the tumor cells as expressed by the longer time it took for those tumor cells to double. (deKernion, Tr. 3057). Dr. deKernion opined that, while such things could never be subject to 100% proof, the same mechanism shown in the *in vitro* and animal studies and in the Pantuck and Carducci human studies also showed, with a "high degree of probability" that POM Juice and POMx would inhibit the clinical development of prostate cancer in men who have not been diagnosed with that disease. (deKernion, Tr. 3119-20). Dr. deKernion opined that in healthy men, who have never been diagnosed with prostate cancer POM Juice and POMx could possibly play a role in preventing them from getting prostate cancer. (PX0351 (deKernion, Dep. at 76-77)). Dr. Heber also testified that there is competent and reliable science showing that POMx and POM Juice are likely to lower the risk of prostate problems for men who have not yet been diagnosed with prostate cancer. (Heber, Tr. 2012-13). Dr. deKernion stated that the data has shown

that the POM products and especially specific polyphenols have an impact on the inflammatory half-ways in the prostate and that is evidence that it could prevent prostate cancer. (PX0351 (deKernion, Dep. at 76-77). In Dr. Miller's expert opinion, it is more likely than not, if POM Wonderful is effective in men with biochemical recurrence, it may prevent prostate cancer in an otherwise healthy but at risk individual. (PX0206-0012). Dr. Heber stated that he would not exclude from the realm of possibility that, based on scientific evidence, that pomegranate ellagitannins in a supplement or juice form could contribute to the prevention of prostate cancer. (CX1352 (Heber, Dep. at 329)). Dr. Heber further opined that, "there's a significant body of scientific evidence to indicate that both pomegranate fruit juice and pomegranate extract can help to prevent or reduce the risk or help to treat prostate cancer." (Heber, Tr. 2156).

Further, Compliant Counsel's reliance on CX1029_0004 to support this proposed finding is misplaced. Complaint Counsel erroneously point to POM's Medical Research Portfolio Review, unaccompanied by any deposition or trial testimony from its authors, as knowledge in their words that POM lacked evidence on prostate cancer prevention.

At trial, Matt Tupper explained that this statement does not accurately assess POM's prostate research and, despite the fact of having sponsored research involving men diagnosed or treated for prostate cancer, "when you include the *in vitro* and the preclinical animal studies as well as the general understanding of the biology of the prostate" the research does "speak to the reduction of risk of the disease, which in men who have not yet been diagnosed could be relevant as well." (Tupper, Tr. 995).

1011. Complaint Counsel's experts also state that the Pantuck Phase II Prostate Cancer Study (2006) on POM Juice cannot provide reliable evidence to support claims about POMx Pills' or POMx Liquid's benefit for prostate cancer. (Eastham, Tr. 1306; CX1293 (Stampfer, Report at 0025); CX1287 (Eastham, Report at 0020)). According to Dr. Eastham, POM Juice is not identical to POMx Pills and POMx Liquid. (CX1287 (Eastham, Report at 0020)). POM Juice has more than one active ingredient. Processing may result in eliminating a needed ingredient. (Eastham, Tr. 1306-07). Even if the active ingredient is known and the alternate compound contains the same amount of active ingredient, the alternate compound may contain some other as yet unknown

compound that might counter-act the benefit of the active agent. (CX1287 (Eastham, Report at 0020)).

Response to Finding No. 1011:

Dr. Eastham is not an expert in bioavailability. Dr. Eastham did not review any of the equivalency studies or articles on POM Juice, POMx Pills or POMx Liquid. (PX0358 (Eastham, Dep. at 94)). Respondents have established that POM Juice, POMx Pills and POMx Liquid are equivalent in providing health benefits to humans and that POMx Pills and POMx Liquid have equivalent bioavailability as POM Juice. (RFF 920, 921). Dr. Heber testified that animal studies indicated that effect of pomegranate juice and POMx Pills on prostate cancer are equivalent. (RFF 922). Further, Dr. Carducci's study, "Safety and efficacy of POMx in men with prostate cancer: an 18-month, randomized, double-blind, dose-finding study of the effects of two (2) doses of pomegranate juice extract capsules (1 or 3 capsules/day) on rising prostate specific antigen levels in men following initial therapy for prostate cancer," obtained a similar result when studying the effect of POMx on PSADT as obtained in Dr. Pantuck's Phase II Study. (RFF 923). Also, Dr. Eastham admitted that Dr. Pantuck's Phase II study was well-designed and was a good study. (RFF 1829-1830).

1012. Finally, Dr. Eastham concluded that the Pantuck Phase II Follow-up Results did not provide support for prostate cancer prevention and treatment claims because the results flow from the original Pantuck Phase II Prostate Cancer Study (2006) and suffer from the same flaws, namely, there was no placebo and PSADT is not accepted as a surrogate endpoint. (CX1287 (Eastham, Report at 0020-21); Eastham, Tr. 1304-05).

Response to Finding No. 1012:

Respondents dispute this finding of fact as contrary to the evidence in the record. Dr. Eastham testified that the Pantuck Phase II study was "very good Phase II study". (Eastham, Tr. 1305). Dr. Eastham also agreed that the Pantuck study as a Phase II study could not be blinded and that blinding would not even be important in such a study. (RFF 1828). Further, numerous published studies have demonstrated the now

widespread acceptance of PSADT as a valid surrogage and predictor of disease and health. (*See generally* RFF 1841-1855 ("Prostate-specific antigen doubling time is an independent predictor of clinical disease recurrence and mortality after surgical biochemical failure." (PX0166)). PSADT can help risk stratify patients for prostate cancer-specie mortality following biochemical recurrence after radical prostatectomy. (PX0165). Further, Complaint Counsel's own expert acknowledged PSADT as a legitimate surrogate marker for prostate cancer specific death. Specifically, Dr. Eastham admitted that PSADT is "an important factor in the evaluation of men with newly diagnosed prostate cancer or prostate cancer that recurs after treatment" and that PSADT can be used as a surrogate marker for prostate cancer specific death. (PX0178).

Respondents aver that competent and reliable scientific evidence supports the conclusion that the consumption of pomegranate juice and pomegranate extract supports prostrate health and the conclusion that the same mechanism in the *in vitro* studies, the animal studies and in the Pantuck and Carducci human studies also showed with a "high degree of probability" that the Challenged Products inhibit the clinical development of prostate cancer cells in men who have not been diagnosed with prostate cancer. (RFF 1577-1578).

b. Carducci Dose Study

(5) About the Study

1013. Respondents have also sponsored a human study looking at POMx use in men who have already been treated for prostate cancer. The study is completed and an abstract summarizing the results has been published. *See* M.A. Carducci, et al., *A Phase II Study of Pomegranate Extract for Men with Rising Prostate-Specific Antigen Following Primary Therapy* ("Carducci Dose Study"), J Clin Oncol 29: 2011 (suppl 7; abstr 11). (PX0175; *see also* CX1174). A final, peer-reviewed study report has not been published, however. (*See* Nonparties Johns Hopkins University and Michael A. Carducci, M.D.'s Motion for *In Camera* Treatment, at 5).[4] The Carducci Dose Study was conducted by Dr. Carducci, a urologist and oncologist at Johns Hopkins University in Baltimore, Maryland. (CX1120). It cost at least $97,000 to conduct. (CX1138_0003).

[4] http://www.ftc.gov/os/adjpro/d9344/110420hopkinscarduccimoincam.pdf

Response to Finding No. 1013:

Respondents have no specific response other than that portions of this proposed finding is partially unsupported by the evidence. Specifically, the $97,000 referenced in this proposed finding is in reference to the Carducci Phase III Study not the Carducci Phase II Study as noted in the proposed finding. (CX1138_0003).

1014. In 2006, Dr. Michael A. Carducci began working with Respondents to design the Carducci Dose Study. (CX0806).

(CX0064_0002, *in camera*).

(CX0064_0002, *in camera*).

Response to Finding No. 1014:

1015. Dr. Carducci submitted a proposed protocol for the Carducci Dose Study to Respondents for a larger randomized study with a placebo arm. (CX1340 (Carducci, Dep. at 28-29)). Respondents conducted a feasibility and cost analysis and decided that the study proposed by Dr. Carducci was too costly. The placebo arm was dropped from the study. (CX1340 (Carducci, Dep. at 28-29)).

Response to Finding No. 1015:

Respondents add the following explanatory facts: Dr. Carducci testified that the placebo arm was dropped in part due to poor patience acceptance of a placebo. Dr. Carducci stated that "people don't necessarily want to go on placebo, enough information out there that patients, you know, reading a consent form think this is going to help and don't want to be randomized to a placebo." (CX1340 (Carducci, Dep. at 29-30)). In addition, Dr. deKernion testified that the use of a placebo group is more important when you have a

subjective reporting as opposed to an objective reporting. (RFF 1767) (deKernion, Tr. 3059). A control arm is not necessary for an objective Phase II study which is exploratory in nature. Many studies on food and many other categories in science are observational type studies without use of a control—a control is important when there is a high risk that the observed effect could be attributed to something other than the substance being tested. (RFF 1768). A control is often used to control for the placebo effect—in POM's clinical studies on prostate health, the researchers are looking and testing objective blood results—there is no evidence to suggest the placebo effect plays any role in modulating the PSADT of the subject. (RFF 1769).

1016. In 2007, Dr. Carducci approached Dr. Kessler, a consultant to Respondents, to discuss the Carducci Dose Study design and to lobby for the original placebo-controlled study. (CX1340 (Carducci, Dep. at 36-38)). Dr. Carducci approached Dr. Kessler because "it was [his] sense that [Kessler] was a more effective counsel to POM and what decisions they were making." (CX1340 (Carducci, Dep. at 38)). Despite his appeal to Dr. Kessler, Respondents did not approve a placebo arm and Dr. Carducci proceeded to conduct the study with no placebo arm. (CX1340 (Carducci, Dep. at 38)). Dr. Liker testified that decisions about the size of a study are "more of a business decision than a scientific decision." (CX1350 (Liker, Dep. at 188-89)).

Response to Finding No. 1016:

Respondents have no specific response other than the characterization of events depicted in this proposed finding as unsupported by the evidence in the record.

1017. The Carducci Dose Study commenced in January 2008. (CX1138_0002). According to the protocol, the Carducci Dose Study was an 18-month, multi-center, randomized, double-blind, dose-finding study of the effect of two doses of POMx capsules (1 or 3 capsules) on PSADT in men who had received initial therapy for prostate cancer. (CX1110_0007).
(*See* CX1088, *in camera*; CX1102, *in camera*).
(CX1146, *in camera*).

Response to Finding No. 1017:

Respondents have no specific response.

1018. Dr. Carducci testified that without a placebo, he cannot be sure that the effect on PSADT observed in the Carducci Dose Study is attributable to POMx. (CX1340 (Carducci, Dep. at 95); *see also* CX1175_0002 (article stating "Dr. Carducci acknowledged that the study

was limited by the lack of placebo, and that a number of reports in literature . . . have shown that placebo can slow PSADT"). According to Dr. Carducci, the Carducci Dose Study was never designed to prove that POMx prevents, reduces the risk of, or treats prostate cancer. (CX1340 (Carducci, Dep. at 87-88)).

Response to Finding No. 1018:

Complaint Counsel mischaracterizes portions of Dr. Carducci's testimony in this proposed finding of fact. Dr. Carducci testified that the use of PSA doubling time as a primary endpoint to determine if POMx has an effect on the disease was scientifically valid. (CX1340 (Carducci, Dep. at 181-182)). He stated that his study was not designed to use endpoints that were "drug-like" but specifically designed for a natural product. (CX1340 (Carducci, Dep. at 50-51)). Dr. Carducci stated that researchers were looking at safety and whether POMx had an effect on rising PSA. (CX1340 (Carducci, Dep. at 51)). He confirmed that the study results as designed and planned were statistically significant. (CX1340 (Carducci, Dep. at 183)). The clinical trial showed that POMx treatment significantly increased the PSA doubling time by over 6 months in both treatment arms. (PX0175). Dr. Carducci's study showed that POMx slowed down the growth of prostate tumor cells as expressed by the longer time it took for those tumor cells to double. (deKernion, Tr. 3057). Further, when asked whether his study showed that POMx was a treatment for prostate cancer Dr. Carducci responded, "it did." (CX1340 (Carducci, Dep. at 87)).

1019. Dr. Carducci presented an abstract summarizing the Carducci Dose Study findings in February 2011 at the American Society of Clinical Oncology ("ASCO") Genitourinary Cancers Symposium. (PX0175; CX1175_0001; *see also* CX1174). According to the abstract, one-hundred and four (104) men were enrolled and treated for up to six (92%), 12 (70%) and 18 months (36%). There was no significant treatment difference (p=.920) in PSADT between the one capsule and three capsule dose groups. Median PSADT lengthened from 11.9 months at baseline to 18.5 months after treatment (p<.001), a within group measurement. (PX0175; CX1174_0001).

Response to Finding No. 1019:

Respondents have no specific response.

1020.

(CX1145_0001, *in camera*).

Response to Finding No. 1020:

Respondents dispute this proposed finding as mischaracterizing the evidence. Respondents believe the exhibit cited in this proposed finding speaks for itself. Further, as Dr. Heber testified in any scientific study nothing works 100 percent of the time in a 100 percent of the people. (PX0353 (Heber, Dep. at 171). In clinical studies there are often different responses in different people, therefore for the fact that not 100 percent of the people had a decline in PSADT does not diminish the statistical significant prolongation of PSADT by both treatment arms in Dr. Carducci's Study. (PX0353 (Heber, Dep. at 171); PX0175).

1021. According to a published report of the symposium, invited discussant Dr. Michael J. Morris of Memorial Sloan-Kettering Cancer Center reportedly said that the study's endpoint (PSADT) has never been prospectively validated to show anything in terms of clinical outcome. (CX1175_001). Dr. Morris further stated, "[i]f you believe that prolonged PSA doubling time is clinically beneficial, what do we say about patients whose disease appears to *accelerate* as a result of taking the pomegranate extract . . . . Do we say or suggest that a third to 40% of patients might be done some harm . . . ? I don't know, but I think that's an issue of concern." (CX1175_0001 (emphasis added)).

Response to Finding No. 1021:

Respondents object to Complaint Counsel's proposed finding as vague, ambiguous, incomplete, and hearsay lacking any exception. Respondents dispute this proposed finding and refer to the published abstract for an accurate description of the Carducci Study Results. (PX0175). Further, as Dr. Heber testified in any scientific study nothing works 100 percent of the time in a 100 percent of the people. (PX0353 (Heber, Dep. at 171). In clinical studies there are often different responses in different people, therefore for the fact that not 100 percent of the people had a decline in PSADT does not diminish

the statistical significant prolongation of PSADT by both treatment arms in Dr. Carducci's Study. (PX0353 (Heber, Dep. at 171); PX0175).

(6) Expert Analysis

1022. The Carducci Dose Study evaluated the effect of POMx in men who had prostate cancer. (PX0175; CX1174_0001). As a result, the Carducci Dose Study cannot provide support for prevention claims. (Eastham, Tr. 1309-10; *see also* CX1293 (Stampfer, Report at 27)).

Response to Finding No. 1022:

Respondents dispute this proposed finding as contrary to the evidence in the record. Dr. deKernion testified that in order to show an effect of POM on cancer, the best way to do that research is on patients whose prostate had been removed because the presence of PSA elevation is almost always indication of remaining cancer. This is how Dr. Carducci's study was conducted. (RFF 1761).

Dr. deKernion also opined that, while such things could never be subject to 100% proof, the same mechanism shown in the *in vitro* and animal studies and in the Pantuck and Carducci human studies also showed, with a "high degree of probability" that POM and POMx would inhibit the clinical development of prostate cancer in men who have not been diagnosed with that disease. (RFF 1777). Dr. Heber also testified that there is competent and reliable science showing that POMx and POM are likely to lower the risk of prostate problems for men who have not yet been diagnosed with prostate cancer. (RFF 1779).

1023. Complaint Counsel's experts stated that the Carducci Dose Study cannot provide support for treatment claims because it lacked a placebo-control group. (Eastham, Tr. 1310; Stampfer, Tr. 789-90). Without a placebo-control group, it is not possible to conclude that POMx caused the change in the patients' PSADT. (Eastham, Tr. 1310; CX1287 (Eastham, Report at 0022); Stampfer, Tr. 789-90; CX1293 (Stampfer, Report at 0028)).

Response to Finding No. 1023:

Respondents dispute this proposed finding as contrary to the evidence in the record. First, Respondents deny making any "treatment claims." Secondly, Dr. Carducci's clinical trial showed that POMx treatment significantly increased the PSA doubling time by over 6 months in both treatment arms. (PX0175). Dr. Carducci's study showed that POMx slowed down the growth of prostate tumor cells as expressed by the longer time it took for those tumor cells to double. (deKernion, Tr. 3057). The researchers measured the doubling time before patients took POM Juice or POMx and then measured doubling time afterwards comparing one to the other. (RFF 1765). This was done in lieu of a separate placebo group. (RFF 1766). Dr. deKernion testified that the use of a placebo group is more important when you have a subjective reporting as opposed to an objective reporting. (RFF 1767). Further, when asked whether his study showed that POMx was a treatment for prostate cancer Dr. Carducci responded, "it did." (CX1340 (Carducci, Dep. at 87)).]

1024. Complaint Counsel's experts also stated that the Carducci Dose Study cannot provide support for treatment claims because the primary endpoint in the study is PSADT, which has not been accepted by experts in the field as a surrogate for overall survival. (Eastham, Tr. 1310; CX1287 (Eastham, Report at 0022); CX1293 (Stampfer, Report at 0028)).

Response to Finding No. 1024:

Respondents dispute this proposed finding as contrary to the evidence in the record. Respondents have not made any "treatment claims". Additionally, Complaint Counsel mischaracterizes portions of Dr. Carducci's testimony. Dr. Carducci testified that the use of PSA doubling time as a primary endpoint to determine if POMx has an effect on the disease was scientifically valid. (CX1340 (Carducci, Dep. at 181-182)). He stated that his study was not designed to use endpoints that were "drug-like" but specifically designed for a natural product. (CX1340 (Carducci, Dep. at 50-51)). Dr. Carducci stated

that researchers were looking at safety and whether POMx had an effect on rising PSA. (CX1340 (Carducci, Dep. at 51)). He confirmed that the study results as designed and planned were statistically significant. (CX1340 (Carducci, Dep. at 183)). The clinical trial showed that POMx treatment significantly increased the PSA doubling time by over 6 months in both treatment arms. (PX0175). Dr. Carducci's study showed that POMx slowed down the growth of prostate tumor cells as expressed by the longer time it took for those tumor cells to double. (deKernion, Tr. 3057). Further, when asked whether his study showed that POMx was a treatment for prostate cancer Dr. Carducci responded, "It did." (CX1340 (Carducci, Dep. at 87)).

1025. As previously noted, the Carducci Dose Study was designed as a "dose finding" study, but in fact showed no difference between a one pill and three pill dose. (*See* CCFF ¶ (1)1019). The lack of a dose response despite a three-fold difference in dosage does not support a causal relationship between POMx and change in PSADT. (Stampfer, Tr. 789; CX1293 (Stampfer, Report at 0028)).

Response to Finding No. 1025:

Respondents dispute this proposed finding as contrary to the evidence in the record. Dr. Carducci's clinical trial showed that POMx significantly increased the PSA doubling time by over 6 months in both treatment arms. (PX0175). Dr. Carducci's study confirmed slowing of PSADT after treatment with POMx as was found with POM Juice in Dr. Pantuck's study. (PX0175; CX1340 (Carducci, Dep. at 178)). Dr. Carducci's study showed that POMx slowed down the growth of prostate tumor cells as expressed by the longer time it took for those tumor cells to double. (deKernion, Tr. 3057).

3. Respondents' Ongoing Prostate Cancer Research

1026.

Response to Finding No. 1026:

1027. Because of the time it took to fully enroll the study, a Data Safety Monitoring Board ("DSMB") at UCLA was established for the Pantuck Phase III Study sometime in 2009. (CX1097_0001; CX1350 (Liker Dep. at 239-40); JX0003 ¶ A.6). The DSMB was established to avoid sponsor bias and maintain study integrity for analysis purposes. (CX1094_0001). It is an independent group of individuals charged with reviewing the blinded data to ensure that it is safe to continue with a study. (CX1349 (Gillespie, Dep. at 164)).

Response to Finding No. 1027:

Respondents add the following facts to Complaint Counsel's proposed finding. Dr. Liker testified that, "one of the challenges in doing a placebo-controlled study, when data has already been published suggesting that pomegranate juice is beneficial to men with rising PSA, is actually putting the patients into the study. So the study took a lot longer to enroll than was anticipated. As such, I believe it was Dr. Pantuck's suggestion that we put together a data monitoring safety board. (CX1350 (Liker, Dep. at 239).

A Data Safety Monitoring Board is an, "independent group that looks at the data without the investigators knowing, without the sponsors or the patients knowing anything about

their deliberations, to make sure primarily that there is no harm being done to the patients." (CX1350 (Liker, Dep. at 239).

1028.

Response to Finding No. 1028:

1029.

Response to Finding No. 1029:

Respondents have no specific response.

1030.

Response to Finding No. 1030:

Respondents have no specific response.

1031.

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Response to Finding No. 1031:

1032.

Response to Finding No. 1032:

Respondents have no specific response.

1033. The Pre-Surgical Study commenced in 2008 and patient enrollment stopped in May 2009 when the Johns Hopkins IRB determined that an IND (investigational new drug application) was needed to conduct the study. (CX1138_0002; CX1340 (Carducci, Dep. at 169-70)). An IND is one of the applications submitted to the FDA in the development cycle of a drug. (CX1377 (Gillespie, OS Dep. at 42-44)).

Response to Finding No. 1033:

Respondents dispute the characterization of portions of this proposed finding. The purpose of an IRB is to review protocols and factors associated with a study and to ensure the safety of the study participants--not to regulate advertising claims. (Dreher, Tr. 578). IRBs have in the past requested that POM file an IND with the FDA because of the science, i.e., the study design and protocols—not because of POM's advertising. When the IRB looks at the study's endpoints, and it sees that it is measuring effects on a cancer population of participants, for example, it (and/or the FDA) will sometimes request an IND to further ensure the safety of the conduct of the study, regardless of the actual safety of the product. (CX1066-0002). Contrary to Complaint Counsel's outrageously false suggestion that POM refused to comply with FDA requirements until forced to, POM responded appropriately to these requests indicating that, despite the study design, the product was not an "unsafe" drug. Moreover, all of the IRBs except for the IRB at Johns Hopkins University were satisfied with POM's response and did not require that an INDA be filed. (CX1340 (Carducci, Dep. at 179-80)).

1034. Johns Hopkins told Respondents that it would shut down the Pre-Surgical Study and the Carducci Dose Study unless they agreed to file an IND. (CX1350 (Liker, Dep. at 249-50; CX1340 (Carducci, Dep. at 157-60)). Respondents committed to filing an IND in order to keep their studies open. (CX1081_0003). Data from the Pre-Surgical Study were not available when fact discovery closed in February 2011. (*See* CX1340 (Carducci, Dep. at 27-28) (Dr. Carducci testifying that data may be available in March or April 2011)).

Response to Finding No. 1034:

Respondents refer to RRFF 1033.

4. Analysis of the Challenged Prostate Cancer Claims in Light of the Scientific Evidence

1035. Respondents advertised that drinking eight ounces of POM Juice or taking one POMx Pill or one teaspoon of POMx Liquid daily is not only effective in treating, preventing or reducing the risk of prostate cancer, including by prolonging PSADT, but that their research establishes that its products are effective for these purposes. (*See supra* Sections V.D.2, V.D.4, V.E, V.F).

Response to Finding No. 1035:

Respondents dispute this proposed finding of fact as Complaint Counsel's entire proposition is wholly without merit and unsupported by the record evidence. Respondents have not made the claim that the Challenged Products treats, prevent, or reduce the risk of prostate cancer nor have Respondents made the claim that the research on the Challenged Products in their words "establishes that its products are effective for these purposes." (*See* Infra; *See also* Appendix of Advertisements and Reply Ad Appendix).

1036. Respondents' substantiation for these claims at the time they were made consisted of sponsored *in vitro* and animal studies and the Pantuck Phase II Prostate Cancer Study (2006) (which was not placebo controlled and did not use a validated endpoint). (*See, e.g.,* CCFF ¶ 373) (Mrs. Resnick testifying that basis for prostate claim was Pantuck's study and the basic science).

Response to Finding No. 1036:

Respondents object to this proposed finding of fact as vague and ambiguous as to the meaning of "these claims" which this proposed finding refers. To the extent that Complaint Counsel asserts that respondents made treat, prevent, or reduce the risk of prostate cancer claims in its advertisements Respondents deny making any such claims.

Respondents aver that competent and reliable scientific evidence supports the conclusion that the consumption of pomegranate juice and pomegranate extract supports prostrate health and the conclusion that the same mechanism in the *in vitro* studies, the animal studies and in the Pantuck and Carducci human studies also showed with a high degree of probability that the Challenged Products inhibit the clinical development of prostate cancer cells in men who have not been diagnosed with prostate cancer. (RFF 1577-1578; 1740-1783; 1919-1922).

b. Expert Analysis

1037. Based upon their review of the totality of the evidence, Complaint Counsel's experts stated that there is not enough valid scientific evidence to claim that drinking eight ounces of POM Juice or taking one POMx Pill or one teaspoon of POMx Liquid daily is

effective in treating, preventing or reducing the risk of cancer, including by prolonging PSADT, and certainly no clinical studies, research and/or trials establish these claimed benefits. (CX1287 (Eastham, Report at 0024-26); Stampfer, Tr. 790-91; CX1293 (Stampfer, Report at 0029-30); *see also* Eastham, Tr. 1317-19)).

Response to Finding No. 1037:

Respondents have no specific response other than to state that Complaint Counsel expert's opinion noted in this proposed finding is without merit and not supported by the evidence in the record. Additionally, Respondents have not made the claim that the Challenged Products treats, prevents, or reduces the risk of cancer. (See Appendix of Advertisements). To the extent that a reduce the risk claim can be implied, it is reduce the risk the way a healthy diet and exercise reduces the risk of disease. Notwithstanding, Respondents research on the Challenged Products constitutes competent and reliable scientific evidence in support of prostate health. Respondents' research has involved *in vitro*, animal studies and successful human clinical trials all showing prostate health benefits. (PX0065; PX0068; PX0069; PX0070; PX0071; PX0060; PX0061; PX0175).

1038. Agreeing with Complaint Counsel's experts, Dr. deKernion testified that there is no clinical study, research, or trial proving that POM Juice, POMx Pills, or POMx Liquid treats, prevents or reduces the risk of prostate cancer. (deKernion, Tr. 3062-63; *see also* PX0161 (deKernion, Report at 0011)).

Response to Finding No. 1038:

Respondents dispute this proposed finding as contrary to the evidence in the record as Complaint Counsel mischaracterize the testimony of Dr. deKernion. Dr. deKernion opined that, while such things could never be subject to 100% proof, the same mechanism shown in the *in vitro* and animal studies and in the Pantuck and Carducci human studies also showed, with a "high degree of probability" that POM and POMx would inhibit the clinical development of prostate cancer in men who have not been diagnosed with that disease. (deKernion, Tr. 3119-20). Dr. deKernion opined that in healthy men, who have never been diagnosed with prostate cancer POM could possibly

play a role in preventing them from getting prostate cancer. (PX0351 (deKernion, Dep. at 76-77)). Dr. deKernion stated that the data has shown that the POM products and especially specific polyphenols have an impact on the inflammatory pathways in the prostate and that is evidence that it could prevent prostate cancer. (PX0351 (deKernion, Dep. at 76-77). Dr. deKernion states in his expert report that the effect of the Challenged Products, "on a patient's tumor cells, as reflected by changes in the PSA doubling time, support the claim that POM affects prostate cancer and is a reasonable adjunct for a patient who wishes to help their general health and help avoid a clinical recurrence of prostate cancer." (PX0161 (deKernion, Report at 0011-0012)).

1039. Dr. Pantuck testified at his deposition that the current level of scientific evidence would not support a public health statement that everyone should drink pomegranate juice. (CX1341 (Pantuck, Dep. at 273); *see also* CX0063). According to Dr. Pantuck, pomegranate juice is not the standard of care for prostate cancer. (CX1341 (Pantuck, Dep. at 270-71)). He would not recommend pomegranate juice to patients with end stage cancer that are refractory to hormones, and to chemotherapy, and having bone pain. (CX1341 (Pantuck, Dep. at 269-70)).

Response to Finding No. 1039:

Respondents have no specific response other than to add that in connection with his follow-up research to his 2006 study, Dr. Pantuck publicly remarked that the increase in doubling time from 15 to 54 months was a "big increase." He said that he was "surprised to see such an improvement in PSA numbers." He also contributed, "In older men 65 to 70, who have been treated for prostate cancer, we can give them pomegranate juice and it may be possible for them to outlive their risk of dying from their cancer." He also commented, "The juice seems to be working." (PX0428_0001; CX1341 (Pantuck, Dep. at 270-271); *see* also RFF 1918).

Further, Dr. Miller opined that, there may be some subcategory of patients, who do not have many or any alternatives, and for them a clinician may reasonably decide to

recommend, among other things, the consumption of pomegranate. Based on the strength of the reported research. (PX0206-0011).

1040. Dr. Pantuck testified that it is reasonable to discuss pomegranate juice with patients like the ones he has studied in the Pantuck Phase II Prostate Cancer Study (2006). These are patients who have had some primary treatment for prostate cancer, who have had a biochemical recurrence of prostate cancer that is asymptomatic, who have no evidence of clinical disease on X-rays, and who would not be a candidate for other immediate treatment. (CX1341 (Pantuck, Dep. at 270)).

Response to Finding No. 1040:

Respondents have no specific response.

1041. Dr. deKernion stated that although he recommends the POM Products to his prostate cancer patients, it is not the only thing he recommends. He recommends exercise, weight control, and restricting their intake of fatty foods to improve their chances of preventing or controlling a tumor. (deKernion, Tr. 3104-05; PX0161 (deKernion, Report at 0012)). Most notably, Dr. deKernion emphasizes to his patients that the POM Products have not been proven to prevent prostate cancer or prolong their lives. (deKernion, Tr. 3105-06).

Response to Finding No. 1041:

Complaint Counsel mischaracterizes testimony in portions of this proposed finding. Specifically, Respondents object to the phrase "Most notably, Dr. deKernion emphasizes to his patients that the POM Products have not been proven to prevent prostate cancer or prolong their lives" as it is unsupported by the record evidence cited by Complaint Counsel. (deKernion, Tr. 3105-06).

Dr. deKernion testified that POM products are a reasonable adjunct, meaning in addition to and not a substitute, for medical care for prostate cancer patients and recommends POM to some of his patients. (RFF 1793). Dr. deKernion stated that POM is a reasonable adjunct for a patient who wishes to help their general health and help avoid a clinical recurrence of prostate cancer. (RFF 1794). Dr. deKernion opined that a food can be used as a treatment for prostate cancer if there is evidence that it might treat it and if there's no toxicity. (RFF 1795).

1042. Respondents' expert Dr. Heber testified that there was a consensus among prostate cancer experts at POM's scientific advisory board meetings that the body of scientific evidence shows that the POM Products can help to treat, prevent, or reduce the risk of prostate cancer. (Heber, Tr. 2155-56). However, Complaint Counsel's rebuttal witness Dr. Philip Kantoff, Chief of the Genitourinary Oncology Division at the Dana-Farber Cancer Institute at Harvard Medical School, testified that he attended these meetings and told the group assembled that although the data was "very encouraging . . . more work needs to be done in order to demonstrate that [POM Products] have effectiveness." (Kantoff, Tr. at 3265).

Response to Finding No. 1042:

Respondents object to portions of this proposed finding of fact as it relies on opinion evidence by Dr. Philip Kantoff that was ruled inadmissible at trial. Below is the text of the relevant trial testimony omitted by Complaint Counsel:

> JUDGE CHAPPELL: All right. Let me ask a few questions. Sir, do you remember what you said at the meeting?
>
> THE WITNESS: I remember -- I remember the essence of the meeting. I don't remember exactly what I said at the meeting. I remember elements of what I said at the meeting.
> JUDGE CHAPPELL: Were you there to give opinions or to state facts? If you recall.
>
> THE WITNESS: I was there to -- not state facts about POM. I was not -- because I have no experience with the product, had done no research on the product, so I was really mostly there for the interpretation of what was presented to me.
>
> JUDGE CHAPPELL: And did you make an interpretation?
> THE WITNESS: My -- yes. I would say I have a general interpretation of what was presented to me.
>
> JUDGE CHAPPELL: And do you recall what you said?
>
> THE WITNESS: I said -- I think in essence what I said was that this was very encouraging, very encouraging data, and that more work needs to be done in order to demonstrate that it has effectiveness.
>
> MR. FIELDS: I move to strike as an opinion, Your Honor. Even though some of it was very good for our side.

> JUDGE CHAPPELL: I will allow the fact he made the statement, but it will not be considered an opinion to support any point or any issue in this case. (Kantoff, Tr. at 3265).

1043. Dr. Heber acknowledges that he is not an expert in the clinical treatment of prostate cancer. (Heber, Tr. 2034-35).

Response to Finding No. 1043:

Respondents add the following fact to this proposed finding of fact: Dr. Heber treats patients with prostate cancer and informs them of the research on pomegranate juice and pomegranate extract. (CX1352 Heber, Dep. at 239); RFF 1800).

c. Respondents' Awareness of Inadequate Evidence

1044. Respondents have always known that PSADT is not an acceptable endpoint to support claims that their products will treat, prevent, or reduce the risk of prostate cancer. Dr. Liker, POM's Medical Director, testified that he became aware that PSADT is not an accepted biomarker for drug approval as early as 2002 or 2003. (CX1350 (Liker, Dep. at 173)). The Pantuck Phase II Prostate Cancer Study (2006) published report clearly stated that PSADT is not an accepted clinical endpoint for prostate cancer treatment trials. (CX0815_0008).

Response to Finding No. 1044:

Complaint Counsel's proposed finding is vague, argumentative, and mischaracterizes the evidence. First, Respondents do not convey the message in POM's advertisements that the Challenged Products, prevent, treat or reduce the risk of prostate cancer. Secondly, although PSADT is not an accepted biomarker for FDA drug approval trials, Respondents' experts, including Dr. deKernion and Dr. Heber, provided ample evidence of the validity of PSADT as a surrogate marker. Dr. Heber opined that PSADT was a valid surrogate for prostate cancer recurrence and death and that PSADT is now widely recognized by doctors in the field as a valid surrogate endpoint. (Heber, Tr. 1996-97). Dr. Heber stated that there is a lot of "enthusiasm for the PSA doubling time" among clinical urologists because it could likely predict clinical benefit and was utilized in clinical decision making. (CX1352 (Heber, Dep. At 314)). Dr. Heber testified that there is a lot of

support from the urological community to get the FDA to accept PSA as a surrogate endpoint. (CX1352 (Heber, Dep. At 316)). Dr. Heber testified that there is, "a lot of feeling in the urological community and scientific agreement that [the] rate of rise of PSA is an important biomarker." (CX1352 (Heber, Dep. at 316-317)). Dr. Heber also opined that, "PSA doubling time is an accepted variable by the vast majority of the urological community, including members of the American Urological Association and all the leading experts in prostate cancer research in the United States. This is not in dispute." (Heber, Tr. 2151).

Complaint Counsel's expert Dr. Eastham admitted that, "PSA doubling time has emerged as an important factor in the evaluation of men with newly diagnosed prostate cancer or prostate cancer that recurs after treatment. PSA doubling time can be used as a surrogate marker for prostate cancer specific death." (PX0178). Dr. Eastham cites studies showing that "only PSADT was a significant predictor of either systematic progression or local recurrence" of disease, that "PSADT was the strongest predictor of eventual clinical recurrence" and that authors, "suggest that PSADT might serve as a possible surrogate for prostate-cancer-specific death." (PX0178-0006-0008). In his article, Dr. Eastham concludes that "PSADT is an important prognostic marker in men with biochemical failure after local therapy for prostate cancer, and it predicts the probable response to salvage radiotherapy, progression to metastatic disease and prostate cancer specific death." (PX0178-0009). Dr. deKernion stated that PSADT is used to determine success or failure of prostate cancer treatment and that multiple studies have associated PSADT with not only the risk of clinical recurrence but also death. (PX0161-0004, 0007; deKernion, Tr. 3050-58). Dr. deKernion stated that because PSA doubling time is used as predictive of risk of clinical recurrence and death, it is simply illogical that radical changes to PSADT due to intervention would not be informative of the intervention's

effectiveness - particularly when you see such large and statistically significant changes in PSADT following consumption of POM Juice. (PX0161-0007, 0011-0012).

1045. POM's analysis in the January 2009 Medical Research Portfolio Review was that it was most likely not worth pursuing an approval for a botanical drug claim for POMx Pills (*e.g.*, prevent/treat prostate cancer) because it was "risky": POM had no clinical data beyond PSA and PSA would not be accepted as an endpoint. (CX1029_0004).

Response to Finding No. 1045:

Respondents dispute Complaint Counsel's proposed finding as it mischaracterizes the evidence. Complaint Counsel erroneously point to POM's Medical Research Portfolio Review, unaccompanied by any deposition or trial testimony from its authors thereby ignoring both Matt Tupper's and Mark Dreher's testimony at trial on the matter.

POM assessed that the required action to obtain botanical drug approval for a prostate health indication and concluded that POM would need to sponsor "2 studies. Total: 1000 ++ patients, $40+ MM" and that "PSA will not be accepted as an endpoint". (CX1029_0004). The Medical Research Portfolio review reflects the perspective of medical professionals oriented and familiar with the FDA's narrow recognition of only a few surrogate markers in connection with approving an intervention as drug. Dr. Dreher affirmed this reading of these statements at trial and testified: "I believe that was the FDA's position, that it – that they didn't currently accept PSA as a – as an official endpoint for prostate cancer. But I think in the scientific community, PSA is well accepted in the totality of the research." (Dreher, Tr. 564). Mr. Tupper also corroborated Mr. Dreher's trial testimony and also testified that these statements were made because of POM's "belief as to actions, worst-case actions in certain senses, associated with getting a drug approval from the FDA". (Tupper, Tr. 977-78). Moreover, Respondents belief that PSA is "in fact a very valid and appropriate endpoint" is supported by Dr. deKernion. (PX0161; RFF 1743-1755).

1046. Similarly, POM concluded that it was probably not worth pursuing an approval for a health claim for the juice or pills (*e.g.*, reduced risk of prostate cancer), because PSA alone was not sufficient; it would require another study using an endpoint of active surveillance of cancer progression via biopsy. (CX1029_0004).

Response to Finding No. 1046:

Respondents dispute this proposed finding as unsupported by the record evidence. (*See* RRFF 1045; RFF 1777-1783).

1047. In its 2009 Medical Research Portfolio Review, POM also recognized that it had a "research gap: no data on prostate cancer prevention, prior to radiation or prostatectomy." (CX1029_0004).

Response to Finding No. 1047:

Respondents object to this proposed finding as it is unsupported by the record evidence. At trial Matt Tupper explained that the quoted statement in this proposed finding does not accurately assess POM's prostate research and, despite the fact of having sponsored research involving men diagnosed or treated for prostate cancer, "when you include the *in vitro* and the preclinical animal studies as well as the general understanding of the biology of the prostate" the research does "speak to the reduction of risk of the disease, which in men who have not yet been diagnosed could be relevant as well." (Tupper, Tr. 995).

1048. Even after this analysis in early 2009, POM continued to try to use PSA or PSADT results to support its position that its prostate cancer studies did not need a placebo control or a different endpoint to establish efficacy for prostate cancer. For example, in July 2009, Mr. Tupper asked Mr. Liker to obtain further explanation of PSADT, stating that he thought Mr. Resnick "was looking for any published data around this latter concept: i.e., once established, does PSADT shift on its own. He seemed to want to understand this in the context of 'pitching' FDA on the concept that not having a placebo is irrelevant." (CX1080_0002).

Response to Finding No. 1048:

Respondents dispute this proposed finding as vague, ambiguous, argumentative, and the characterization of events both without merit and unsupported by the record evidence. As

Respondents' expert Dr. deKernion testified, a control is often used to control for the placebo effect—in POM's clinical studies on prostate health, the researchers are looking and testing objective blood results—there is no evidence to suggest the placebo effect plays any role in modulating the PSADT of the subject. (deKernion, Tr. 3059-3060; PX0351 (deKernion, Dep. at 97-99; RFF 1743-1755; 1841-1851).

1049. In response to Mr. Tupper's question, Dr. Pantuck told Dr. Liker (in a July 2009 email that was forwarded to Mr. Tupper and Dr. Gillespie) that PSA "has not been validated prospectively as a surrogate endpoint for a meaningful prostate cancer outcome. . . . [A]lthough PSA changes are thought to be prognostically important, it is based on level 2 evidence, and nobody has ever shown conclusively that changes in PSA kinetics arising from therapeutic intervention is meaningful." (CX1080_0001).

Response to Finding No. 1049:

Respondents dispute this proposed finding as contrary to the evidence in the record. (CX1080_0001). Dr. Pantuck in this proposed finding is answering a question from Matt Tupper through the lens of the FDA and not whether the use of PSADT is a valid surrogate endpoint marker in clinical trials. (RFF 1743-1759; 1841-1851).

The lack of clarity of whether the FDA would accept PSADT as an endpoint to which Dr. Pantuck is speaking in this proposed finding does not diminish the competent and reliable scientific studies that Respondents and many more others have conducted that have used PSADT as a marker. As Complaint Counsel expert Dr. Eastham states "PSADT is an important prognostic marker in men with biochemical failure after local therapy for prostate cancer, and it predicts the probable response to salvage radiotherapy, progression to metastatic disease and prostate cancer specific death." (PX0178-0009). Further, as Dr. Eastham notes, authors, "suggest that PSADT might serve as a possible surrogate for prostate-cancer-specific death." (PX0178-0006-0008).

1050. Dr. Pantuck also told POM that if it "want[ed] to ask for an approval based on PSA kinetic changes in a single arm study without a placebo comparison, I think your odds of being successful are approaching infinitely remote. . . . You could never definitively make the case that a single arm study does not just reflect the biology of the patients." (CX1080_0001).

Response to Finding No. 1050:

Respondents dispute portions of this finding of fact as contrary to the evidence in the record. Complaint Counsel omits the following sentence from CX1080_0001 cited in full here: "You could never definitively make the case that a single arm study does not just reflect the biology of the patients. The only conceivable way I could see that being successful would be if the Phase III study was positive, then you might have a leg to stand on. With the data from a placebo controlled, multicenter Phase III study pending, the FDA would never at the present time approve the concept based on data from the single arm phase II alone." In this proposed finding Dr. Pantuck is merely conveying to POM that POM would not likely get FDA drug approval based on PSA kinetic changes or PSADT, a surrogate marker not approved by the FDA (although the best marker available).

Respondents further dispute this proposed finding to the extent it attempts to deny the validity of PSADT as a surrogate marker. Dr. Pantuck stated that PSA doubling time is clinically important for prostate cancer treatment and one of the most important variables that you can discuss to characterize a prostate cancer patient. (CX1341 (Pantuck Dep. At 254-255)). Dr. Pantuck stated that from a patient care standpoint PSA doubling time is extremely important. (CX1341 (Pantuck, Dep. At 255); See also (RFF 1743-1759; 1841-1851).

The lack of clarity of whether the FDA would accept PSADT as an endpoint to which Dr. Pantuck is speaking in this proposed finding does not diminish the value of the competent and reliable scientific studies that Respondents and many more others have conducted that have used PSADT as a marker. As Complaint Counsel expert Dr. Eastham states "PSADT is an important prognostic marker in men with biochemical failure after local therapy for prostate cancer, and it predicts the probable response to salvage radiotherapy,

progression to metastatic disease and prostate cancer specific death." (PX0178-0009). Further, as Dr. Eastham notes, authors, "suggest that PSADT might serve as a possible surrogate for prostate-cancer-specific death." (PX0178-0006-0008).

1051. In 2010, POM acknowledged in an internal research summary that "[t]o date, all POM Wonderful clinical evaluations of pomegranate-derived products in prostate cancer have used PSADT as the primary endpoint" and conceded that "it is unclear whether PSADT is acceptable as a registrational endpoint" for a drug approval. (CX1104_0004).

Response to Finding No. 1051:

Respondents dispute portions of this proposed finding as vague, ambiguous, and argumentative. Respondents dispute the characterization of this proposed finding as it is vague, ambiguous, argumentative and unsupported by the record evidence. Complaint Counsel takes portions of CX1104_0004 out of context. The complete quote noted in CX1104_0004 states, "To date, all POM Wonderful clinical evaluations of pomegranate-derived products in prostate cancer have used PSADT as the primary endpoint. While data obtained using this approach has generated a high degree of interest from patients and urologists, it is unclear whether PSADT is acceptable as a registrational endpoint for a drug designed to prolong the time to disease progression after initial therapy for prostate cancer." (CX1104_0004) (emphasis added).

The lack of clarity of whether the FDA would accept PSADT as an endpoint does not diminish the competent and reliable scientific studies that Respondents and many more others have conducted that have used PSADT as a marker. As Dr. Eastham states "PSADT is an important prognostic marker in men with biochemical failure after local therapy for prostate cancer, and it predicts the probable response to salvage radiotherapy, progression to metastatic disease and prostate cancer specific death." (PX0178-0009). Further, as Dr. Eastham notes, authors, "suggest that PSADT might serve as a possible surrogate for prostate-cancer-specific death." (PX0178-0006-0008).

1052. Undeterred, POM convened meetings of prostate cancer experts to continue to "discuss how to best position PSADT for acceptance as a primary endpoint." (CX1104_0001; *see also* CX1265_0001, *in camera*
).

Response to Finding No. 1052:

Respondents dispute portions of this proposed finding as vague, ambiguous, and argumentative. POM did convene a meeting in January 2010 focused on prostate cancer. (Liker, Dep. at 266). However, the characterization of the meeting in this proposed finding is unsupported by the record evidence. Respondents believe that exhibit CX1104_0001 noted in this proposed finding speaks for itself. The document states under the heading objectives that: "POM Wonderful is planning to file for a botanical drug approval of our pomegranate extract (POMx) with FDA to slow progression of prostate cancer recurrence. Selection of an appropriate study endpoint for drug approval is of utmost concern. We have used PSADT as an endpoint in earlier trials, and while we believe that it is a good marker of disease progression, it is unclear if this endpoint would support approval."

Finally, the primary focus of the November 2010 meeting cited in CX1265_0001 was to review and get input on the meaning or interpretation of Dr. Carducci's results from the POMx study. (Liker, Dep. at 267-268).

1053. Nevertheless, POM has continued to advertise the POM Products from 2007 to as late as 2010, citing Dr. Pantuck's study, touting the "statistically significant prolongation of PSA doubling times" and claiming that the study showed "hopeful results for prostate health," among other things. (*See, e.g.*, CCFF ¶¶ 368-84, 397-434, 439-41, 446, 524).

Response to Finding No. 1053:

Respondents object to portions of this proposed finding as it is vague, and ambiguous as to the terms "touting" and "among other things." The proposed finding is also argumentative and the characterization of events unsupported by the record evidence.

1054. With respect to helping healthy people with prostate conditions and helping people with prostate cancer, Mr. Tupper testified at trial that he would rate POM's science an eight out of ten. (Tupper, Tr. 3012-13).

Response to Finding No. 1054:

Respondents add the following explanatory facts to this proposed finding: Matt Tupper also testified that, "when you include the *in vitro* and the preclinical animal studies as well as the general understanding of the biology of the prostate" the research does "speak to the reduction of risk of the disease, which in men who have not yet been diagnosed could be relevant as well." (Tupper, Tr. 995). Dr. deKernion opined that, while such things could never be subject to 100% proof, the same mechanism shown in the *in vitro* and animal studies and in the Pantuck and Carducci human studies also showed, with a "high degree of probability" that POM and POMx would inhibit the clinical development of prostate cancer in men who have not been diagnosed with that disease. (deKernion, Tr. 3119-20). Dr. deKernion opined that in healthy men, who have never been diagnosed with prostate cancer POM could possibly play a role in preventing them from getting prostate cancer. (PX0351 (deKernion, Dep. At 76-77)). Dr. Heber also testified that there is competent and reliable science showing that POMx and POM are likely to lower the risk of prostate problems for men who have not yet been diagnosed with prostate cancer. (Heber, Tr. 2012-13).

E. Analysis of Respondents' Research Related to Erectile Dysfunction

1. Background Information

1055. To substantiate a claim that pomegranate juice or any other food or supplement prevents, reduces the risk of, or treats erectile dysfunction, one needs data from at least one well-designed, human RCT involving several investigation sites. The RCT should use an appropriate sample population, large enough to produce a statistically significant ($p < .05$) result. It also must show a clinically significant result, meaning that the participant is able to achieve an erection hard enough to engage in sexual intercourse and have sexual satisfaction. (Melman, Tr. 1092-1105; CX1289 (Melman, Report at 0008-11)).

Response to Finding No. 1055:

Complaint Counsel's erectile expert, Dr. Melman, takes the extreme position that "pomegranate juice is a drug," and therefore should be subjected to pharmaceutical type trials. (RFF 2161-63; PX0360 (Melman, Dep. at 17-19); Melman, Tr. 1140-41). However, pomegranate juice is not a drug, but a nutraceutical (a safe and healthy 100% pure and natural fruit juices) and need not be subject to FDA scrutiny for approval of a pharmaceutical before concluding that the whole food product has a beneficial effect on erectile health, erectile function or erectile dysfunction. (RFF 2122, 2123, 2164; PX0149-0006-0007; Burnett, Tr. 2272-74, 2303 (testifying that RCTs are not necessary to deal with studies of drinking pomegranate juice); PX0189-0003, 0014; PX0352 (Goldstein, Dep. at 50-52, 61); Goldstein, Tr. 2600-02, 2611, 2620 (testifying that pharmaceutical type trials should not be applied to nutraceuticals—"a natural food product [from a plant] with health benefits").

1056. Both Complaint Counsel's and Respondents' erectile dysfunction experts agree that experts in the field would use a validated tool when conducting a human clinical trial investigating whether a product treats, prevents, or reduces the risk of erectile dysfunction. (Melman, Tr. 1099; CX1289 (Melman, Report at 0010); Burnett, Tr. 2266 (agreeing that experts would rely on a validated tool when conducting a human clinical trial investigating whether a product treats erectile dysfunction)). Experts in the erectile dysfunction field would not rely on data from a nonvalidated measure alone to show efficacy of a product in treating, preventing, or reducing the risk of erectile dysfunction in humans. (Melman, Tr. 1101; *see also* Burnett, Tr. 2268).

Response to Finding No. 1056:

Complaint Counsel have mischaracterized Respondents' experts' testimony. (RFF 1992-2002, 2171). Dr. Burnett testified that the GAQ is very "informative and . . . valuable to use in clinical studies." (RFF 1997; Burnett, Tr. 2294). Dr. Goldstein testified that the GAQ's "clinical meaningfulness based on its simplicity makes it extremely widely used and very important in assessing erectile function." (Goldstein, Tr. 2634). Dr. Goldstein further testified that "The use of instruments like GAQ in pharmaceutical research . . .

are taken seriously." (PX0352 (Goldstein, Dep. at 109)). In fact, the GAQ is commonly accepted as a standardized instrument among those conducting erectile dysfunction research, and was used in every sildenafil (Viagra), vardenafil (Levitra) and tadalafil (Cialis) trial. (RFF 1997-2002; Goldstein, Tr. 2602-03; PX0352 (Goldstein, Dep. at 57, 73, 76); Burnett, Tr. 2304; CX1337 (Forest, Dep. at 79)). Indeed, Dr. Goldstein testified that "in the development of pharmaceutical products for sexual medicine the [FDA] widely approves of nonvalidated PROs [patient-reported outcomes, such as the GAQ]." (PX0352 (Goldstein, Dep. at 57)). To that end, Dr. Goldstein testified "it has to be strongly suspicious that an unvalidated questionnaire constantly gets repeated." (PX0352 (Goldstein, Dep. at 90)).

1057. A validated tool is "established as measuring erectile dysfunction through rigorous assessments involving reliability testing, validity testing, construct validity, and other criteria[,]" unlike a non-validated measure. (Burnett, Tr. 2266; *see also* Melman, Tr. 1100 (stating that validation means that a measure has been shown to have statistical reliability)). Validation is important because, as Respondent's expert Dr. Goldstein has written, "[r]igorous assessment of patient-reported outcomes is necessary to ensure reliability, responsiveness, and discriminant and predictive validity. These attributes ensure that the instrument measures what it states it measures, and that the results are reproducible and sensitive to change." (PX0352a02-0002; PX0352 (Goldstein, Dep. at 55-56)).

Response to Finding No. 1057:

Dr. Burnett testified that the GAQ, a non-validated measure, is very "informative and . . . valuable to use in clinical studies." (RFF 1997; Burnett, Tr. 2294). Moreover, Dr. Goldstein testified that the GAQ's "clinical meaningfulness based on its simplicity makes it extremely widely used and very important in assessing erectile function." (Goldstein, Tr. 2634). Dr. Goldstein further testified that "The use of instruments like GAQ in pharmaceutical research . . . are taken seriously." (PX0352 (Goldstein, Dep. at 109)). In fact, Respondents experts agreed the GAQ is commonly accepted as a standardized instrument among those conducting erectile dysfunction research, and was used in every sildenafil (Viagra), vardenafil (Levitra) and tadalafil (Cialis) trial. (RFF 1997-2002;

Goldstein, Tr. 2602-03; PX0352 (Goldstein, Dep. at 57, 73, 76); Burnett, Tr. 2304; CX1337 (Forest, Dep. at 79). Indeed, Dr. Goldstein testified that "in the development of pharmaceutical products for sexual medicine the [FDA] widely approves of nonvalidated PROs [patient-reported outcomes, such as the GAQ]." (PX0352 (Goldstein, Dep. at 57)). To that end, Dr. Goldstein testified "it has to be strongly suspicious that an unvalidated questionnaire constantly gets repeated." (PX0352 (Goldstein, Dep. at 90)).

1058. The International Index of Erectile Function ("IIEF") is a validated measure for evaluating change in erectile function. (JX0003 ¶ A.9; Melman, Tr. 1099; CX1289 (Melman, Report at 0010); Burnett, Tr. 2293; PX0352 (Goldstein, Dep. at 65); CX1193_0002; *see also* CX1240_0003, *in camera*

The IIEF questions that evaluate change in erectile function are referred to as the erectile function domain. (Melman, Tr. 1099-1101; CX0686_0026-27; CX1193_0002 (stating that the "IIEF is a validated questionnaire whose erectile function domain score has been demonstrated to correlate with ED [erectile dysfunction] intensity")).

Response to Finding No. 1058:

Respondents have no specific response.

1059. Dr. Goldstein described the IIEF as "cross-culturally valid, psychometrically sound, and relatively easy to administer with a high degree of sensitivity and specificity to the effects of treatment across all five domains in patients with ED." (PX0352 (Goldstein, Dep. at 66-67)).

Response to Finding No. 1059:

Dr. Goldstein, who was at the Pfizer meeting where the IIEF was developed for its pharmaceutical product Viagra, testified that the IIEF was originally intended for pharmaceutical products in patients with IIEF scores consistent with erectile dysfunction. (PX0352 (Goldstein, Dep. at 67-69)). Dr. Goldstein testified "it's assessed on a monthly basis . . . [a]nd it's a recall measure." (PX0352 (Goldstein, Dep. at 68)). Dr. Goldstein further testified that the IIEF was "not necessarily designed for a nutraceutical," like safe and healthy 100% pure and natural fruit juice. (RFF 2005; Goldstein, Tr. 2604, 2633).

Dr. Goldstein also testified some of the questions of the IIEF are ambiguous. (Goldstein, Tr. 2603). For example, Dr. Goldstein testified that one question asks how often do you get an erection, but does not qualify as to what type of erection, *i.e.*, mild erection; moderate erection, *etc*. (Goldstein, Tr. 2603). Dr. Burnett also testified that the IIEF has its deficiencies as it requires patient recall and involves patients' subjective interpretation of their erection physiology. (RFF 2004; Burnett, Tr. 2293-94).

1060. The Global Assessment Questionnaire ("GAQ") is not a validated measure for assessing erectile function. (Melman, Tr. 1118; Burnett, Tr. 2294; PX0352 (Goldstein, Dep. at 73)). Dr. Goldstein testified that the GAQ is a single-sentence question that has not been systematically reviewed for sensitivity, reliability, and specificity. (Goldstein, Tr. 2634; *see also* Melman, Tr. 1120 (testifying that the GAQ has not been tested for statistical reliability)). As a nonvalidated measure, the GAQ does not measure the degree of improvement, indicate how often a study participant experienced improved erections, or show whether he was able to complete sexual intercourse. (Melman, Tr. 1120, 1122; CX1289 (Melman, Report at 0014)). Without the ability to show meaningful change of erectile function, the GAQ does not provide clinically significant information. (Melman, Tr. 1120, 1122; CX1289 (Melman, Report at 0014)).

Response to Finding No. 1060:

Although Complaint Counsel's expert, Dr. Melman, testified that he had never heard of the ubiquitous GAQ before his involvement in this case, Dr. Melman still testified it was a "lousy test." (Melman, Tr. 1180-81). Respondents' experts wholeheartedly disagree. (RFF 1992-2002, 2171). Dr. Burnett testified that the GAQ is very "informative and . . . valuable to use in clinical studies." (RFF 1997; Burnett, Tr. 2294). Dr. Goldstein testified that the GAQ's "clinical meaningfulness based on its simplicity makes it extremely widely used and very important in assessing erectile function." (Goldstein, Tr. 2634). Dr. Goldstein further testified that "The use of instruments like GAQ in pharmaceutical research . . . are taken seriously." (PX0352 (Goldstein, Dep. at 109)). In fact, Respondents experts agreed the GAQ is commonly accepted as a standardized instrument among those conducting erectile dysfunction research, and was used in every sildenafil (Viagra), vardenafil (Levitra) and tadalafil (Cialis) trial. (RFF 1997-2002; Goldstein, Tr. 2602-03; PX0352 (Goldstein, Dep. at 57, 73, 76); Burnett, Tr. 2304;

CX1337 (Forest, Dep. at 79). Indeed, Dr. Goldstein testified that "in the development of pharmaceutical products for sexual medicine the [FDA] widely approves of nonvalidated PROs [patient-reported outcomes, such as the GAQ]." (PX0352 (Goldstein, Dep. at 57)). To that end, Dr. Goldstein testified "it has to be strongly suspicious that an unvalidated questionnaire constantly gets repeated." (PX0352 (Goldstein, Dep. at 90)).

1061. Dr. Burnett testified that experts would not consider the GAQ, by itself, to be a sufficient endpoint in a clinical study evaluating a treatment for erectile dysfunction. (Burnett, Tr. 2294-95) (agreeing that the GAQ was more vague and nonspecific than a validated tool in measuring whether a therapy had an effect on the ability to achieve and maintain erections).

Response to Finding No. 1061:

Complaint Counsel mischaracterizes Dr. Burnett's testimony. Dr. Burnett testified that the GAQ is "informative and still valuable to use in clinical studies" and was in fact widely used in testing pharmaceutical erectile dysfunction drugs such as Viagra and Levitra and Cialis. (RFF 1995-97; Burnett, Tr. 2294, 2304; PX0349 (Burnett, Dep. at 127, 131-132)). Dr. Burnett also testified that the GAQ has sensitivity to evaluate a man's erectile function. (PX0349 (Burnett, Dep. at 38)). Dr. Goldstein also testified that the GAQ's "clinical meaningfulness based on its simplicity makes it extremely widely used and very important in assessing erectile function." (Goldstein, Tr. 2634; *see also*, (RFF 1997-2002; Goldstein, Tr. 2602-03; PX0352 (Goldstein, Dep. at 57, 73, 76); Burnett, Tr. 2304; CX1337 (Forest, Dep. at 79)). Dr. Goldstein further testified that "The use of instruments like GAQ in pharmaceutical research . . . are taken seriously." (PX0352 (Goldstein, Dep. at 109)). In fact, Respondents experts agreed the GAQ is commonly accepted as a standardized instrument among those conducting erectile dysfunction research, and was used in every sildenafil (Viagra), vardenafil (Levitra) and tadalafil (Cialis) trial. (RFF 1997-2002; Goldstein, Tr. 2602-03; PX0352 (Goldstein, Dep. at 57, 73, 76); Burnett, Tr. 2304; CX1337 (Forest, Dep. at 79). Indeed, Dr. Goldstein testified that "in the development of pharmaceutical products for sexual

medicine the [FDA] widely approves of nonvalidated PROs [patient-reported outcomes, such as the GAQ]." (PX0352 (Goldstein, Dep. at 57)). To that end, Dr. Goldstein testified "it has to be strongly suspicious that an unvalidated questionnaire constantly gets repeated." (PX0352 (Goldstein, Dep. at 90)).

1062. Respondents have conducted at least six *in vitro* and animal studies looking at nitric oxide metabolism in an effort to identify a potential erectile dysfunction benefit from pomegranate. (PX0051-0001; PX0056-0001; PX0057-0001; PX0059-0001; PX0004-0001; PX0058-0001). In addition, Respondents have sponsored two human studies looking at erectile dysfunction-related endpoints. (CX1193_0001; CX0716_0029). These studies are discussed in CCFF ¶¶ 1063-81.

Response to Finding No. 1062:

Respondents object to complaint counsel's characterization of its basic science studies. Specifically, the following areas were investigated in each study:

- In the study entitled *Pomegranate Juice Consumption Reduces Oxidative Stress, Atherogenic Modifications to LDL, and Platelet Aggregation: Studies in Humans and in Atherosclerotic Apolipoprotein E-Deficient Mice*, Dr. Aviram and colleagues studied, in healthy male volunteers (and in atherosclerotic apolipoprotein E-deficient mice), the effect of consumption of pomegranate juice on such outcomes as lipoprotein oxidation, aggregation and retention, macrophage atherogenicity, platelet aggregation and atherosclerosis. (RFF 1940; PX0189-0012; PX0004).
- In the study entitled *The Influence of Pomegranate Fruit Extract in Comparison to Regular Pomegranate Juice and Seed Oil on Nitric Oxide and Arterial Function in Obese Zucker Rats*, Dr. de Nigris and colleagues evaluated the effect of pomegranate extract and pomegranate juice and its potent antoxidative properties on the biological actions of nitric oxide and the arterial function in an animal model of metabolic syndrome represented by the obese Zucker rats, and found that pomegranate juice and

extract increased the biological actions of nitric oxide and ameliorates arterial function in obese Zucker rats. (PX0057).

- In the study entitled *Beneficial effects of pomegranate juice on oxidation-sensitive genes and endothelial nitric oxide synthase activity at sites of perturbed shear stress*, Dr. de Nigris and colleagues evaluated the effects of pomegranate juice intervention on oxidation-sensitive genes and endothelial nitric oxide synthase expression induced by high shear stress *in vitro* in cultured human coronary artery endothelial cells and *in vivo* in hypercholesterolemic mice. (RFF 1955; PX0059).
- In the study entitled *Oxidative stress in arteriogenic erectile dysfunction: Prophylactic role of antioxidants*, Dr. Azadzoi and colleagues examined the antioxidant potency of several known antioxidant beverages, which found that pomegranate juice had the highest free radical scavenging activity, and then examined the effect of long term pomegranate juice intake on arteriogenic erectile dysfunction in the rabbit. (RFF 1948-49; PX0189-0011-0012; PX0051; PX0352 (Goldstein, Dep. at 123-124); Goldstein, Tr. 2595).
- In the study entitled *Pomegranate juice protects nitric oxide against oxidative destruction and enhances the biological actions of nitric oxide*, Nobel-prize-winner Dr. Louis Ignarro (for his discoveries concerning nitric oxide) and colleagues studied pomegranate juice's capacity to protect nitric oxide against oxidative destruction. (RFF 1965; PX0189-0011; PX0058; Goldstein, Tr. 2593-95; Heber, Tr. 1995-96; Burnett, Tr. 2252-53).
- In the study entitled *Effects of a pomegranate fruit extract rich in punicalagin on oxidation-sensitive genes and eNOS activity at sites of perturbed shear stress and*

atherogenesis, Dr. de Nigris and colleagues evaluated the effects of intervention with pomegranate fruit extract on endothelial nitric oxide synthase *in vitro* in cultured human endothelial cells and *in vivo* in atherosclerosis-prone areas of hypercholesterolemic mice. (RFF 1959-60; PX0189-0010-0011; PX0056).

Moreover, Respondents dispute the characterization of the Davidson BART/FMD Study. The Davidson BART/FMD Study was primarily a cardiovascular study and therefore the protocols did not include any of the type of inclusion or exclusion criteria one would expect to see in even a basic ED clinical trial. (RFF 2188; CX0716; PX0019; Melman, Tr. 1092).

2. Erectile Dysfunction Studies

a. Forest Erectile Dysfunction Study (2007)

(1) About the Study

1063. POM sponsored a study by Mr. Christopher Forest, Dr. Harin Padma-Nathan, and Dr. Harley Liker, *Efficacy and Safety of Pomegranate Juice on Improvement of Erectile Dysfunction in Male Patients with Mild to Moderate Erectile Dysfunction: A Randomized, Placebo-Controlled, Double-Blind, Crossover Study* ("Forest Erectile Dysfunction Study (2007)"). (CX1147_0004; CX1193_0001, 0004). The Forest clinical trial was conducted in 2004 to 2005, and the results were later published in the *International Journal of Impotence Research* in 2007. (CX1193_0001; CX1147_0004). POM spent approximately $100,000 to $300,000 for the Forest Erectile Dysfunction Study (2007). (CX0626_0001).

Response to Finding No. 1063:

Complaint Counsel fail to cite to any evidence indicating exactly how much POM spent on the *Forest/Padma-Nathan RCT Study*. Moreover, Respondents previously objected to CX0626 (listed on Attachment B to JX2 as a conditionally admitted exhibit) and hereby reaffirm its objections on the grounds that Mr. Liker's alleged statements to Mr. Forest constitutes unreliable hearsay, lacking any exception, and is being offered as proof of the

matters stated therein. As a result, this exhibit and/or statement should be excluded from record.

1064. The Forest Erectile Dysfunction Study (2007) was a randomized, double-blinded, placebo-controlled pilot study that examined the efficacy of POM Juice versus placebo in improving erections in 53 men with mild to moderate erectile dysfunction. (CX1193_0001; CX1289 (Melman, Report at 0012-13)). A pilot study is designed to investigate whether there is any evidence of a treatment effect. (CX1338 (Padma-Nathan, Dep. at 87-88, 155) (describing a pilot study as a proof of concept study); *see also* CX1193_0001; Melman, Tr. 1116 (stating that the study was a pilot study, which is a small or exploratory study)).

Response to Finding No. 1064:

Respondents have no specific response.

1065. The Forest Erectile Dysfunction Study (2007) used a crossover design, and the fifty-three participants who completed the study received a different beverage during the two twenty-eight-day treatment periods. (CX1289 (Melman, Report at 0012-13); CX1193_0002-03). Participants in cohort one drank POM Juice in period one and then switched to the placebo beverage in period two. (CX1193_0002-03). Participants in cohort two consumed the placebo beverage in period one and POM Juice in period two. (CX1193_0002-03).

Response to Finding No. 1065:

Respondents have no specific response.

1066. The Forest Erectile Dysfunction Study (2007) used the GAQ as the primary outcome measure and the IIEF as the secondary outcome measure. (CX1337 (Forest, Dep. at 84); CX1193_0002; Melman, Tr. 1120; CX0686_0008). The Forest Erectile Dysfunction Study (2007) hypothesized that treatment of the participants with POM Juice would produce: 1) statistically significant positive GAQ scores when compared to placebo-controlled patients, and 2) changes in the erectile function domain of the IIEF when the values are compared with the baseline and between the two groups. (CX0686_0008).

Response to Finding No. 1066:

Respondents have no specific response.

1067. The Forest Erectile Dysfunction Study (2007)'s GAQ asked participants the following yes or no question: "While using the study beverage, did you feel that your erections improved?" (CX0686_0025). Dr. Padma-Nathan, the lead researcher, testified that the GAQ is not a validated measure for measuring erectile function. (CX1338 (Padma-Nathan Dep. at 90-91) (stating that validation was not appropriate for a single-question questionnaire)). In developing the Forest Erectile Dysfunction Study (2007)'s protocol,

POM was aware that the GAQ was not a validated measure. (CX0655_0003) (questioning by Germaine Tupper, Respondent Tupper's wife, who reviewed the protocol for POM, about whether the GAQ was a validated tool)).

Response to Finding No. 1067:

Complaint Counsel state that Dr. Padma-Nathan "testified that the GAQ is not a validated measure for measuring erectile function." (CCFF 1067). Complaint Counsel, however, omitted to cite the full text of his testimony where Dr. Padam-Nathan testified that he is "not an expert in that area." (CX1338 (Padma-Nathan, Dep. at 90-91)). Nonetheless, Dr. Padma-Nathan further testified, however, that "it's not unreasonable to have it as a single question, to try to capture a signal for any evidence of [erectile] treatment effect". (CX1338 (Padma-Nathan, Dep. at 94)) (emphasis added).

Additionally, Respondents previously objected to CX0655 (listed on Attachment B to JX2 as a conditionally admitted exhibit) and hereby reaffirm its objections on the grounds that it is unreliable hearsay, lacking any exception and it is being offered as proof of the matters stated therein. Respondents also object to this exhibit on the grounds that it lacks a foundation. Finally, Respondents object to CX0655 as it does not support the proposition that POM was aware that the GAQ was not a validated measure. (CX0655_0003). As a result, this exhibit should be excluded from record.

1068. The IIEF's erectile function domain questions have graded response scales and ask specific questions relating to erectile function, such as "Over the last month, when you attempted sexual intercourse, how often were you able to penetrate (enter) your partner?" and "Over the last month, during sexual intercourse, how often were you able to maintain your erection after you had penetrated (entered) your partner?" (CX0686_0026-27; *see also* Melman, Tr. 1123). Dr. Padma-Nathan stated that the IIEF was a validated measure and the "gold standard." (CX1338 (Padma-Nathan, Dep. at 90)).

Response to Finding No. 1068:

Respondents have no specific response.

1069. The Forest Erectile Dysfunction Study (2007) authors, Dr. Padma-Nathan and Mr. Forest, testified that neither the erectile function domain of the IIEF nor the GAQ had

statistically significant results. (CX1338 (Padma-Nathan, Dep. at 183-84); CX1337 (Forest, Dep. at 162)).

Response to Finding No. 1069:

While statistical significance was not reached, Respondents' experts testified that the *Forest/Padma-Nathan RCT Study* shows clinically significant results. (RFF 1986; PX0189-0013; PX0149-0006; CX0908; Heber, Tr. 1979, 2001; Goldstein, Tr. 2598-99; PX0352 (Goldstein, Dep. at 105-109); Burnett, Tr. 2256; PX0349 (Burnett, Dep. at 138-139); CX1350 (Liker, Dep. at 190-191)).

Dr. Goldstein, testified that the *Forest/Padma-Nathan RCT Study* "provides very valuable information" regarding erectile health and function and is absolutely "clinically significant because "it supports the conclusion that the positive results in the basic science are borne out in human function." (RFF 1986, 2098-99; PX0189-0013; Goldstein, Tr. 2598-99, 2605, 2608; PX0352 (Goldstein, Dep. at 34-47, 105-109)). Dr. Goldstein also testified that the study is clinically significant because it proved pomegranate juice was safe, unlike pharmaceutical ED drugs. (PX0352 (Goldstein, Dep. at 106, 109, 178)). Dr. Goldstein also testified that *Forest/Padma-Nathan RCT Study* "is of extreme relevance to the clinician and consumer" and is "suggestive evidence that use of pomegranate juice would benefit [a] patient with erectile dysfunction." (RFF 2098-99; PX0189-0014; Goldstein, Tr. 2605; PX0352 (Goldstein, Dep. at 34, 105-106)). Overall, Dr. Goldstein said that he would take the results of the study "to the bank." (PX0352 (Goldstein, Dep. at 105-106)).

Similarly, Dr. Burnett mirrored Dr. Goldstein's views. Dr. Burnett opined that the *Forest/Padma-Nathan RCT Study* supports the conclusion that pomegranate juice has a beneficial effect on erectile tissue physiology, health, and function, and is "a potential treatment for ED." (RFF 1986-87, 2100-2106; PX0149-0006; Burnett, Tr. 2255-56; PX0349 (Burnett, Dep. at 103, 112, 116-118, 138-139, 142)). Moreover, Dr. Burnett

testified that pomegranate juice studies, *i.e.*, the *Forest/Padma-Nathan RCT Study*, do not need to reach statistical significance in order to communicate its benefits to consumers. (Burnett, Tr. 2305-06; PX0149-0006-0007).

Moreover, Dr. Heber similarly testified that the *Forest/Padma-Nathan RCT Study* "could [not] be disregarded" and that "it is a positive in providing important scientific information consistent with the basic science that pomegranate juice may be helpful for men with erectile dysfunction." (Heber, Tr. 2001). Dr. Heber also testified that POM's competent and reliable science shows that pomegranate juice is likely to lessen the risk of erectile disease and enhance erectile function. (Heber, Tr. 2012). Finally, Dr. Padma-Nathan, the principal researcher of the *Forest/Padma-Nathan RCT Study*, testified that the "study concluded that [pomegranate juice has] a potential benefit" on erectile dysfunction. (CX1338 (Padma-Nathan, Dep. at 23, 184)).

1070. Dr. Liker, POM's medical director, was involved with the Forest Erectile Dysfunction Study (2007)'s design, conduct, and statistical analysis of the data. (CX0626_0001; CX0637_0001; CX0622_0001; CX0704_0001; CX0644_0001-02; CX0834_0001-02). Dr. Liker also reviewed and approved changes to the article prior to publication. (CX0881_0001-02; *see also* CX0856_0001) (sending revised draft of manuscript to Dr. Liker)).

Response to Finding No. 1070:

The evidence cited does not support the proposition that Dr. Liker was involved with the conduct or statistical analysis of the data for the *Forest/Padma-Nathan RCT Study*. Moreover, Respondents previously objected to CX0626 (listed on Attachment B to JX2 as a conditionally admitted exhibit) and hereby reaffirm its objections on the grounds that Mr. Liker's alleged statements to Mr. Forest constitutes unreliable hearsay, lacking any exception, and is being offered as proof of the matters stated therein. As a result, this exhibit and/or statements should be excluded from record.

1071. Respondents underpowered the Forest Erectile Dysfunction Study (2007) in order to stay within their budget despite Dr. Padma-Nathan's belief that the population should have been larger. (CX0626_0001; CX1350 (Liker, Dep. at 188-89); Liker, Tr. at 1882-83,

1886, 1914; CX1338 (Padma-Nathan, Dep. at 108)). Mr. Forest stated that Dr. Liker "would like to keep the cost of the trial in the $100K to $300K range . . . [and] would rather under-power the study than go out of this range." (CX626_0001).

Response to Finding No. 1071:

Respondents previously objected to CX0626 (listed on Attachment B to JX2 as a conditionally admitted exhibit) and hereby reaffirm its objections on the grounds that Mr. Liker's alleged statements to Mr. Forest constitutes unreliable hearsay, lacking any exception, and is being offered as proof of the matters stated therein. As a result, this exhibit and/or statement should be excluded from record.

In addition, although Complaint Counsel's expert, Dr. Melman testified that there was a decent turnout of people in the *Forest/Padma-Nathan RCT Study*, (PX0360 (Melman, Dep. at 71)), Dr. Padma-Nathan, the principal researcher of the *Forest/Padma-Nathan RCT Study*, testified that that the *Forest/Padma-Nathan RCT Study* was "[u]nder-powered to achieve statistical significance . . . [and] that shouldn't be misconstrued to mean that the study was a deficient one." (CX1338 (Padma-Nathan, Dep. at 23, 106, 108)). Dr. Padma-Nathan testified that a pilot trial "doesn't always try to strive to achieve statistical significance, but show a signal or a trend . . . so powering . . . in this case, would have been completely a guesstimation . . . because there's no other comparable – it's not like [pomegranate juice is] a drug, so one didn't know what impact it was." (CX1338 (Padma-Nathan, Dep. at 103-105)). As such, Dr. Padma-Nathan further testified that he did not think they were "trying to achieve [statistical significance] and didn't believe [they would] get statistical significance." (CX1338 (Padma-Nathan, Dep. at 106)).

Dr. Liker also testified that POM underpowered the *Forest/Padma-Nathan RCT Study* because it was primarily interested in seeing whether pomegranate juice offered some

benefit, and not whether it reached statistical significance—as pomegranate juice "was not a drug . . . [and was] not going after a drug claim . . . ." (Liker, Tr. 1882-83).

1072. After the Forest Erectile Dysfunction Study (2007) was submitted for publication, a peer reviewer for the *International Journal of Impotence Research* stated that it was "a negative study, not a positive study, and should be presented that way." At this time, Dr. Liker was informed that the study was "negative." (CX0856_0001 (noting that Mr. Forest sent the peer reviewers' comments to Dr. Liker)).

Response to Finding No. 1072:

Dr. Goldstein testified that he clearly does not agree that the *Forest/Padma-Nathan RCT Study* is negative. (Goldstein, Tr. 2636). Similarly, Dr. Burnett testified that the *Forest/Padma-Nathan RCT Study* "has positive benefits . . . [and] not negative aspects . . . ." (PX0349 (Burnett, Dep. at 138-139)). Both experts both agree that the *Forest/Padma-Nathan RCT Study* shows clinically significant results. (RFF 1986; PX0189-0013; PX0149-0006; CX0908; Heber, Tr. 1979, 2001; Goldstein, Tr. 2598-99; PX0352 (Goldstein, Dep. at 105-109); Burnett, Tr. 2256; PX0349 (Burnett, Dep. at 138-139); CX1350 (Liker, Dep. at 190-191)).

Dr. Goldstein, testified that the *Forest/Padma-Nathan RCT Study* "provides very valuable information" regarding erectile health and function and is absolutely "clinically significant because "it supports the conclusion that the positive results in the basic science are borne out in human function." (RFF 1986, 2098-99; PX0189-0013; Goldstein, Tr. 2598-99, 2605, 2608; PX0352 (Goldstein, Dep. at 34-47, 105-109)). Dr. Goldstein also testified that the study is clinically significant because it proved pomegranate juice was safe, unlike pharmaceutical ED drugs. (PX0352 (Goldstein, Dep. at 106, 109, 178)). Dr. Goldstein also testified that *Forest/Padma-Nathan RCT Study* "is of extreme relevance to the clinician and consumer" and is "suggestive evidence that use of pomegranate juice would benefit [a] patient with erectile dysfunction." (RFF 2098-99; PX0189-0014; Goldstein, Tr. 2605; PX0352 (Goldstein, Dep. at 34, 105-106)). Overall,

Dr. Goldstein said that he would take the results of the study "to the bank." (PX0352 (Goldstein, Dep. at 105-106)).

Similarly, Dr. Burnett mirrored Dr. Goldstein's views. Dr. Burnett opined that the *Forest/Padma-Nathan RCT Study* supports the conclusion that pomegranate juice has a beneficial effect on erectile tissue physiology, health, and function, and is "a potential treatment for ED." (RFF 1986-87, 2100-2106; PX0149-0006; Burnett, Tr. 2255-56; PX0349 (Burnett, Dep. at 103, 112, 116-118, 138-139, 142)). Indeed, Dr. Burnett testified that the results of the *Forest/Padma-Nathan RCT Study* provides support that pomegranate juice "may be an intervention that would complement conventional ED treatment, and [he] would support its use by patients." (Burnett, Tr. 2298). Moreover, Dr. Burnett testified that pomegranate juice studies, *i.e.*, the *Forest/Padma-Nathan RCT Study*, do not need to reach statistical significance in order to communicate its benefits to consumers. (Burnett, Tr. 2305-06; PX0149-0006-0007).

Moreover, Dr. Heber similarly testified that the *Forest/Padma-Nathan RCT Study* "could [not] be disregarded" and that "it is a positive in providing important scientific information consistent with the basic science that pomegranate juice may be helpful for men with erectile dysfunction." (Heber, Tr. 2001). Dr. Heber also testified that POM's competent and reliable science shows that pomegranate juice is likely to lessen the risk of erectile disease and enhance erectile function. (Heber, Tr. 2012). Finally, Dr. Padma-Nathan, the principal investigator of the *Forest/Padma-Nathan RCT Study*, testified that the "study concluded that [pomegranate juice has] a potential benefit" on erectile dysfunction. (CX1338 (Padma-Nathan, Dep. at 23, 184)).

1073. A published review by Dr. Jacob Rajfer, Professor of Urology at UCLA, *Pomegranate Juice: Is It the New, All-Natural Phosphodiesterase Type 5 Inhibitor?*, 10 Rev. Urol. 168-69 (2008), stated that the Forest Erectile Dysfunction Study (2007) had negative results. Dr. Rajfer's review also stated that the study "highlights the fact that not all bench findings prove clinically efficacious and demonstrates the necessity of randomized, double-blind, placebo-controlled studies." (CX1290 (Melman, Report at Ex. C); Melman, Tr. 1128-29; CX1289 (Melman, Report at 0016)).

Response to Finding No. 1073:

Dr. Goldstein indicated that he "clearly . . . wouldn't agree with Dr. Rajfer['s]" perspective that the *Forest/Padma-Nathan RCT Study* is negative. (Goldstein, Tr. 2636). Dr. Goldstein further testified that he thinks Dr. Rajfer is missing "the totality of evidence of pomegranate juice and he's only focusing on a single Forest trial in a small number of patients, not even taking into account his own research from UCLA, his colleagues Ignarro and De Negris and others." (Goldstein, Tr. 2637). Similarly, Dr. Burnett testified that the *Forest/Padma-Nathan RCT Study* "has positive benefits . . . [and] not negative aspects" as it offers "clinical weight to suggest the likely beneficial effect of this therapy with respect to erectile function." (PX0349 (Burnett, Dep. at 138-139)).

1074. The Forest Erectile Dysfunction Study (2007) authors testified that their study did not conclude that POM Juice treats, prevents, or reduces the risk of erectile dysfunction. (CX1338 (Padma-Nathan, Dep. at 157-58); CX1337 (Forest, Dep. at 165-66)). In fact, the authors stated that "[f]urther studies are warranted to clarify the efficacy and clinical role of POM [Juice] on male ED." (CX1193_0004; *see also* CX1338 (Padma-Nathan, Dep. at 184)).

Response to Finding No. 1074:

Dr. Padma-Nathan, the principal investigator of the *Forest/Padma-Nathan RCT Study* testified that the "study concluded that [pomegranate juice has] a potential benefit" on erectile dysfunction. (CX1338 (Padma-Nathan, Dep. at 23, 184)).

Moreover, although statistical significance was not reached in the *Forest/Padma-Nathan RCT Study*, Respondents' experts testified there was "significant clinical findings in this study." (RFF 1986; PX0189-0013; PX0149-0006; CX0908; Heber, Tr. 1979, 2001; Goldstein, Tr. 2598-99; PX0352 (Goldstein, Dep. at 105-109, 116); Burnett, Tr. 2256; PX0349 (Burnett, Dep. at 138-139); CX1350 (Liker, Dep. at 190-191)).

Particularly, Dr. Goldstein, testified that the *Forest/Padma-Nathan RCT Study* "provides very valuable information" regarding erectile health and function and is absolutely

"clinically significant because "it supports the conclusion that the positive results in the basic science are borne out in human function." (RFF 1986, 2098-99; PX0189-0013; Goldstein, Tr. 2598-99, 2605, 2608; PX0352 (Goldstein, Dep. at 34-47, 105-109)). Dr. Goldstein also testified that the study is clinically significant because it proved pomegranate juice was safe, unlike pharmaceutical ED drugs. (PX0352 (Goldstein, Dep. at 106, 109, 178)). Dr. Goldstein also testified that *Forest/Padma-Nathan RCT Study* "is of extreme relevance to the clinician and consumer" and is "suggestive evidence that use of pomegranate juice would benefit [a] patient with erectile dysfunction." (RFF 2098-99; PX0189-0014; Goldstein, Tr. 2605; PX0352 (Goldstein, Dep. at 34, 105-106)). Overall, Dr. Goldstein said that he would take the results of the study "to the bank." (PX0352 (Goldstein, Dep. at 105-106)).

Similarly, Dr. Burnett mirrored Dr. Goldstein's views. Dr. Burnett opined that the *Forest/Padma-Nathan RCT Study* supports the conclusion that pomegranate juice has a beneficial effect on erectile tissue physiology, health, and function, and is "a potential treatment for ED." (RFF 1986-87, 2100-2106; PX0149-0006; Burnett, Tr. 2255-56; PX0349 (Burnett, Dep. at 103, 112, 116-118, 138-139, 142)). Indeed, Dr. Burnett testified that the results of the *Forest/Padma-Nathan RCT Study* provides support that pomegranate juice "may be an intervention that would complement conventional ED treatment, and [he] would support its use by patients." (Burnett, Tr. 2298). Moreover, Dr. Burnett testified that pomegranate juice studies, *i.e.*, the *Forest/Padma-Nathan RCT Study*, do not need to reach statistical significance in order to communicate its benefits to consumers. (Burnett, Tr. 2305-06; PX0149-0006-0007).

Moreover, Dr. Heber similarly testified that the *Forest/Padma-Nathan RCT Study* "could [not] be disregarded" and that "it is a positive in providing important scientific information consistent with the basic science that pomegranate juice may be helpful for men with erectile dysfunction." (Heber, Tr. 2001). Dr. Heber also testified that POM's

competent and reliable science shows that pomegranate juice is likely to lessen the risk of erectile disease and enhance erectile function. (Heber, Tr. 2012).

Furthermore, although the authors stated that further studies are warranted, Dr. Goldstein testified that "[t]hat sentence is a part of every end of every manuscript in the Journal of Sexual Medicine, virtually." (PX0352 (Goldstein, Dep. at 97)). Dr. Goldstein further testified that "[w]e always need more studies," and that "there isn't any aspect of sexual medicine where further studies are not warranted." (PX0352 (Goldstein, Dep. at 97)). Dr. Goldstein testified that, in fact, "further studies are warranted for Viagra and Levitra and Cialis despite more than 10 years of studies." (PX0352 (Goldstein, Dep. at 98)).

1075. In the Forest Erectile Dysfunction Study (2007) article, Dr. Liker indicated his academic affiliation with UCLA, but did not disclose his affiliation with POM as its Medical Director. (Liker, Tr. 1931-32).

Response to Finding No. 1075:

While the study did not list Dr. Liker's affiliation with POM, Dr. Liker, nonetheless, expressly requested that the researchers disclose his affiliation as Medical Director of POM in the study. (CX0834_0001).

(2) Expert Analysis

1076. All the erectile dysfunction experts in this case agree that the Forest Erectile Dysfunction Study (2007)'s IIEF erectile function domain results achieved a *p* value of 0.72, *i.e.*, not statistically significant. (Melman, Tr. 1120-21; Burnett, Tr. 2297 (agreeing that a *p* value of 0.72 is "nowhere near approaching statistical significance"); PX0352 (Goldstein, Dep. at 65); CX1193_0003; CX1213_0001 (comparing the change from baseline for the treatment group versus the control group)).

Response to Finding No. 1076:

While statistical significance was not reached, Respondents' experts testified that the *Forest/Padma-Nathan RCT Study* shows clinically significant results. (RFF 1986; PX0189-0013; PX0149-0006; CX0908; Heber, Tr. 1979, 2001; Goldstein, Tr. 2598-99;

PX0352 (Goldstein, Dep. at 105-109); Burnett, Tr. 2256; PX0349 (Burnett, Dep. at 138-139); CX1350 (Liker, Dep. at 190-191)).

Dr. Goldstein, testified that the *Forest/Padma-Nathan RCT Study* "provides very valuable information" regarding erectile health and function and is absolutely "clinically significant because "it supports the conclusion that the positive results in the basic science are borne out in human function." (RFF 1986, 2098-99; PX0189-0013; Goldstein, Tr. 2598-99, 2605, 2608; PX0352 (Goldstein, Dep. at 34-47, 105-109)). Dr. Goldstein also testified that the study is clinically significant because it proved pomegranate juice was safe, unlike pharmaceutical ED drugs. (PX0352 (Goldstein, Dep. at 106, 109, 178)). Dr. Goldstein also testified that *Forest/Padma-Nathan RCT Study* "is of extreme relevance to the clinician and consumer" and is "suggestive evidence that use of pomegranate juice would benefit [a] patient with erectile dysfunction." (RFF 2098-99; PX0189-0014; Goldstein, Tr. 2605; PX0352 (Goldstein, Dep. at 34, 105-106)). Overall, Dr. Goldstein said that he would take the results of the study "to the bank." (PX0352 (Goldstein, Dep. at 105-106)).

Similarly, Dr. Burnett mirrored Dr. Goldstein's views. Dr. Burnett opined that the *Forest/Padma-Nathan RCT Study* supports the conclusion that pomegranate juice has a beneficial effect on erectile tissue physiology, health, and function, and is "a potential treatment for ED." (RFF 1986-87, 2100-2106; PX0149-0006; Burnett, Tr. 2255-56; PX0349 (Burnett, Dep. at 103, 112, 116-118, 138-139, 142)). Indeed, Dr. Burnett testified that the results of the *Forest/Padma-Nathan RCT Study* provides support that pomegranate juice "may be an intervention that would complement conventional ED treatment, and [he] would support its use by patients." (Burnett, Tr. 2298). Moreover, Dr. Burnett testified that pomegranate juice studies, *i.e.*, the *Forest/Padma-Nathan RCT Study*, do not need to reach statistical significance in order to communicate its benefits to consumers. (Burnett, Tr. 2305-06; PX0149-0006-0007).

Moreover, Dr. Heber similarly testified that the *Forest/Padma-Nathan RCT Study* "could [not] be disregarded" and that "it is a positive in providing important scientific information consistent with the basic science that pomegranate juice may be helpful for men with erectile dysfunction." (Heber, Tr. 2001). Dr. Heber also testified that POM's competent and reliable science shows that pomegranate juice is likely to lessen the risk of erectile disease and enhance erectile function. (RFF 2107). Finally, Dr. Padma-Nathan, the principal investigator of the *Forest/Padma-Nathan RCT Study*, testified that the "study concluded that [pomegranate juice has] a potential benefit" on erectile dysfunction. (CX1338 (Padma-Nathan, Dep. at 23, 184)).

1077. All the erectile dysfunction experts in this case also agree that the Forest Erectile Dysfunction Study (2007)'s GAQ results achieved a *p* value of 0.058 and were not statistically significant. (Melman, Tr. 1120-21; Burnett, Tr. 2298; PX0189 (Goldstein, Report at 0013); *see also* CX1193_0003). Nearly achieving statistical significance is insufficient to prove a product's efficacy in treating, preventing, or reducing the risk of erectile dysfunction in humans. (Melman, Tr. 1103, 1121).

Response to Finding No. 1077:

The *Forest/Padma-Nathan RCT Study's* probability value ("p-value") of 0.058 was a hair above a statistical significance measure of 0.050. (RFF 1982; PX0189-0012-0013; CX0908; Heber, Tr. 1978; Goldstein, Tr. 2598). This means the *Forest/Padma-Nathan RCT Study* had a 94.2%, rather than 95%, probability of being valid and not the result of chance. (RFF 1983-84; Heber, Tr. 1978; Goldstein, Tr. 2598-99; Burnett, Tr. 2305). Overall, the GAQ scores demonstrated that pomegranate juice drinkers enjoyed a nearly 50% better improvement in erections over placebo drinkers. (RFF 1985; CX0908-0003; PX0352 (Goldstein, Dep. at 109, 144); CX1338 (Padma-Nathan, Dep. at 191-192)).

Although statistical significance was not reached, Respondents' experts testified that the *Forest/Padma-Nathan RCT Study* shows clinically significant results. (RFF 1986; PX0189-0013; PX0149-0006; CX0908; Heber, Tr. 1979, 2001; Goldstein, Tr. 2598-99;

PX0352 (Goldstein, Dep. at 105-109); Burnett, Tr. 2256; PX0349 (Burnett, Dep. at 138-139); CX1350 (Liker, Dep. at 190-191)).

Dr. Goldstein, testified that the *Forest/Padma-Nathan RCT Study* "provides very valuable information" regarding erectile health and function and is absolutely "clinically significant because "it supports the conclusion that the positive results in the basic science are borne out in human function." (RFF 1986, 2098-99; PX0189-0013; Goldstein, Tr. 2598-99, 2605, 2608; PX0352 (Goldstein, Dep. at 34-47, 105-109)). Dr. Goldstein also testified that the study is clinically significant because it proved pomegranate juice was safe, unlike pharmaceutical ED drugs. (PX0352 (Goldstein, Dep. at 106, 109, 178)). Dr. Goldstein also testified that *Forest/Padma-Nathan RCT Study* "is of extreme relevance to the clinician and consumer" and is "suggestive evidence that use of pomegranate juice would benefit [a] patient with erectile dysfunction." (RFF 2098-99; PX0189-0014; Goldstein, Tr. 2605; PX0352 (Goldstein, Dep. at 34, 105-106)). Overall, Dr. Goldstein said that he would take the results of the study "to the bank." (PX0352 (Goldstein, Dep. at 105-106)).

Similarly, Dr. Burnett mirrored Dr. Goldstein's views. Dr. Burnett opined that the *Forest/Padma-Nathan RCT Study* supports the conclusion that pomegranate juice has a beneficial effect on erectile tissue physiology, health, and function, and is "a potential treatment for ED." (RFF 1986-87, 2100-2106; PX0149-0006; Burnett, Tr. 2255-56; PX0349 (Burnett, Dep. at 103, 112, 116-118, 138-139, 142)). Indeed, Dr. Burnett testified that the results of the *Forest/Padma-Nathan RCT Study* provides support that pomegranate juice "may be an intervention that would complement conventional ED treatment, and [he] would support its use by patients." (Burnett, Tr. 2298). Moreover, Dr. Burnett testified that pomegranate juice studies, *i.e.*, the *Forest/Padma-Nathan RCT Study*, do not need to reach statistical significance in order to communicate its benefits to consumers. (Burnett, Tr. 2305-06; PX0149-0006-0007).

Moreover, Dr. Heber similarly testified that the *Forest/Padma-Nathan RCT Study* "could [not] be disregarded" and that "it is a positive in providing important scientific information consistent with the basic science that pomegranate juice may be helpful for men with erectile dysfunction." (Heber, Tr. 2001). Dr. Heber also testified that POM's competent and reliable science shows that pomegranate juice is likely to lessen the risk of erectile disease and enhance erectile function. (Heber, Tr. 2012). Finally, Dr. Padma-Nathan, the principal investigator of the *Forest/Padma-Nathan RCT Study*, testified that the "study concluded that [pomegranate juice has] a potential benefit" on erectile dysfunction. (CX1338 (Padma-Nathan, Dep. at 23, 184)).

1078. As the Forest Erectile Dysfunction Study (2007) report noted, the treatment period was a limitation because it might not have been long enough to allow for a clinical response. (CX1193_0004). Dr. Melman testified that the study was not conducted over a sufficient duration to show a sustained clinically significant effect on erectile function. (Melman, Tr. 1125, 1127; CX1289 (Melman, Report at 0014)). Experts in the erectile dysfunction field would require that a study be conducted over an appropriate duration because, even if there is improvement in the quality of erection, a treatment is not efficacious when the participant is still unable to complete intercourse. (CX1289 (Melman, Report at 0011-12)).

Response to Finding No. 1078:

While the authors of the *Forest/Padma-Nathan RCT Study* noted there were study limitations of a short treatment period, Dr. Goldstein opined that this "actually resulted in less favorable findings such that one would anticipate that a more robustly designed study would certainly have obtained statistically significant results." (PX0189-0013; PX0352 (Goldstein, Dep. at 80)). Similarly, the authors of the *Forest/Padma-Nathan RCT Study* also concluded that the possibility of "longer treatment periods could possibly demonstrate statistical significance." (CX1193_0004).

Moreover, Dr. Goldstein "couldn't disagree more" with Dr. Melman's opinion that a patient must have an orgasm before his ED is deemed treated. (RFF 2181-84; Goldstein, Tr. 2604; Melman, Tr. 1146-47) (Dr. Melman testified that in the hypothetical case of "a

man [that] hasn't been able to have an erection for five years, then he tries [a] product and he now has an erection and he can penetrate his wife and bring her to sexual satisfaction, but he doesn't have an orgasm himself," the maker of the product "can't tell the public about what [the product has] done.") Dr. Goldstein testified that Dr. Melman's statement was also contrary to the IIEF for which Dr. Melman advocates, as that domain gathers no information regarding a patient's orgasm. (RFF 2183-84; Goldstein, Tr. 2604).

b. Davidson IIEF Study

1079. A subset of 27 participants from the Davidson BART/FMD Study, a randomized, double blind, and placebo-controlled cardiovascular study funded by Roll (discussed in CCFF ¶¶ 879-911), also completed the IIEF. (CX1065_0001; CX0716_0029; CX0684_0001, 0014). This analysis was planned for in the protocol for the Davidson Study. (CX0716_0029).

Response to Finding No. 1079:

Respondents dispute that the characterization of the Davidson BART/FMD as one that looked at erectile dysfunction-related endpoints. The Davidson BART/FMD was primarily a cardiovascular study and therefore its protocols did not include any of the type of inclusion or exclusion criteria one would expect to see in even a basic ED clinical trial. (RFF 2188; CX0716; PX0019; Melman, Tr. 1092). In fact, the ED findings in the Davidson BART/FMD were flawed as one of the two study sites was unable to collect any data for the baseline IIEF measurement. (RFF 2189; CX0654_0001 – "IIEF data not collected on most subjects at site 2; Mary Sue was aware of this and site staff reported that subjects are uncomfortable completing this questionnaire in the office (close quarters) so they tried to send it to them prior to their visit for them to bring in completed, yet it still was incomplete. Unfortunately, this baseline data will be missing.") (emphasis added).

1080. The unpublished IIEF results from the Davidson BART/FMD Study were not statistically significant for the intent to treat population. (Melman, Tr. 1130-31; CX1289 (Melman, Report at 0017; CX1336 (Davidson, Dep. at 88-89)). The *p* value was 0.7887 when

comparing the intent to treat population's change in IIEF erectile function domain scores for the treatment group versus the control group. (CX0684_0014). These results do not show that drinking eight ounces of POM Juice daily treats, prevents, or reduces the risk of erectile dysfunction in humans. (Melman, Tr. 1130-31; CX1289 (Melman, Report at 0017)).

Response to Finding No. 1080:

Respondents dispute that the characterization of the Davidson BART/FMD as one that looked at erectile dysfunction-related endpoints. The Davidson BART/FMD was primarily a cardiovascular study and therefore its protocols did not include any of the type of inclusion or exclusion criteria one would expect to see in even a basic ED clinical trial. (RFF 2188; CX0716; PX0019; Melman, Tr. 1092). In fact, the ED findings in the Davidson BART/FMD were flawed as one of the two study sites was unable to collect any data for the baseline IIEF measurement. (RFF 2189; CX0654_0001 – "IIEF data not collected on most subjects at site 2; Mary Sue was aware of this and site staff reported that subjects are uncomfortable completing this questionnaire in the office (close quarters) so they tried to send it to them prior to their visit for them to bring in completed, yet it still was incomplete. Unfortunately, this baseline data will be missing.") (emphasis added).

1081. Neither Dr. Burnett nor Dr. Goldstein reviewed the IIEF data from the Davidson BART/FMD Study. (PX0352 (Goldstein, Dep. at 142); PX0349 (Burnett, Dep. at 170)).

Response to Finding No. 1081:

Respondents have no specific response.

c. Nitric Oxide Studies

1082. Respondents have sponsored at least six *in vitro* and/or animal studies investigating the effects of pomegranate juice on nitric oxide levels, including:

- *Oxidative Stress in Arteriogenic Erectile Dysfunction: Prophylactic Role of Antioxidants by Dr. Azadzoi (animal study);*
- *Effects of a Pomegranate Fruit Extract Rich in Punicalagin on Oxidation-Sensitive Genes and eNOS Activity at sites of Perturbed Shear Stress and Atherogenesis by Dr. De Nigris (in vitro and animal study);*

- *The Influence of Pomegranate Fruit Extract in Comparison to Regular Pomegranate Juice and Seed Oil on Nitric Oxide and Arterial Function in Obese Zucker Rats by Dr. De Nigris (animal study);*

- *Beneficial Effects of Pomegranate Juice on Oxidation-Sensitive Genes and Endothelial Nitric Oxide Synthase Activity at Sites of Perturbed Shear Stress by Dr. de Nigris (in vitro study);*

- *Pomegranate Juice Consumption Reduces Oxidative Stress, Atherogenic Modifications to LDL, and Platelet Aggregation: Studies in Humans and in Atherosclerotic Apolipoprotein E-Deficient Mice by Dr. Aviram (animal study in part); and*

- *Pomegranate Juice Protects Nitric Oxide Against Oxidative Destruction and Enhances the Biological Actions of Nitric Oxide by Dr. Ignarro (in vitro study).*

(PX0051-0001; PX0056-0001; PX0057-0001; PX0059-0001; PX0004-0001; PX0058-0001).

Response to Finding No. 1082:

Respondents object to Complaint Counsel's lump characterization of POM's *in vitro* and *in vivo* studies. Specifically, the following areas were investigated in each study:

- In the study entitled *Pomegranate Juice Consumption Reduces Oxidative Stress, Atherogenic Modifications to LDL, and Platelet Aggregation: Studies in Humans and in Atherosclerotic Apolipoprotein E-Deficient Mice*, Dr. Aviram and colleagues studied, in healthy male volunteers (and in atherosclerotic apolipoprotein E-deficient mice), the effect of consumption of pomegranate juice on such outcomes as lipoprotein oxidation, aggregation and retention, macrophage atherogenicity, platelet aggregation and atherosclerosis. (RFF 1940; PX0189-0012; PX0004).

- In the study entitled *The Influence of Pomegranate Fruit Extract in Comparison to Regular Pomegranate Juice and Seed Oil on Nitric Oxide and Arterial Function in Obese Zucker Rats*, Dr. de Nigris and colleagues evaluated the effect of pomegranate extract and pomegranate juice and its potent antoxidative

properties on the biological actions of nitric oxide and the arterial function in an animal model of metabolic syndrome represented by the obese Zucker rats, and found that pomegranate juice and extract increased the biological actions of nitric oxide and ameliorates arterial function in obese Zucker rats. (PX0057).

- In the study entitled *Beneficial effects of pomegranate juice on oxidation-sensitive genes and endothelial nitric oxide synthase activity at sites of perturbed shear stress*, Dr. de Nigris and colleagues evaluated the effects of pomegranate juice intervention on oxidation-sensitive genes and endothelial nitric oxide synthase expression induced by high shear stress *in vitro* in cultured human coronary artery endothelial cells and *in vivo* in hypercholesterolemic mice. (RFF 1955; PX0059).
- In the study entitled *Oxidative stress in arteriogenic erectile dysfunction: Prophylactic role of antioxidants*, Dr. Azadzoi and colleagues examined the antioxidant potency of several known antioxidant beverages, which found that pomegranate juice had the highest free radical scavenging activity, and then examined the effect of long term pomegranate juice intake on arteriogenic erectile dysfunction in the rabbit. (RFF 1948-49; PX0189-0011-0012; PX0051; PX0352 (Goldstein, Dep. at 123-124); Goldstein, Tr. 2595).
- In the study entitled *Pomegranate juice protects nitric oxide against oxidative destruction and enhances the biological actions of nitric oxide*, Nobel-prize-winner Dr. Louis Ignarro (for his discoveries concerning nitric oxide) and colleagues studied pomegranate juice's capacity to protect nitric oxide against oxidative destruction. (RFF 1965; PX0189-0011; PX0058; Goldstein, Tr. 2593-95; Heber, Tr. 1995-96; Burnett, Tr. 2252-53).

- In the study entitled *Effects of a pomegranate fruit extract rich in punicalagin on oxidation-sensitive genes and eNOS activity at sites of perturbed shear stress and atherogenesis*, Dr. de Nigris and colleagues evaluated the effects of intervention with pomegranate fruit extract on endothelial nitric oxide synthase *in vitro* in cultured human endothelial cells and *in vivo* in atherosclerosis-prone areas of hypercholesterolemic mice. (RFF 1959-60; PX0189-0010-0011; PX0056).

1083. Both Drs. Burnett and Goldstein describe such studies as basic research. (PX0149 (Burnett, Report at 0005-06); PX0189 (Goldstein, Report at 0010-13 (describing the De Nigris, Aviram, Ignarro, and Azadzoi studies as *in vitro* or *in vivo*); CX0982_0011-14 (describing the De Nigris, Aviram, Ignarro, and Azadzoi studies as "pre-clinical" studies)).

Response to Finding No. 1083:

While Respondents do not dispute that POM's *in vitro* and *in vivo* studies are "basic science" or "pre-clinical," Respondents object to any suggestion that they are not compelling or demonstrate a probable benefit of pomegranate juice on erectile health and function at the human level.

Respondents' expert, Dr. Burnett testified that POM's basic science alone "support[s] the potential benefit at the human level to improve the physiology of erectile tissue preserving erect tissue health." (RFF 2103-06; PX0149-0003,0005; PX0349 (Burnett, Dep. at 103, 112, 116-118)). Dr Burnett also opined in his expert report that "basic scientific evidence exists that establishes that pomegranate juice possesses potent anti-oxidative molecular effects and these effects operate by activating endothelial NO mechanisms in vasculature [structures involved in human penile erection]." (RFF 2093; PX0149-0005-0006). Moreover, Dr. Burnett testified that "animal studies are very informative to the extent that some of the basic physiology is there . . . [and it] can

characterize what's going on at the human level." (PX0349 (Burnett, Dep. at 111)). Dr. Burnett also testified that POM's basic science alone:

> "provide powerful support for pomegranate juice. . . as antioxidants; that they work with very potent effects on the nitric oxide regulatory mechanism; that there's evidence that they do demonstrate antioxidant effects on genes that have to do with the oxidative stress mechanisms and the nitric oxide release mechanisms; that there is evidence that these agents do reduce some of the pathophysiologic effects at the tissue level including structural changes on the tissue in terms of atherosclerosis, that is, hardening of vessels that leads to the functional changes where the tissue is not able to properly relax and is consistent with how the blood vessels have to dilate and allow blood flow to occur within target organs."

(PX0349 (Burnett, Dep. at 116)).

Dr. Burnett further testified that he believes pomegranate juice has a "potential benefit on the basis of animal studies or *in vitro* studies to likely improve one's erection physiology," not just maintain it. (Burnett, Tr., 2262-63) (emphasis added). To that end, Dr. Burnett testified that which helps erectile function may also help improve one's erectile dysfunction. (Burnett, Tr., 2303).

Dr. Goldstein also testified that "pomegranate juice has excellent basic science both in animal tissue and human tissue and excellent animal model data." (PX0352 (Goldstein, Dep. at 51)). Dr. Goldstein opined that POM's "strong *in vitro* and *in vivo* studies . . . suggest a probable benefit of pomegranate juice on erectile health," and that "in and of itself has shown huge pieces of information that will be helpful in understanding how it works in humans . . . ." (PX0189-0013; Goldstein, Tr. 2642 ("[I]n general, in the field of erectile function and dysfunction, preclinical studies have managed to mimic how agents work in a human being.") Moreover, Dr. Goldstein opined that the large body of basic science supports the mechanism by which consuming pomegranate juice promotes

erectile health—*i.e.*, "through the data that pomegranate juice possesses antioxidant properties, antioxidants help maintain endothelial health, endothelial health is strongly associated with erectile health, and therefore, pomegranate juice helps to maintain erectile health." (PX0189-0003, 0008-0009; PX0190-0006).

Moreover, Complaint Counsel's expert, Dr. Melman, testified that based on the results of his gene therapy erectile dysfunction product in an animal model, he was "personally satisfied" that it would also work in humans. (PX0360 (Melman, Dep. at 56-57)).

1084. While nitric oxide plays an important role in erectile function, nitric oxide alone does not produce erections. Many types of cells and molecules, in addition to nitric oxide, participate in the erection process. (CX1289 (Melman, Report at 0005-07); Melman, Tr. 1088-90; *see also* Burnett, Tr. 2274-75 (agreeing that the erection process involves many different molecules and pathways)). Diagnosis of erectile dysfunction does not necessarily mean that there is a corresponding loss of nitric oxide production. (Burnett, Tr. 2276-77).

Response to Finding No. 1084:

Respondents object to Complaint Counsel's attempt to understate the importance of nitric oxide ("NO") molecule in the erectile process. While many types of molecules participate in the erection process, NO "is the key molecule that governs penile erection," and is "known to be of paramount importance in the maintenance of good erectile function." (RFF 2068; PX0149-0004; Burnett, Tr. 2249-50, 2276; PX0190-0006). In fact, Complaint Counsel's own erectile expert, Dr. Melman, testified that NO employs a critical role in the erectile process. (RFF 2069; Melman, Tr. 1169). Dr. Melman also testified that there are men whose erectile dysfunction is caused by the inadequate production of NO. (PX0360 (Melman, Dep. at 32)).

1085. Basic research studies about antioxidants' effects on nitric oxide levels may relate to the biochemical process for erectile function. (CX1289 (Melman, Report at 0017-18)). However, such studies do not directly involve erectile function in humans and cannot alone prove that POM Juice treats, prevents, or reduces the risk of erectile dysfunction in humans. (CX1289 (Melman, Report at 0017-18)).

3. Analysis of the Challenged Erectile Dysfunction Claims in Light of the Scientific Evidence

a. Expert Analysis

Response to Finding No. 1085:

Complaint Counsel's proposed finding is conclusory. As explained by Respondents' world renown nitric oxide ("NO") expert, Dr. Burnett, POM's basic science alone "support[s] the potential benefit at the human level to improve the physiology of erectile tissue preserving erect tissue health." (RFF 2019, 2020, 2103-06; PX0149-0003,0005; PX0349 (Burnett, Dep. at 103, 112, 116-118)). Dr Burnett, whose lab was also instrumental in describing NO as a physiologic mediator of penile erection and the mechanism of NO-dependent penile erection, (PX0149-0005; PX0349 (Burnett, Dep. at 89)), stated in his expert report that "basic scientific evidence exists that establishes that pomegranate juice possesses potent anti-oxidative molecular effects and these effects operate by activating endothelial NO mechanisms in vasculature [structures involved in human penile erection]." (RFF 2093; PX0149-0005-0006). Moreover, Dr. Burnett testified that "animal studies are very informative to the extent that some of the basic physiology is there . . . [and it] can characterize what's going on at the human level." (PX0349 (Burnett, Dep. at 111)). Dr. Burnett also testified that POM's basic science alone:

> "provide powerful support for pomegranate juice. . . as antioxidants; that they work with very potent effects on the nitric oxide regulatory mechanism; that there's evidence that they do demonstrate antioxidant effects on genes that have to do with the oxidative stress mechanisms and the nitric oxide release mechanisms; that there is evidence that these agents do reduce some of the pathophysiologic effects at the tissue level including structural changes on the tissue in terms of atherosclerosis, that is, hardening of vessels that leads to the functional changes where the tissue is not able to properly relax and is consistent with how the blood vessels have to dilate and allow blood flow to occur within target organs."

(PX0349 (Burnett, Dep. at 116)).

Dr. Burnett further testified that he believes pomegranate juice has a "potential benefit on the basis of animal studies or *in vitro* studies to likely improve one's erection physiology," not just maintain it. (Burnett, Tr., 2262-63) (emphasis added). To that end, Dr. Burnett testified that which helps erectile function may also help improve one's erectile dysfunction. (Burnett, Tr., 2303).

Dr. Goldstein also testified that "pomegranate juice has excellent basic science both in animal tissue and human tissue and excellent animal model data." (PX0352 (Goldstein, Dep. at 51)). Dr. Goldstein opined that POM's "strong *in vitro* and *in vivo* studies . . . suggest a probable benefit of pomegranate juice on erectile health," and that "in and of itself has shown huge pieces of information that will be helpful in understanding how it works in humans . . . ." (PX0189-0013; Goldstein, Tr. 2642 ("[I]n general, in the field of erectile function and dysfunction, preclinical studies have managed to mimic how agents work in a human being.") Moreover, Dr. Goldstein opined that the large body of basic science supports the mechanism by which consuming pomegranate juice promotes erectile health—*i.e.*, "through the data that pomegranate juice possesses antioxidant properties, antioxidants help maintain endothelial health, endothelial health is strongly associated with erectile health, and therefore, pomegranate juice helps to maintain erectile health." (PX0189-0003, 0008-0009; PX0190-0006).

Moreover, Complaint Counsel's expert, Dr. Melman, testified that based on the results of his gene therapy erectile dysfunction product in an animal model, he was "personally satisfied" that it would also work in humans. (PX0360 (Melman, Dep. at 56-57)).

1086. Dr. Melman concluded that neither the Forest Erectile Dysfunction Study (2007) nor the unpublished data from the Davidson BART/FMD Study support a claim that drinking eight ounces of POM Juice daily treats, prevents, or reduces the risk of erectile dysfunction in humans. (Melman, Tr. 1118-19; CX1289 (Melman, Report at 0016-18)).

Response to Finding No. 1086:

Respondents object to this proposed finding. Dr. Goldstein testified that the *Forest/Padma-Nathan RCT Study* to be "suggestive evidence that use of pomegranate juice would benefit the patient with erectile dysfunction." (PX0352 (Goldstein, Dep. at 34)). He testified that the study is "[a]bsolutely" clinically significant and "extremely relevant" and would take its results "to the bank." (RFF 1986, 2098-99; PX0189-0013; Goldstein, Tr. 2598-99, 2605, 2608; PX0352 (Goldstein, Dep. at 34-47, 105-109)). Indeed, Dr. Burnett also testified that the *Forest/Padma-Nathan RCT Study* demonstrates pomegranate juice is "a potential treatment for ED." (RFF 1987; PX0349 (Burnett, Dep. at 142); Burnett, Tr. 2298). Moreover, Dr. Burnett testified that the results of the *Forest/Padma-Nathan RCT Study* provides support that pomegranate juice "may be an intervention that would complement conventional ED treatment, and [he] would support its use by patients." (Burnett, Tr. 2298). Based on this clinical study and the competent and reliable basic science, Dr. Goldstein therefore testified that he "would strongly suggest and encourage" use of pomegranate juice to treat/improve ED in a subpopulation of men who have had an insufficient response to PDE5 inhibitors (like Viagra, Levitra and Cialis) and who wish to reestablish erectile function without invasive or mechanical technology or therapies. (PX0352 (Goldstein, Dep. at 37-42, 46)). Dr. Goldstein believes that "there are patients in whom there are erectile dysfunction and/or erectile health problems related to inflammatory endothelial dysfunctions, and . . . that pomegranate juice has a logical context in the treatment of those patients." (PX0352 (Goldstein, Dep. at 80)). Dr. Goldstein also testified that based on the reasonable and competent science, he believes pomegranate juice reduces the risk of, or ameliorates erectile dysfunction in men caused by endothelial dysfunction or blood flow impairment or oxidative stress. (RFF 2119; Goldstein, Tr. 2605). In fact, Dr. Goldstein testified that he uses pomegranate juice in his own clinical practice. (PX0352 (Goldstein, Dep. at 34)).

Moreover, Dr. Heber testified that the *Forest/Padma-Nathan RCT Study* "could [not] be disregarded" and that "it is a positive in providing important scientific information consistent with the basic science that pomegranate juice may be helpful for men with erectile dysfunction." (Heber, Tr. 2001). Dr. Heber also testified that POM's competent and reliable science shows that pomegranate juice is likely to lessen the risk of erectile disease and enhance erectile function. (Heber, Tr. 2012). Finally, Dr. Padma-Nathan, the principal investigator of the *Forest/Padma-Nathan RCT Study*, testified that the "study concluded that [pomegranate juice has] a potential benefit" on erectile dysfunction. (CX1338 (Padma-Nathan, Dep. at 23, 184)).

Respondents further dispute that the characterization of the Davidson BART/FMD Study as one that looked at erectile dysfunction-related endpoints. The Davidson BART/FMD Study was primarily a cardiovascular study and therefore its protocols did not include any of the type of inclusion or exclusion criteria one would expect to see in even a basic ED clinical trial. (RFF 2188; CX0716; PX0019; Melman, Tr. 1092). In fact, the ED findings in the Davidson BART/FMD Study were flawed as one of the two study sites was unable to collect any data for the baseline IIEF measurement. (RFF 2189; CX0654_0001 – "IIEF data not collected on most subjects at site 2; Mary Sue was aware of this and site staff reported that subjects are uncomfortable completing this questionnaire in the office (close quarters) so they tried to send it to them prior to their visit for them to bring in completed, yet it still was incomplete. Unfortunately, this baseline data will be missing.") (emphasis added).

1087. Dr. Melman stated that aside from the Forest Erectile Dysfunction Study (2007), he did not find any other published human clinical study investigating the efficacy of POM Juice, or any other pomegranate product, in treating, preventing, or reducing the risk of erectile dysfunction in humans. (Melman, Tr. 1129; CX1289 (Melman, Report at 0016)).

Response to Finding No. 1087:

In addition to the *Forest/Padma-Nathan RCT Study*, a significant body of erectile scientific literature, including human clinical studies, also support the validity of the mechanisms of action by which pomegranate juice promotes erectile function, *i.e.*, antioxidant activity augmenting the biologic actions of nitric oxide. (RFF 1988-1991; PX0189-0003, 0013; PX0352 (Goldstein, Dep. at 100-101)). For example, Dr. Esposito's clinical study entitled *Dietary Factors, Mediterranean Diet and Erectile Dysfunction*, showed that the adoption of the Mediterranean diet—which pomegranate juice is consistent with—for two years by obese men with erectile dysfunction had statistically significant improvement in their erectile dysfunction score compared to men in the control group. (RFF 1990; PX0190; Goldstein, Tr. 2641-42; PX0352 (Goldstein, Dep. at 134-135); PX0189-0013). Moreover, Dr. Goldstein also testified that a study involving the treatment of ED with antioxidants, entitled *Endothelial antioxidant administration ameliorates the erectile response to PDE5 regardless of the extension of the atherosclerotic process* (published in the Journal of Sexual Medicine in 2010), also showed clinical statistical significance in men. (PX0352 (Goldstein, Dep. at 81, 82, 120, 162, 177)).

1088. Respondents' experts, Dr. Burnett and Dr. Goldstein, do not believe that POM Juice treats erectile dysfunction. Dr. Burnett would be concerned about relying on the Forest Erectile Dysfunction Study (2007) to conclude that POM Juice is efficacious in treating erectile dysfunction and would want additional data. (Burnett, Tr. 2298). Dr. Burnett agreed with Dr. Melman that there was insufficient evidence to conclude that drinking eight ounces of POM Juice daily treats, prevents, or reduces the risk of erectile dysfunction in humans. (Burnett, Tr. 2274 (agreeing that prevention is the same as reducing the risk)).

Response to Finding No. 1088:

Complaint Counsel have grossly mischaracterized Dr. Burnett and Dr. Goldstein's testimony regarding pomegranate juice's affect on erectile health, function and dysfunction.

Dr. Goldstein testified that there is "without a question" competent and reliable science showing that pomegranate juice provides a benefit to erectile health and erectile function. (Goldstein, Tr. 2605, 2608). To that end, Dr. Goldstein testified that he would strongly suggest and encourage the use of pomegranate juice for men with endothelial related erectile dysfunction who have had an insufficient response to PDE5 inhibitors (*i.e.*, Viagra, Levitra and Cialis) and who are unwilling to consider invasive or mechanical therapies. (PX0352 (Goldstein, Dep. at 37-42, 80); Goldstein, Tr. 2609). Dr. Goldstein testified that "pomegranate juice has evidence for dealing with the underlying pathophysiology [of endothelial-related erectile dysfunction], and antioxidants like pomegranate juice have shown [statistically significant] benefit in treating men who have similar situations." (PX0352 (Goldstein, Dep. at 42); Goldstein, Tr. 2641). In fact, Dr. Goldstein uses and "personally recommends" pomegranate juice in his own clinical practice. (PX0352 (Goldstein, Dep. at 34); Goldstein, Tr. 2609).

Dr. Burnett also testified that based on POM's basic science and human clinical study, he "believe[s] that [pomegranate juice] has a likely beneficial effect on erectile function," and that it is "a potential treatment for ED." (PX0349 (Burnett, Dep. at 60); Burnett, Tr. 2255-56)). Moreover, Dr. Burnett testified that he "[m]ost certainly" believes that if a man has erectile dysfunction and does something that improves his erectile function, he has thereby helped his erectile dysfunction. (Burnett, Tr. 2303). To that end, Dr. Burnett testified that pomegranate juice "could be a treatment [to erectile dysfunction] in the sense that it offers some potential health benefits." (Burnett, Tr. 2312) (Dr. Burnett testified that "treatment can have different meanings behind it, and treatment in the context of a pharmaceutical drug that is approved by the FDA as an intervention for a disease state, that may have a different meaning for treatment than the broad term of treatment, which is to intervene for a condition.")

In the preventive context, Dr. Goldstein testified that he "would personally suggest to a patient to use pomegranate juice" who would appear to have the earliest signs of endothelial related erectile dysfunction. (PX0352 (Goldstein, Dep. at 43-44); Goldstein, Tr. 2609). Dr. Goldstein also noted, that in this context, pomegranate juice costs far less than Viagra and "there is no side effects to taking pomegranate juice . . . And there is substantial scientific data that it can counter the inflammatory endothelial problems and there's suggestive evidence, based on one clinical trial, that people improved their erectile function." (PX0352 (Goldstein, Dep. at 44, 157) ("So exposure of your body to antioxidants would, if you had erectile health, arguably, hypothetically, prophylax the development of an erectile problem.")

Dr. Burnett also testified that if prevention means "something that potentially has a risk modification benefit, that may help preserve erectile function" then, he thinks there is competent and reliable scientific evidence "that pomegranate juice has that potential role" of prevention. (Burnett, Tr. 2301; 2272-73 ("I don't think there's a therapy out there in the world of sexual medicine that we've established as of yet to be a true preventative intervention for erectile dysfunction. We do think there are various sorts of interventions that we believe likely have some potential benefit, anything from dietary changes to weight loss and perhaps things that we're still evaluating, but we're not sure really have a role, but because they seem to be potentially beneficial and do not necessarily have harms and likely have benefits, that we feel comfortable in promoting.")

Finally, Dr. Goldstein testified that reasonable and competent science shows that pomegranate juice "reduces the risk" of or ameliorates erectile dysfunction caused by endothelial dysfunction or blood flow impairment or oxidative stress. (Goldstein, Tr. 2605; PX0352 (Goldstein, Dep. at 46-47) (there is substantial evidence that pomegranate juice reduces the risk of endothelial related erectile dysfunction, which is the underlying mechanism of dysfunction for many patients who lose erectile health).

1089. Likewise, Dr. Goldstein did not testify that the Forest Erectile Dysfunction Study (2007) proves that POM Juice treats erectile dysfunction. (Goldstein, Tr. 2611 (stating that he does not propose that pomegranate juice is a treatment for erectile dysfunction); *see also* Goldstein, Tr. 2627-28 (noting that he was an author of an article published in 2011 evaluating the results of randomized clinical trials on the use of ginseng and yohimbine to treat erectile dysfunction)).

Response to Finding No. 1089:

Dr. Goldstein testified that the *Forest/Padma-Nathan RCT Study* to be "suggestive evidence that use of pomegranate juice would benefit the patient with erectile dysfunction." (PX0352 (Goldstein, Dep. at 34)). Based on this clinical study and the competent and reliable basic science, Dr. Goldstein therefore testified that he "would strongly suggest and encourage" use of pomegranate juice to treat/improve ED in a subpopulation of men who have had an insufficient response to PDE5 inhibitors (like Viagra, Levitra and Cialis) and who wish to reestablish erectile function without invasive or mechanical technology or therapies. (PX0352 (Goldstein, Dep. at 37-42, 46)). Dr. Goldstein believes that "there are patients in whom there are erectile dysfunction and/or erectile health problems related to inflammatory endothelial dysfunctions, and . . . that pomegranate juice has a logical context in the treatment of those patients." (PX0352 (Goldstein, Dep. at 80)). Dr. Goldstein also testified that based on the reasonable and competent science, he believes pomegranate juice reduces the risk of, or ameliorates erectile dysfunction in men caused by endothelial dysfunction or blood flow impairment or oxidative stress. (RFF 2119; Goldstein, Tr. 2605).

Furthermore, Complaint Counsel's reference to Dr. Goldstein's article regarding yohimbine and ginseng is entirely misplaced and does not support their proposed finding. Nonetheless, although the evidence cited is irrelevant to their proposed finding, it is worth noting that Dr. Goldstein testified that RCTs would be useful for yohimbine and ginseng because they "have been viewed as pharmaceuticals." (Goldstein, Tr. 2628). Dr. Goldstein testified that, for example, yohimbine is an "alpha-2 receptor blocker" and is

therefore "clearly a pharmaceutical agent." (Goldstein, Tr. 2628). Indeed, Complaint Counsel's expert, Dr. Melman agreed yohimbine is a "drug" and "if not taken properly, could be harmful." (PX0360 (Melman, Dep. at 127-128)) (emphasis added). On cross-examination, Dr. Goldstein also testified that acupuncture would need a RCT in order to prove efficacy in treating ED because there are "adverse effects from acupuncture . . . . " (Goldstein, Tr. 2623-2624). Dr. Goldstein further testified there is "no parallel" between "pomegranate juice safety to acupuncture safety. . . it's oil and water." (Goldstein, Tr. 2624).

1090. Dr. Goldstein considered the Forest Erectile Dysfunction Study (2007) to be "suggestive evidence that use of pomegranate juice would benefit the patient with erectile dysfunction," but does not recommend POM Juice as a treatment for erectile dysfunction. (Goldstein, Tr. 2607, 2611 (stating also that he would "not suggest[] that pomegranate juice is going to replace Viagra or is consistent with the pharmaceutical evidence for treatment of erectile dysfunction"); PX0352 (Goldstein, Dep. at 34, 120) (noting that the Forest Erectile Dysfunction Study (2007) was the only human clinical study investigating the effects of pomegranate juice in treating erectile dysfunction he relied on)).

Response to Finding No. 1090:

Dr. Goldstein testified that the *Forest/Padma-Nathan RCT Study* to be "suggestive evidence that use of pomegranate juice would benefit the patient with erectile dysfunction." (PX0352 (Goldstein, Dep. at 34)). He testified that the study is "[a]bsolutely" clinically significant and "extremely relevant" and "would take that to the bank." (PX0352 (Goldstein, Dep. at 106, 108-109)). Indeed, Dr. Burnett also testified that the *Forest/Padma-Nathan RCT Study* demonstrates pomegranate juice is "a potential treatment for ED." (RFF 1987; PX0349 (Burnett, Dep. at 142); Burnett, Tr. 2298). Moreover, Dr. Burnett testified that the results of the *Forest/Padma-Nathan RCT Study* provides support that pomegranate juice "may be an intervention that would complement conventional ED treatment, and [he] would support its use by patients." (Burnett, Tr. 2298).Based on this clinical study and the competent and reliable basic science, Dr. Goldstein therefore testified that he "would strongly suggest and encourage" use of

pomegranate juice to treat/improve ED in a subpopulation of men who have had an insufficient response to PDE5 inhibitors (like Viagra, Levitra and Cialis) and who wish to reestablish erectile function without invasive or mechanical technology or therapies. (PX0352 (Goldstein, Dep. at 37-42, 46)). Dr. Goldstein believes that "there are patients in whom there are erectile dysfunction and/or erectile health problems related to inflammatory endothelial dysfunctions, and . . . that pomegranate juice has a logical context in the treatment of those patients." (PX0352 (Goldstein, Dep. at 80)). In fact, Dr. Goldstein testified that he uses pomegranate juice in his own clinical practice. PX0352 (Goldstein, Dep. at 34)).

In addition to the *Forest/Padma-Nathan RCT Study*, Dr. Goldstein testified there is a significant body of erectile scientific literature, including human clinical studies, that also support the validity of the mechanisms of action by which pomegranate juice promotes erectile function, *i.e.*, antioxidant activity augmenting the biologic actions of nitric oxide. (RFF 1988-1991; PX0189-0003, 0013; PX0352 (Goldstein, Dep. at 100-101)). For example, Dr. Esposito's clinical study entitled *Dietary Factors, Mediterranean Diet and Erectile Dysfunction*, showed that the adoption of the Mediterranean diet—which pomegranate juice is consistent with—for two years by obese men with erectile dysfunction had statistically significant improvement in their erectile dysfunction score compared to men in the control group. (RFF 1990; PX0190; Goldstein, Tr. 2641-42; PX0352 (Goldstein, Dep. at 134-135); PX0189-0013). Moreover, Dr. Goldstein also testified that a study involving the treatment of ED with antioxidants, entitled *Endothelial antioxidant administration ameliorates the erectile response to PDE5 regardless of the extension of the atherosclerotic process* (published in the Journal of Sexual Medicine in 2010), also showed clinical statistical significance in men. (PX0352 (Goldstein, Dep. at 81, 82, 120, 162, 177)).

1091. Both Dr. Goldstein and Dr. Burnett distinguished between erectile dysfunction and erectile health. (Burnett, Tr. 2259-61; PX0352 (Goldstein, Dep. at 31-32); PX0189

(Goldstein, Report at 0008)). Erectile dysfunction is the recognized clinical disorder while erectile health refers to interventions that have a benefit to erectile function. (Burnett, Tr. 2260-61; PX0352 (Goldstein, Dep. at 31-32); PX0189 (Goldstein, Report at 0008)).

Response to Finding No. 1091:

Complaint Counsel have mischaracterized Dr. Burnett and Dr. Goldstein's testimony regarding erectile heath. "Erectile health is having a healthy erectile mechanism." (RFF 2047; PX0189-0008; PX0349 (Burnett, Dep. at 59)) (Erectile health means "the general overall wellness of the erectile tissue, the physiology of the tissue to be as functional as possible . . . ."). Erectile health is promoted when the male practices strategies that encourage endothelial health. (RFF 2048; PX0352 (Goldstein, Dep. at 148); PX0189-0008). "Erectile health is distinguished from erectile dysfunction, which is the loss of erectile health." (RFF 2049; PX0189-0008). Erectile dysfunction is the consistent or persistent inability to obtain and/or sustain an erection adequate for sexual intercourse. (RFF 2051; PX0189-0008-0009).

1092. Dr. Burnett believes that POM Juice can be a complimentary therapy for erectile health, but does not endorse POM Juice as a "primary intervention." (Burnett, Tr. 2298, 2313 (stating that he would support patients' use of pomegranate juice as a complement to conventional erectile dysfunction treatments); PX0149 (Burnett, Report at 0006) (stating that although pomegranate juice has a "potential benefit for vascular blood flow and vascular health of the penis[,] . . . drinking pomegranate juice is not advocated as an alternative to following medical advice")).

Response to Finding No. 1092:

The evidence and parenthetical information cited by Complaint Counsel contradict the proposed finding that Dr. Burnett believes POM Juice to be a complimentary therapy for "erectile health." As the parenthetical itself notes, Dr. Burnett would support patients' use of pomegranate juice as a complement to "erectile dysfunction" treatments—not "erectile health." (Burnett, Tr. 2298; PX0349 (Burnett, Dep. at 78-79)) ("To the extent that any intervention out there has some potential benefit of a better a better benefit than harm that meets some level of safety, I would support that intervention, at least as a

complimentary intervention and not a mainstay of ED treatment.") Indeed, Dr. Burnett testified that the results of the *Forest/Padma-Nathan RCT Study* provides support that pomegranate juice "may be an intervention that would complement conventional ED treatment, and [he] would support its use by patients." (Burnett, Tr. 2298).

1093. As part of an overall strategy to promote erectile health, Dr. Goldstein recommends POM Juice along with exercise and the Mediterranean diet, which is a low fat diet based on eating fruits, vegetables, fish, nuts, whole grains, and wine, for two specific subpopulations: 1) people who have erectile dysfunction, but for whom PDE-5 inhibitors (such as Viagra, Levitra, and Cialis) do not work and do not want more invasive therapies, and 2) people who do not have erectile dysfunction, but have experienced a loss in erectile health. (Goldstein, Tr. 2608-09, 2637-40; PX0189 (Goldstein, Report at 0008, 0014-15)).

Response to Finding No. 1093:

Dr. Goldstein opined that erectile health is promoted overall when the "man practices strategies that encourage endothelial health" which include exercise and the Mediterranean diet, which pomegranate juice is a part of. (PX0189-0008).

Dr. Goldstein also testified that he would strongly suggest and encourage the use of the Mediterranean diet, which pomegranate juice is part of, for men with endothelial related erectile dysfunction who have had an insufficient response to PDE5 inhibitors (*i.e.*, Viagra, Levitra and Cialis) and who are unwilling to consider invasive or mechanical therapies. (PX0352 (Goldstein, Dep. at 37-42, 80); Goldstein, Tr. 2609). Dr. Goldstein testified that "pomegranate juice has evidence for dealing with the underlying pathophysiology [of endothelial-related erectile dysfunction], and antioxidants like pomegranate juice have shown [statistically significant] benefit in treating men who have similar situations." (PX0352 (Goldstein, Dep. at 42); Goldstein, Tr. 2641) Dr. Goldstein further testified that he "would personally suggest to a patient to use pomegranate juice" who would appear to have the earliest signs of endothelial related erectile dysfunction. (PX0352 (Goldstein, Dep. at 43-44); Goldstein, Tr. 2609; PX0189-0014).

1094. Dr. Goldstein testified that his recommendation of pomegranate juice to promote erectile health would be made in the context of the doctor-patient relationship only. (Goldstein, Tr. 2638-39; PX0352 (Goldstein, Dep. at 158) (stating that "the use of pomegranate juice in this context requires dialogue with a healthcare provider")). In the doctor-patient relationship, the doctor can evaluate the patient's overall health, monitor progress, and provide guidance on any side effects. (Goldstein, Tr. 2638).

Response to Finding No. 1094:

Complaint Counsel have mischaracterized Dr. Goldstein's testimony regarding the context in which he would recommend a dialogue with a healthcare provider. Dr. Goldstein testified a dialogue with a healthcare provider would be recommended under two selected clinical settings: 1) where a patient has experienced a loss in erectile health, but does not have erectile dysfunction yet, and wants to know what they can do safely to keep their erectile health, especially where they have a family history of erectile dysfunction; (PX0382 (Goldstein, Dep. at 157-158)), and 2) where a patient has erectile dysfunction and first line therapies have not worked for him, and they do not want more invasive therapies as they are risk aversive and want a more positive risk-benefit ratio. (PX0382 (Goldstein, Dep. at 159)). Dr. Goldstein never testified that one should consult with a physician prior to drinking a safe healthy pure fruit juice as Complaint Counsel suggest.

1095. As Dr. Goldstein so aptly stated: "[T]he use of pomegranate juice in this context requires dialogue with a healthcare provider. This is not somebody who just goes to . . . a supermarket and just drinks pomegranate juice for no reason. This would be done in a context of a dialogue with the patient and a physician who understood the sexual issues of that person." (PX0352 (Goldstein, Dep. at 158); Goldstein, Tr. at 2639).

Response to Finding No. 1095:

Complaint Counsel have mischaracterized Dr. Goldstein's testimony regarding the context in which he would recommend a dialogue with a healthcare provider. Dr. Goldstein testified a dialogue with a healthcare provider would be recommended under two selected clinical settings: 1) where a patient has experienced a loss in erectile health, but does not have erectile dysfunction yet, and wants to know what they can do

safely to keep their erectile health, especially where they have a family history of erectile dysfunction; (PX0382 (Goldstein, Dep. at 157-158)), and 2) where a patient has erectile dysfunction and first line therapies have not worked for him, and they do not want more invasive therapies as they are risk aversive and want a more positive risk-benefit ratio. (PX0382 (Goldstein, Dep. at 159)). Dr. Goldstein never testified that one should consult with a physician prior to drinking a safe and healthy pure fruit juice as Complaint Counsel suggest.

b. Respondents' Awareness of Inadequate Evidence

1096. POM's 2009 Medical Research Portfolio Review on erectile dysfunction clearly shows Respondents knew they did not have enough science to make treat, prevent, or reduce the risk of erectile dysfunction claims. The summary listed only one published human study in the erectile dysfunction / sexual function area, the Forest Erectile Dysfunction Study (2007). The summary acknowledged that the study "has limitations: it was small (n=53) and just missed statistical significance (p=0.058)" and that POM's results compared to placebo in its small study of 53 patients (under 50% improvement) paled in comparison to drug benchmarks (*e.g.*, Cialis and Viagra studies of between 200 and 500 patients showed a nearly 300% improvement over placebo). (CX1029_0013; *see also* CX0128_0003 (POM press release stating that the Forest Erectile Dysfunction Study (2007) "did not achieve overall statistical significance")). Respondents posited that they could "explore 1 larger ED clinical study to achieve statistical significance and stronger marketing value." (CX1029_0013).

Response to Finding No. 1096:

Respondents object to the characterization of POM's January 13, 2009 Medical Research Portfolio Review (CX1029_0013) and press release (CX0128_0003), the contents of which speak for itself. Moreover, the evidence cited does not support the proposition that - "Respondents knew they did not have enough science to make treat, prevent, or reduce the risk of erectile dysfunction claims." Rather, POM possesses competent and reliable scientific evidence that support erectile claims much stronger than those actually made in its advertisements, *i.e.*, claims that drinking pomegranate juice can improve one's erection, as well as "treat," "prevent," and "reduce the risk of" ED in certain men. (RRFF 764, 1085, 1088).

Moreover, although statistical significance was not reached in the *Forest/Padma-Nathan RCT Study*, Respondents' experts testified there was "significant clinical findings in this study." (RFF 1986; PX0189-0013; PX0149-0006; CX0908; Heber, Tr. 1979, 2001; Goldstein, Tr. 2598-99; PX0352 (Goldstein, Dep. at 105-109, 116); Burnett, Tr. 2256; PX0349 (Burnett, Dep. at 138-139); CX1350 (Liker, Dep. at 190-191)).

Particularly, Dr. Goldstein, testified that the *Forest/Padma-Nathan RCT Study* "provides very valuable information" regarding erectile health and function and is absolutely "clinically significant because "it supports the conclusion that the positive results in the basic science are borne out in human function." (RFF 1986, 2098-99; PX0189-0013; Goldstein, Tr. 2598-99, 2605, 2608; PX0352 (Goldstein, Dep. at 34-47, 105-109)). Dr. Goldstein also testified that the study is clinically significant because it proved pomegranate juice was safe, unlike pharmaceutical ED drugs. (PX0352 (Goldstein, Dep. at 106, 109, 178)). Dr. Goldstein also testified that *Forest/Padma-Nathan RCT Study* "is of extreme relevance to the clinician and consumer" and is "suggestive evidence that use of pomegranate juice would benefit [a] patient with erectile dysfunction." (RFF 2098-99; PX0189-0014; Goldstein, Tr. 2605; PX0352 (Goldstein, Dep. at 34, 105-106)). Overall, Dr. Goldstein said that he would take the results of the study "to the bank." (PX0352 (Goldstein, Dep. at 105-106)).

Similarly, Dr. Burnett mirrored Dr. Goldstein's views. Dr. Burnett opined that the *Forest/Padma-Nathan RCT Study* supports the conclusion that pomegranate juice has a beneficial effect on erectile tissue physiology, health, and function, and is "a potential treatment for ED." (RFF 1986-87, 2100-2106; PX0149-0006; Burnett, Tr. 2255-56; PX0349 (Burnett, Dep. at 103, 112, 116-118, 138-139, 142)). Moreover, Dr. Burnett testified that pomegranate juice studies, *i.e.*, the *Forest/Padma-Nathan RCT Study*, do not need to reach statistical significance in order to communicate its benefits to consumers. (Burnett, Tr. 2305-06; PX0149-0006-0007).

Moreover, Dr. Heber similarly testified that the *Forest/Padma-Nathan RCT Study* "could [not] be disregarded" and that "it is a positive in providing important scientific information consistent with the basic science that pomegranate juice may be helpful for men with erectile dysfunction." (Heber, Tr. 2001). Dr. Heber also testified that POM's competent and reliable science shows that pomegranate juice is likely to lessen the risk of erectile disease and enhance erectile function. (Heber, Tr. 2012). Finally, Dr. Padma-Nathan, the principal investigator of the *Forest/Padma-Nathan RCT Study*, testified that the "study concluded that [pomegranate juice has] a potential benefit" on erectile dysfunction. (CX1338 (Padma-Nathan, Dep. at 23, 184)).

1097. In July 2009, Respondents' Vice President of Clinical Development, Dr. Gillespie, prepared discussion points and brief summaries of POM's past research efforts, for a medical research review meeting. (CX1081_0001). Dr. Gillespie's July 2009 research summary acknowledged that although results from one endpoint in the Forest Erectile Dysfunction Study (2007) "trended towards improvement" versus the placebo, in the end, "the primary endpoints were not met in this trial" and "the study failed to meet its objectives." (CX1081_0006). Dr. Gillespie also noted that "the design of this study may have been flawed" and that a consultant had identified problems with the study's crossover design, population, questionnaire, and duration. (CX1081_0006; *see also* CX1039_0002 (summary assessment of study)).

Response to Finding No. 1097:

Respondents object to the characterization of the July 2009 research summaries, the content of which speaks for itself.

1098. Dr. Gillespie concluded in his July 2009 research summary: "It will be difficult to further publicize existing [erectile dysfunction] data as it is relatively weak, and not fresh." (CX1081_0006).

Response to Finding No. 1098:

Respondents object to the characterization of the July 2009 research summaries, the content of which speaks for itself.

1099.

(CX1152_0005, 0021, *in camera*). As of January 2011, POM had not finished planning this study. (CX1349 (Gillespie, Dep. at 182)).

Response to Finding No. 1099:

Respondents have no specific response.

1100. Despite the internal assessment from Dr. Gillespie, Mr. Tupper testified that with respect to erectile dysfunction, he would give POM's science an eight out of ten, moving to ten out of ten. POM would not be pursuing a drug registration with FDA if it didn't feel its science was extraordinarily strong and positive. (Tupper, Tr. 3013-14).

Response to Finding No. 1100:

Respondents have no specific response.

1101. POM has continued to advertise erectile dysfunction claims for POMx and POM Juice from at least April 2009 to as late as July 2010, citing efficacy data from the Forest Erectile Dysfunction Study (2007). (CCFF ¶¶ 425, 447).

Response to Finding No. 1101:

Respondents dispute that POM made "prevent," "treat," or "reduces the risk" of erectile dysfunction claims, and object to Complaint Counsel's characterization of the evidence cited, the content of which speaks for itself. Nowhere in the ad that Complaint Counsel cites in its proposed finding (CCFF No. 425 – "The Only Antioxidant Supplement Rated X") do Respondents expressly (*i.e.*, unequivocally and directly) state that (a) taking one POMx Pill per day "prevents," "treats," or "reduces the risk" of erectile dysfunction; or (b) taking one POMx Pill per day is "clinically proven" to "prevent," "treat," or "reduce the risk" of erectile dysfunction. (CX0351_0001). Indeed, the only phrasing referring to "erectile dysfunction" relates to a direct quote from the *Forest/Padma-Nathan RCT Study* which stated verbatim that "POM has potential in the management of ED…further studies are warranted." (CX0351_0001). Accurately summarizing and quoting the highly qualified results of a published scientific study about preliminary and potential benefits cannot convey the net impression that using the Challenged Products treats,

prevents, or reduces the risk of ED, or that they are clinically proven to do so without qualification. (PX0158-0024). The net impression of such ads mentioning "erectile dysfunction", if any, is that the product "could" or "may help" reduce the risk of erectile dysfunction, like a healthy diet of fruits and vegetables and exercise reduce the risk of disease, and not like a drug reduces the risk of disease. (RFF 2211(i)). Moreover, the language of the ad itself uses such qualifiers as "preliminary," "promising," "emerging science," "has potential" and specifically highlights that "further studies are warranted." (CX0351_0001). Respondents further object to proposed finding No. 1101 to the extent it suggests that Respondents would run the ad in the future; and Complaint Counsel have failed to present any such evidence. (Ad Appendix, ¶ 497)

F. Competent and Reliable Scientific Evidence Consisting of Well Conducted Randomized Clinical Trials (RCTs) Is the Appropriate Level of Substantiation for Respondents' Disease Benefit Claims and Respondents Lack This Level of Evidence

1. Experts in the Disease Disciplines at Issue and in the Field of Food Science Adopt the View That RCTs Are Required to Substantiate Disease Treatment or Prevention Claims for the POM Products

1102. According to experts in the fields of nutrition, cardiovascular disease, prostate cancer, and erectile function, claims that a food or supplement treats, prevents, or reduces the risk of heart disease, prostate cancer, or erectile dysfunction must be supported by data from well-designed, well-conducted, randomized, placebo-controlled, and double-blinded human clinical trials. (Sacks, Tr. at 1430-31; CX1291 (Sacks, Report at 0010-11) (heart disease); Stampfer, Tr. at 706-07, 718 (cardiovascular disease and prostate cancer; stating that "most scientists in the field of clinical trials, epidemiology, and the prevention of cardiovascular disease and prostate cancer would agree" that RCTs are required, because it "is what we teach in medical schools and schools of public health [and] write about in journals"); CX1293 (Stampfer, Report at 0009); Eastham, Tr. 1265-66 (prostate cancer; stating that this is the opinion shared by the bulk of the scientific community, based on his work on safety monitoring, scientific committees, and expert panels); and CX1287 (Eastham, Report at 1002) (prostate cancer); Melman Tr. 1092-1110; CX1289 (Melman, Report at 0008, 0012) (erectile dysfunction); Burnett, Tr. 2264 (RCTs are the standard of evidence for evaluating erectile dysfunction treatment); Goldstein, Tr. 2612-15 (articles that he has authored state that RCTs are the criterion standard for determining causality)).

Response to Finding No. 1102:

[Complaint Counsel's proposed finding is conclusory, ambiguous, and Respondents vehemently dispute they are making or have ever made "disease" claims. To the extent

Complaint Counsel states Respondents' science and claims center around antioxidants, Respondents do not dispute this and Respondents direct the ALJ to those sections of the Findings regarding the science and claims Respondents are making with regard to heart, prostate, and erectile health.

With that said, the evidence, both basic and clinical is strong that POM may have an effect on heart health, prostate health, and erectile health. For example, Professor Stampfer admitted that basic science can be enough to provide sufficient substantiation for a beneficial effect in humans. (RFF 569-582, 618-656, 1784-1792, 2122, 2123; PX0206-0010-0011, 0013; Miller Tr. 2194; Heber, Tr. 2086, 2149, 2182; CX1352 (Heber, Dep. at 243); PX192-0011,0037,0038,0047-0055; Burnett, Tr. 2255; PX0349 (Burnett, Dep. at 103, 116-118); PX0149-0006-0007).

Dr. Burnett similarly testified that POM's basic science alone "support[s] the potential benefit at the human level to improve the physiology of erectile tissue preserving erect tissue health." (RFF 2103-06; PX0149-0003,0005; PX0349 (Burnett, Dep. at 103, 112, 116-118)). Dr Burnett also opined in his expert report that "basic scientific evidence exists that establishes that pomegranate juice possesses potent anti-oxidative molecular effects and these effects operate by activating endothelial NO mechanisms in vasculature [structures involved in human penile erection]." (RFF 2093; PX0149-0005-0006). Dr. Burnett also testified that POM's basic science alone:

> "provide powerful support for pomegranate juice. . . as antioxidants; that they work with very potent effects on the nitric oxide regulatory mechanism; that there's evidence that they do demonstrate antioxidant effects on genes that have to do with the oxidative stress mechanisms and the nitric oxide release mechanisms; that there is evidence that these agents do reduce some of the pathophysiologic effects at the tissue level including structural changes on the tissue in terms of atherosclerosis, that is, hardening of vessels that leads to the functional changes where the tissue is not able to properly relax and is consistent with how the blood

> vessels have to dilate and allow blood flow to occur within target organs."

(PX0349 (Burnett, Dep. at 116)).

Dr. Burnett further testified that he believes pomegranate juice has a "potential benefit on the basis of animal studies or *in vitro* studies to likely improve one's erection physiology," not just maintain it. (Burnett, Tr., 2262-63) (emphasis added). To that end, Dr. Burnett testified that which helps erectile function may also help improve one's erectile dysfunction. (Burnett, Tr., 2303).

Similarly, Dr. Goldstein also testified that "pomegranate juice has excellent basic science both in animal tissue and human tissue and excellent animal model data." (PX0352 (Goldstein, Dep. at 51)). Dr. Goldstein opined that POM's "strong *in vitro* and *in vivo* studies . . . suggest a probable benefit of pomegranate juice on erectile health," and that "in and of itself has shown huge pieces of information that will be helpful in understanding how it works in humans . . . ." (PX0189-0013; Goldstein, Tr. 2642 ("[I]n general, in the field of erectile function and dysfunction, preclinical studies have managed to mimic how agents work in a human being.") Moreover, Dr. Goldstein opined that the large body of basic science supports the mechanism by which consuming pomegranate juice promotes erectile health—*i.e.*, "through the data that pomegranate juice possesses antioxidant properties, antioxidants help maintain endothelial health, endothelial health is strongly associated with erectile health, and therefore, pomegranate juice helps to maintain erectile health." (PX0189-0003, 0008-0009; PX0190-0006).

Additionally, Dr. Heber testified "that the scientific community believes that the research done by Dr. Ornish and Dr. Aviram and Dr. Davidson on the basis of the basic science does provide a significant scientific agreement" that pomegranate helps to reduce the risk of heart disease. (RFF 582; Heber, Tr. 2081).

Moreover, Complaint Counsel's cardio expert, Dr. Sacks, testified that *in vitro* studies can be competent and reliable evidence of an agent's effect on a particular mechanism. (RFF 576; Sacks, Tr. 1578; PX0361 (Sacks, Dep. at 123-124)).

Furthermore, Respondents' cardio expert, Dr. Ornish, opined that it is an extreme position to state that evidence from *in vitro* and animal studies should not be considered in determining the therapeutic value of an intervention. (RFF 574; PX0025-0007). He further opined that while there are limitations to extrapolating from *in vitro* and animal studies to human studies, it is false to say this research has no value in determining therapeutic efficacy. (RFF 575; PX0025-0007).

Additionally, Respondents' prostate expert, Dr. deKernion, testified that the *in vitro* and animal studies alone showed that pomegranate juice inhibited the growth of prostate cancer cells and actually killed them. (RFF 580; deKernion, Tr. 3044-45, 3120). Dr. Heber testified "that the scientific community believes that the research done by Dr. Ornish and Dr. Aviram and Dr. Davidson on the basis of the basic science does provide a significant scientific agreement" that pomegranate helps to reduce the risk of heart disease. (RFF 582; Heber, Tr. 2081).

Moreover, Complaint Counsel's experts agree with this position.. Dr. Sacks, Complaint Counsel's cardio expert, testified that he considers all levels of science in issuing national guidelines for the prevention or treatment of cardiovascular disease. (PX0361 (Sacks Dep. at 71)). Similarly, Complaint Counsel's erectile expert, Dr. Melman, testified that based on the results of his gene therapy erectile dysfunction product in an animal model, he was "personally satisfied" that it would also work in humans. (PX0360 (Melman, Dep. at 56-57)).

While data from RCTs may provide the best evidence of a causal relationship between a treatment and a disease outcome in a pharmaceutical drug, Respondents' experts and

Complaint Counsel's experts agree that RCTs are not required, nor even preferred to substantiate the health benefits of 100% natural, safe and healthy foods such as the Challenged Products. (RFF 569-744, 1184-1205, 1784-92, 2122, 2123; PX0149-0006-0007; Burnett, Tr. 2272-74, 2303 (testifying RCTs are not necessary to deal with studies of drinking pomegranate juice); PX0189-0003, 0014; PX0352 (Goldstein, Dep. at 50-52, 61); Goldstein, Tr. 2600-02, 2611, 2620 (testifying that pharmaceutical type trials should not be applied to nutraceuticals—"a natural food product [from a plant] with health benefits"); deKernion, Tr. 3060 (in the case of fruit juice such as POM Juice, that has low or no toxicity, it is not necessary to have a RCT, placebo-controlled test); Miller, Tr. 2194, 2201; PX0206-0010-0015; Heber, Tr. at 1948-50, 2056, 2166; PX0149-0006-0007; PX0025-0007; Sacks, Tr. 1545-46; PX0361 (Sacks, Dep. at 134-135); Stampfer, Tr. 830; CX1293_0029-0030; RX5007 to RPTB; PX0362 (Stampfer, Dep. at 73-79, 98)).

Complaint Counsel's designated expert on this matter, Professor Stampfer, testified that RCTs are not required to conclude a causal link regarding a nutrient and disease. (RFF 624-644; Stampfer, Tr. 830; PX0362 (Stampfer, Dep. at 73-79, 98)). Professor Stampfer further testified that in a nutritional context, a hypothesis about disease causation can, rarely, if ever, be directly tested in humans using the RCT design. (RFF 640; Stampfer, Tr. 832-33; PX0362 (Stampfer, Dep. at 73, 98); RX5007 to RPTB).

In his expert report, Professor Stampfer also admitted that he "believe[s] that it may be appropriate to use evidence short of randomized clinical trials for crafting public health recommendations regarding nutrient guidelines even when causality cannot be established, <u>because everyone eats and the public should be given advice based on the best evidence available</u>." (RFF 628; CX1293_0029-0030) (emphasis added).

Also, in a recently published article entitled "*Evidence-based criteria in the nutritional context*," Professor Stampfer opined that the general principles of evidence-based

nutrition "can provide a sufficient foundation for establishing nutrient requirements and dietary guidelines in the absence of RCTs for every nutrient and food group." (RFF 630; Stampfer, Tr. 831; RX5007 to RPTB) (opining that because RCT study designs may not be "available" (economically or scientifically) for nutrients, "nutrient related decisions could be made at a level of certainty somewhat below that required for drugs.") Professor Stampfer also noted that some of the intellectual fathers of evidence based medicine "stressed" that evidence based medicine was "'not restricted to randomized trials and meta-analyses.'" (RFF 643; RX5007 to RPTB). In the article, Professor Stampfer stated that "certain features of [evidence-based medicine] seem ill-suited to the nutrition context." (RFF 631; RX5007 to RPTB). He also opined that "to fail to act in the absence of conclusive RCT evidence increases the risk of forgoing benefits that might have been achieved with little risk and at low cost." (RFF 644; RX5007 to RPTB).

Professor Stampfer noted that some of the differences between the evaluation of drugs and nutrients are:

> "(i) medical interventions are designed to cure a disease not produced by their absence, while nutrients prevent dysfunction that would result from their inadequate intake; (ii) it is usually not plausible to summon clinical equipoise for basic nutrient effects, thus creating ethical impediments to many trials; (iii) drug effects are generally intended to be large with limited scope of action, while nutrient effects are typically polyvalent in scope and, in effect size, are typically within the "noise" range of biological variability; (iv) drug effects are tend to be monotonic, with response varying in proportion to dose, while nutrient effects are often of a sigmoid character, with useful response occurring only across a portion of the intake range; (v) drug effects can be tested against a non-exposed (placebo) contrast group, whereas it is impossible and/or unethical to attempt a zero intake group for nutrients; and (vi) therapeutic drugs are intended to be efficacious within a relatively short term while the impact of nutrients on the reduction of risk of chronic disease may require decades to

> demonstrate –a difference with significant implications for the feasibility of conducting pertinent RCTs."

(RFF 634; RX5007 to RPTB; PX0362 (Stampfer, Dep. at 78)) (emphasis added).

Additionally, Complaint Counsel's expert, Dr. Sacks, concedes that a causal influence can be demonstrated between an agent and its effect on humans without the use of RCTs. (RFF 647; PX0361 (Sacks, Dep. at 134-135)). Dr. Sacks testified that you do not need RCT trials to test the benefit of food categories that are included in a diet already tested, like the DASH diet, which includes pomegranates. (RFF 648; Sacks, Tr. 1545-46). Dr. Ornish noted that most of Dr. Sacks' published studies have been epidemiological and observational in nature, rather than RCTs, and include relatively small numbers of patients. (RFF 1186; PX0025-0007).

Respondents' expert, Dr. Miller, confirms that when a food product is safe, and where the claim or advertisement does not suggest that the product be used as a substitute for conventional medical care or treatment, then it is appropriate to look at the totality of the science (and in some cases, only basic science), and not require only RCTs, to substantiate health claims. (RFF 657-744; Miller, Tr. 2194, 2201; PX0206-0010-0015; Heber, Tr. at 1948-50, 2056, 2166; PX0149-0006-0007; Burnett, Tr. 2272-74, 2303; PX0189-0003; Goldstein, Tr. 2600-02, 2611, 2620); deKernion, Tr. 3060; PX0025-0007). Dr. Miller testified that if a fruit juice were claiming to prevent prostate cancer and there was reliable scientific data to support that you could make that claim without a RCT. (RFF 1878; Miller, Tr. 2201).

Similarly, Dr. Heber testified that most experts in the field of nutrition consider competent and reliable science to support health claims for pomegranate juice based upon the totality of evidence, which does not necessarily include RCTs. (RFF 652; Heber, Tr. 1948-49, 2166, 2182). Dr. Heber further testified that in dealing with nutrients, RCTs are

often infeasible and too expensive and that the drug standard should not be applied. (RFF 646; Heber, Tr. 1950; RX5007 to RPTB).

Moreover, Respondents' prostate expert, Dr. deKernion, testified that in the case of fruit juice such as POM Juice, that has low or no toxicity, it is not necessary to have a RCT, placebo-controlled test. (RFF 1784; deKernion, Tr. 3060).

Respondents' erectile and nitric oxide experts, Drs. Goldstein and Burnett, also testified that urologist who treat men with erectile health concerns would not require that pomegranate juice be subjected to RCTs before concluding that pomegranate juice has a beneficial effect on preserving erectile function and erectile dysfunction. (RFF 650-651; 2122, 2123, 2164; PX0149-0006-0007; Burnett, Tr. 2272-74, 2303 (testifying RCTs are not necessary to deal with studies of drinking pomegranate juice); PX0189-0003, 0014; PX0352 (Goldstein, Dep. at 50-52, 61); Goldstein, Tr. 2600-02, 2611, 2620 (testifying that pharmaceutical type trials should not be applied to nutraceuticals—"a natural food product [from a plant] with health benefits").

Furthermore, Respondents cardio expert, Dr. Ornish, opined in his expert report that "it is an extreme position to state that the therapeutic efficacy of a fruit juice or extract of pomegranate juice should be held to the same standard of evidence as a new drug." (RFF 1192; PX0025-0008). Dr. Ornish opined that the study of pomegranates or pomegranate juice is different than studying a new drug, in which harmful side-effects, both short-term and long-term, are the rule rather than the exception. (RFF 1195; PX0025-0008). Dr. Ornish opined that he is "not aware of any studies showing any harmful effects of consuming pomegranates or pomegranate juice." (RFF 1194; PX0025-0008). Dr. Ornish testified that a new drug needs to be held to a higher standard than a juice that has been around for thousands of years. (RFF 1196; Ornish, Tr. 2340). Dr. Ornish noted that RCTs, even when conducted perfectly, do not control for all sources of bias and may

inject new ones unique to RCTs. (RFF 1190; PX0025-0008). Rather, Dr. Ornish noted that a more thoughtful way of analyzing therapeutic efficacy is to carefully examine the totality of scientific evidence, including but not limited to RCTs that are perfectly conducted. (RFF 1191; PX0025-0008).

In fact, much of what physicians provide patients in their clinical practices has not been proven to be beneficial in RCTs. (RFF 745-751; PX0025-0007; Sacks, Tr. 1559; PX0361 (Sacks Dep. at 111); CX1341 (Pantuck, Dep. at 276-277)). For example, Complaint Counsel's own expert, Dr. Eastham, admitted he has performed over 200 radical prostatectomies per year for a number of years before there were any RCTs showing that it worked. (RFF 746; Eastham Tr. 1331-32; PX0358 (Eastham, Dep. at 154-155)). Dr. Eastham performed these radical operations without RCTs despite the fact that the side-effects of this operation are significant and include impotence, incontinence, bleeding, embolisms, infection plus risks of general anesthetic. (RFF 747; Eastham, Tr. 1331-32). Also, Dr. Pantuck stated that clinicians remove kidneys without a RCT showing the benefits of nephrectomy. (RFF 748; CX1341 (Pantuck, Dep. at 276-277)).

Dr. Ornish also noted that randomized controlled trials have shown that angioplasties and stents do not prevent heart attacks or prolong life, yet the number of these procedures performed is greater than ever. (RFF 749; PX0025-0007). Dr. Miller indicated that although health professionals, third party insurance carriers, and health related agencies highly recommend that eating 5 portions of fresh fruits and vegetables may prevent cancer, it is accepted without requiring controlled non-clinical or clinical trials. (RFF 750; PX0206-0012-0013).

Further, Complaint Counsel's experts, Professor Stampfer and Dr. Sacks, admitted that they have made public health recommendations that were not supported by RCTs. (RFF

751; Stampfer, Tr. at 810, 813-14; PX0300 (Stampfer, Dep. at 173); PX0361 (Sacks, Dep. at 35-38, 130-131)).

1103. Respondents' disease claims are founded in large part on the premise that POM products contain high levels of antioxidants, which may play a role in the prevention or treatment of disease, as illustrated in some of their *in vitro* and *in vivo* testing. (*See, e.g.,* PX0004 (Aviram 2000 study); CX0543 (Aviram 2001 study); CX0765 (Rosenblat 2006 study); CX1188 (Seeram 2005 study)). This preliminary basic research fails, however, to substantiate claims that POM's products will prevent or treat heart disease, prostate cancer, or erectile dysfunction. (CX1293 (Stampfer, Report at 0015, 0029-30)).

Response to Finding No. 1103:

Respondents refer to their response to Finding No. 1102, above.

1104. High levels of antioxidants shown in *in vitro* tests may or may not translate to increased antioxidant levels in the human body. (CX1291 (Sacks, Report at 0015-16); Stampfer, Tr. 736-37, 725-26, 773; CX1293 (Stampfer, Report at 0016-17)). Respondents' expert, Dr. Heber, concedes that *in vitro* testing does not show how an antioxidant will work in the body. (CX1352 (Heber, Dep. at 183, 277) (no "standardized method" to evaluate how pomegranate acts as an antioxidant in humans; difficult to show antioxidant activity in humans). He explained, "we know that we have antioxidants in the test tube, and we know it's a very potent antioxidant in a test tube. But once it gets in the body, it gets metabolized, it has to interact with all the other antioxidant defense mechanisms, and what do you have? . . . Still not sure." (CX1352 (Heber, Dep. at 186)).

Response to Finding No. 1104:

Respondents refer to their response to Finding No. 1102, above.

1105. In his report, Dr. Stampfer explains that "[i]t has been hypothesized that diets high in [antioxidant] nutrients may prevent or treat chronic diseases, such as [cardiovascular disease] or cancer, by neutralizing free radicals," which may be responsible for cellular damage in the human body. (CX1293 (Stampfer, Report at 0010-11)). However, according to Dr. Stampfer, "there is conflicting scientific evidence on the benefits of specific nutrients with antioxidant activity in preventing or treating diseases." (CX1293 (Stampfer, Report at 0011)). Dr. Stampfer states that "[a]lthough observational and laboratory studies suggest that these nutrients have beneficial effects, several randomized controlled clinical trials have found no consistent benefit for specific nutrient antioxidants." (CX1293 (Stampfer, Report at 0011)).

Response to Finding No. 1105:

Respondents refer to their response to Finding No. 1102 above.

1106. For example, several antioxidant nutrients have been associated with reduced risk of prostate cancer in *in vitro* and observational studies. (CX1293 (Stampfer, Report at

0015)). The data from these studies, along with secondary analyses or randomized trials, was strongest for vitamin E and selenium, which prompted the Selenium and Vitamin E Cancer Prevention Trial ("SELECT") RCT. (CX1293 (Stampfer, Report at 0015)). SELECT terminated early because an initial review of the data showed that neither supplement prevented cancer and that there were slightly more cases of prostate cancer in men taking vitamin E. (CX1293 (Stampfer, Report at 0015); CX1287 (Eastham, Report at 0002, fn. 1); Eastham, Tr. 1210-11)). Although Vitamin E and selenium worked in *in vitro* studies, these nutrients did not have the same effect when studied in humans. (Eastham, Tr. 1286; CX1293 (Stampfer, Report at 0015)). Therefore, randomized, double-blind, placebo-controlled trials are needed "before drawing firm conclusions regarding causality[.]" (CX1293 (Stampfer, Report at 0015)). Complaint Counsel's experts point to the SELECT trial as demonstrating the need for randomized clinical trials. (Eastham, Tr. 1286-87; CX1293 (Stampfer, Report at 0015).

Response to Finding No. 1106:

Respondents refer to their response to Finding No. 1102, above.

1107. Similarly, "[b]oth observational and *in vitro* studies suggest that vitamin E can prevent or delay coronary heart disease" but randomized clinical trials have failed to demonstrate the same association. (CX1293 (Stampfer, Report at 0012)).

Response to Finding No. 1107:

Respondents refer to their response to Finding No. 1102 above.

1108. Thus, to demonstrate that the POM Products treat, prevent, or reduce the risk of heart disease, prostate cancer, and erectile dysfunction, well conducted RCTs are the type of competent and reliable science required before such a claim can be made. (CCFF ¶¶ C.1.784, D.1.974, E.1.1055). As established through the detailed analysis of Respondents' research in each relevant disease area, Respondents lack the necessary competent and reliable evidence in the form of RCTs for their claims. (*See supra* CCFF Sections VII.C.4, VII.D.4, and VII.E.4).

Response to Finding No. 1108:

Respondents refer to their response to Finding No. 1102, above.

2. Respondents' Experts' Argument That Disease Benefit Claims for Food Products Do Not Need RCTs to Establish Such Efficacy Is Unpersuasive

1109. In his testimony and expert report, Dr. Heber has stated that RCTs do not work well for studying nutrients, are infeasible, and are too expensive. (Heber, Tr. 1948-50; PX0353 (Heber, Dep. at 98-99 (placebo-controlled trials are not the gold standard for nutritional research)).

Response to Finding No. 1109:

Respondents have no specific response.

1110. This assertion, however, is inconsistent with his conduct over the past decade. In fact, Dr. Heber designed, solicited Respondents' funding for, and conducted several randomized, controlled human clinical studies with the purpose of proving health benefits for POM products on endpoints such as cognitive function, sports performance, and heart disease. (Heber, Tr. 2016-17, 2045-50, 2053-57; CX1352 (Heber, Dep. at 94-95); *see* CX0859_0003 (identifying Heber as primary investigator in San Diego Study RCT); CX0949_0007-13 (identifying Heber as principal investigator in RCT evaluating the effect of POMx on heart-related endpoints in diabetics); CX0659 (RCT to test pomegranate extract sports drink on sports performance)). Dr. Heber never told Respondents that randomized, controlled human clinical trials were not appropriate or necessary to study the effects of POM products on various areas of health. (Heber, Tr. 2053-57). Dr. Heber also has previously testified in federal court that randomized, placebo-controlled clinical trials were necessary to support advertising claims that a dietary supplement causes weight loss. (Heber, Tr. 2041-45).

Response to Finding No. 1110:

Respondents dispute this finding as contrary to the evidence in the record and as being nonsensical. While Dr. Heber has opined that RCTs are not necessary for pure fruit juice or whole foods, he is not testifying that RCTs are bad, just not the most effective means to determine a causal link between a 100% derived fruit product and a health benefit. (Heber, Tr. 2178-79) ("RCTs are not necessary, but they're fine"). Rather, Dr. Heber believes that most experts would consider the totality of the evidence, not necessarily RCTs, to support health claims for pomegranate juice. (Heber, Tr. 2182). The mere fact that Dr. Heber has engaged in RCT studies does not contradict this belief.

This position is confirmed repeatedly by both Complaint Counsel's and Respondents' experts. (RFF 569-744, 1184-1205, 1784-92, 2122, 2123; PX0149-0006-0007; Burnett, Tr. 2272-74, 2303 (testifying that RCTs are not necessary to deal with studies of drinking pomegranate juice); PX0189-0003, 0014; PX0352 (Goldstein, Dep. at 50-52, 61); Goldstein, Tr. 2600-02, 2611, 2620 (testifying that pharmaceutical type trials should not be applied to nutraceuticals—"a natural food product [from a plant] with health

benefits"); deKernion, Tr. 3060 (in the case of fruit juice such as POM Juice, that has low or no toxicity, it is not necessary to have a RCT, placebo-controlled test); Miller, Tr. 2194, 2201; PX0206-0010-0015; Heber, Tr. at 1948-50, 2056, 2166; PX0149-0006-0007; PX0025-0007; Sacks, Tr. 1545-46; PX0361 (Sacks, Dep. at 134-135); Stampfer, Tr. 830; CX1293_0029-0030; RX5007 to RPTB; PX0362 (Stampfer, Dep. at 73-79, 98)).

Complaint Counsel's designated expert on this matter, Professor Stampfer, testified that RCTs are not required to conclude a causal link regarding a nutrient and disease. (RFF 624-644; Stampfer, Tr. 830; PX0362 (Stampfer, Dep. at 73-79, 98)). Professor Stampfer further testified that in a nutritional context, a hypothesis about disease causation can, rarely, if ever, be directly tested in humans using the RCT design. (RFF 640; Stampfer, Tr. 832-33; PX0362 (Stampfer, Dep. at 73, 98); RX5007 to RPTB).

In his expert report, Professor Stampfer also admitted that he "believe[s] that it may be appropriate to use evidence short of randomized clinical trials for crafting public health recommendations regarding nutrient guidelines even when causality cannot be established, <u>because everyone eats and the public should be given advice based on the best evidence available</u>." (RFF 628; CX1293_0029-0030) (emphasis added).

Also, in a recently published article entitled "*Evidence-based criteria in the nutritional context*," Professor Stampfer opined that the general principles of evidence-based nutrition "can provide a sufficient foundation for establishing nutrient requirements and dietary guidelines in the absence of RCTs for every nutrient and food group." (RFF 630; Stampfer, Tr. 831; RX5007 to RPTB) (opining that because RCT study designs may not be "available" (economically or scientifically) for nutrients, "nutrient related decisions could be made at a level of certainty somewhat below that required for drugs.") Professor Stampfer also noted that some of the intellectual fathers of evidence based medicine "stressed" that evidence based medicine was "'not restricted to randomized

trials and meta-analyses.'" (RFF 643; RX5007 to RPTB). In the article, Professor Stampfer stated that "certain features of [evidence-based medicine] seem ill-suited to the nutrition context." (RFF 631; RX5007 to RPTB). He also opined that "to fail to act in the absence of conclusive RCT evidence increases the risk of forgoing benefits that might have been achieved with little risk and at low cost." (RFF 644; RX5007 to RPTB).

Professor Stampfer noted that some of the differences between the evaluation of drugs and nutrients are:

> "(i) medical interventions are designed to cure a disease not produced by their absence, while nutrients prevent dysfunction that would result from their inadequate intake; (ii) it is usually not plausible to summon clinical equipoise for basic nutrient effects, thus creating ethical impediments to many trials; (iii) drug effects are generally intended to be large with limited scope of action, while nutrient effects are typically polyvalent in scope and, in effect size, are typically within the "noise" range of biological variability; (iv) drug effects are tend to be monotonic, with response varying in proportion to dose, while nutrient effects are often of a sigmoid character, with useful response occurring only across a portion of the intake range; (v) drug effects can be tested against a non-exposed (placebo) contrast group, whereas it is impossible and/or unethical to attempt a zero intake group for nutrients; and (vi) therapeutic drugs are intended to be efficacious within a relatively short term while the impact of nutrients on the reduction of risk of chronic disease may require decades to demonstrate – a difference with significant implications for the feasibility of conducting pertinent RCTs."

(RFF 634; RX5007 to RPTB; PX0362 (Stampfer, Dep. at 78)) (emphasis added).

Additionally, Complaint Counsel's expert, Dr. Sacks, concedes that a causal influence can be demonstrated between an agent and its effect on humans without the use of RCTs. (RFF 647; PX0361 (Sacks, Dep. at 134-135)). Dr. Sacks testified that you do not need RCT trials to test the benefit of food categories that are included in a diet already tested,

like the DASH diet, which includes pomegranates. (RFF 648; Sacks, Tr. 1545-46). Dr. Ornish noted that most of Dr. Sacks' published studies have been epidemiological and observational in nature, rather than RCTs, and include relatively small numbers of patients. (RFF 1186; PX0025-0007).

Respondents' expert, Dr. Miller, confirms that when a food product is safe, and where the claim or advertisement does not suggest that the product be used as a substitute for conventional medical care or treatment, then it is appropriate to look at the totality of the science (and in some cases, only basic science), and not require only RCTs, to substantiate health claims. (RFF 657-744; Miller, Tr. 2194, 2201; PX0206-0010-0015; Heber, Tr. at 1948-50, 2056, 2166; PX0149-0006-0007; Burnett, Tr. 2272-74, 2303; PX0189-0003; Goldstein, Tr. 2600-02, 2611, 2620); deKernion, Tr. 3060; PX0025-0007). Dr. Miller testified that if a fruit juice were claiming to prevent prostate cancer and there was reliable scientific data to support that you could make that claim without a RCT. (RFF 1878; Miller, Tr. 2201).

Similarly, Dr. Heber testified that most experts in the field of nutrition consider competent and reliable science to support health claims for pomegranate juice based upon the totality of evidence, which does not necessarily include RCTs. (RFF 652; Heber, Tr. 1948-49, 2166, 2182).

Moreover, Respondents' prostate expert, Dr. deKernion, testified that in the case of fruit juice such as POM Juice, that has low or no toxicity, it is not necessary to have a RCT, placebo-controlled test. (RFF 1784; deKernion, Tr. 3060).

Respondents' erectile and nitric oxide experts, Drs. Goldstein and Burnett, also testified that urologist who treat men with erectile health concerns would not require that pomegranate juice be subjected to RCTs before concluding that pomegranate juice has a beneficial effect on preserving erectile function and erectile dysfunction. (RFF 650-651;

2122, 2123, 2164; PX0149-0006-0007; Burnett, Tr. 2272-74, 2303 (testifying that RCTs are not necessary to deal with studies of drinking pomegranate juice); PX0189-0003, 0014; PX0352 (Goldstein, Dep. at 50-52, 61); Goldstein, Tr. 2600-02, 2611, 2620 (testifying that pharmaceutical type trials should not be applied to nutraceuticals—"a natural food product [from a plant] with health benefits").

Furthermore, Respondents cardio expert, Dr. Ornish, opined in his expert report that "it is an extreme position to state that the therapeutic efficacy of a fruit juice or extract of pomegranate juice should be held to the same standard of evidence as a new drug." (RFF 1192; PX0025-0008). Dr. Ornish opined that the study of pomegranates or pomegranate juice is different than studying a new drug, in which harmful side-effects, both short-term and long-term, are the rule rather than the exception. (RFF 1195; PX0025-0008). Dr. Ornish opined that he is "not aware of any studies showing any harmful effects of consuming pomegranates or pomegranate juice." (RFF 1194; PX0025-0008). Dr. Ornish testified that a new drug needs to be held to a higher standard than a juice that has been around for thousands of years. (RFF 1196; Ornish, Tr. 2340). Dr. Ornish noted that RCTs, even when conducted perfectly, do not control for all sources of bias and may inject new ones unique to RCTs. (RFF 1190; PX0025-0008). Rather, Dr. Ornish noted that a more thoughtful way of analyzing therapeutic efficacy is to carefully examine the totality of scientific evidence, including but not limited to RCTs that are perfectly conducted. (RFF 1191; PX0025-0008).

In fact, much of what physicians provide patients in their clinical practices has not been proven to be beneficial in RCTs. (RFF 745-751; PX0025-0007; Sacks, Tr. 1559; PX0361 (Sacks Dep. at 111); CX1341 (Pantuck, Dep. at 276-277)). For example, Complaint Counsel's own expert, Dr. Eastham, admitted he has performed over 200 radical prostatectomies per year for a number of years before there were any RCTs showing that it worked. (RFF 746; Eastham Tr. 1331-32; PX0358 (Eastham, Dep. at 154-155)). Dr.

Eastham performed these radical operations without RCTs despite the fact that the side-effects of this operation are significant and include impotence, incontinence, bleeding, embolisms, infection plus risks of general anesthetic. (RFF 747; Eastham, Tr. 1331-32). Also, Dr. Pantuck stated that clinicians remove kidneys without a RCT showing the benefits of nephrectomy. (RFF 748; CX1341 (Pantuck, Dep. at 276-277)).

Dr. Ornish also noted that randomized controlled trials have shown that angioplasties and stents do not prevent heart attacks or prolong life, yet the number of these procedures performed is greater than ever. (RFF 749; PX0025-0007). Dr. Miller indicated that although health professionals, third party insurance carriers, and health related agencies highly recommend that eating 5 portions of fresh fruits and vegetables may prevent cancer, it is accepted without requiring controlled non-clinical or clinical trials. (RFF 750; PX0206-0012-0013).

Further, Complaint Counsel's experts, Professor Stampfer and Dr. Sacks, admitted that they have made public health recommendations that were not supported by RCTs. (RFF 751; Stampfer, Tr. at 810, 813-14; PX0300 (Stampfer, Dep. at 173); PX0361 (Sacks, Dep. at 35-38, 130-131)).

Finally, Respondents object to Complaint Counsel's insinuation that because Dr. Heber testified that RCTs are necessary for a dietary weight loss supplement in federal court, RCTs are also therefore necessary for the Challenged Products. However, unlike in this case where the product is a 100% wholesome pure fruit juice, the weight loss dietary supplements Dr. Heber testified about were "a mixture of number of ingredients or herbals." (Heber, Tr. 2041, 2178). This is "a very different case" from the instant matter, and therefore Complaint Counsel's insinuation should be disregarded.

1111. Moreover, in his report, Dr. Heber points out that his research led to the initiation of a Phase III placebo-controlled, randomized study "to determine" whether intake of POM Juice can lengthen PSA in a certain group of prostate cancer patients. (PX0192 (Heber, Report at 0031-32)). He also states in his report that Respondents followed up the

Aviram heart studies with "larger [human] studies," implying that this is the right thing to do. (PX0192 (Heber, Report at 0052)). Dr. Heber is also one of the investigators taking part in the an RCT. (CX1118_0002, *in camera*; *see* CCFF ¶ D.3.1030).

Response to Finding No. 1111:

Respondents dispute this finding as contrary to the evidence in the record and as being nonsensical. While Dr. Heber has opined that RCTs are not necessary for pure fruit juice or whole foods, he is not testifying that RCTs are bad, just not the most effective means to determine a causal link between a 100% derived fruit product and a health benefit. (Heber, Tr. 2178-79) ("RCTs are not necessary, but they're fine"). Rather, Dr. Heber believes that most experts would consider the totality of the evidence, not necessarily RCTs, to support health claims for pomegranate juice. (Heber, Tr. 2182). The mere fact that Dr. Heber has engaged in RCT studies does not contradict this belief.

This position is confirmed repeatedly by both Complaint Counsel's and Respondents' experts. (RFF 569-744, 1184-1205, 1784-92, 2122, 2123; PX0149-0006-0007; Burnett, Tr. 2272-74, 2303 (testifying that RCTs are not necessary to deal with studies of drinking pomegranate juice); PX0189-0003, 0014; PX0352 (Goldstein, Dep. at 50-52, 61); Goldstein, Tr. 2600-02, 2611, 2620 (testifying that pharmaceutical type trials should not be applied to nutraceuticals—"a natural food product [from a plant] with health benefits"); deKernion, Tr. 3060 (in the case of fruit juice such as POM Juice, that has low or no toxicity, it is not necessary to have a RCT, placebo-controlled test); Miller, Tr. 2194, 2201; PX0206-0010-0015; Heber, Tr. at 1948-50, 2056, 2166; PX0149-0006-0007; PX0025-0007; Sacks, Tr. 1545-46; PX0361 (Sacks, Dep. at 134-135); Stampfer, Tr. 830; CX1293_0029-0030; RX5007 to RPTB; PX0362 (Stampfer, Dep. at 73-79, 98)).

Complaint Counsel's designated expert on this matter, Professor Stampfer, testified that RCTs are not required to conclude a causal link regarding a nutrient and disease. (RFF 624-644; Stampfer, Tr. 830; PX0362 (Stampfer, Dep. at 73-79, 98)). Professor Stampfer

further testified that in a nutritional context, a hypothesis about disease causation can, rarely, if ever, be directly tested in humans using the RCT design. (RFF 640; Stampfer, Tr. 832-33; PX0362 (Stampfer, Dep. at 73, 98); RX5007 to RPTB).

In his expert report, Professor Stampfer also admitted that he "believe[s] that it may be appropriate to use evidence short of randomized clinical trials for crafting public health recommendations regarding nutrient guidelines even when causality cannot be established, because everyone eats and the public should be given advice based on the best evidence available." (RFF 628; CX1293_0029-0030) (emphasis added).

Also, in a recently published article entitled "*Evidence-based criteria in the nutritional context*," Professor Stampfer opined that the general principles of evidence-based nutrition "can provide a sufficient foundation for establishing nutrient requirements and dietary guidelines in the absence of RCTs for every nutrient and food group." (RFF 630; Stampfer, Tr. 831; RX5007 to RPTB) (opining that because RCT study designs may not be "available" (economically or scientifically) for nutrients, "nutrient related decisions could be made at a level of certainty somewhat below that required for drugs.") Professor Stampfer also noted that some of the intellectual fathers of evidence based medicine "stressed" that evidence based medicine was "'not restricted to randomized trials and meta-analyses.'" (RFF 643; RX5007 to RPTB). In the article, Professor Stampfer stated that "certain features of [evidence-based medicine] seem ill-suited to the nutrition context." (RFF 631; RX5007 to RPTB). He also opined that "to fail to act in the absence of conclusive RCT evidence increases the risk of forgoing benefits that might have been achieved with little risk and at low cost." (RFF 644; RX5007 to RPTB).

Professor Stampfer noted that some of the differences between the evaluation of drugs and nutrients are:

> "(i) medical interventions are designed to cure a disease not produced by their absence, while nutrients prevent dysfunction that would result from their inadequate intake; (ii) it is usually not plausible to summon clinical equipoise for basic nutrient effects, thus creating ethical impediments to many trials; (iii) drug effects are generally intended to be large with limited scope of action, while nutrient effects are typically polyvalent in scope and, in effect size, are typically within the "noise" range of biological variability; (iv) drug effects are tend to be monotonic, with response varying in proportion to dose, while nutrient effects are often of a sigmoid character, with useful response occurring only across a portion of the intake range; (v) drug effects can be tested against a non-exposed (placebo) contrast group, whereas it is impossible and/or unethical to attempt a zero intake group for nutrients; and (vi) therapeutic drugs are intended to be efficacious within a relatively short term while the impact of nutrients on the reduction of risk of chronic disease may require decades to demonstrate – a difference with significant implications for the feasibility of conducting pertinent RCTs."

(RFF 634; RX5007 to RPTB; PX0362 (Stampfer, Dep. at 78)) (emphasis added).

Additionally, Complaint Counsel's expert, Dr. Sacks, concedes that a causal influence can be demonstrated between an agent and its effect on humans without the use of RCTs. (RFF 647; PX0361 (Sacks, Dep. at 134-135)). Dr. Sacks testified that you do not need RCT trials to test the benefit of food categories that are included in a diet already tested, like the DASH diet, which includes pomegranates. (RFF 648; Sacks, Tr. 1545-46). Dr. Ornish noted that most of Dr. Sacks' published studies have been epidemiological and observational in nature, rather than RCTs, and include relatively small numbers of patients. (RFF 1186; PX0025-0007).

Respondents' expert, Dr. Miller, confirms that when a food product is safe, and where the claim or advertisement does not suggest that the product be used as a substitute for conventional medical care or treatment, then it is appropriate to look at the totality of the science (and in some cases, only basic science), and not require only RCTs, to

substantiate health claims. (RFF 657-744; Miller, Tr. 2194, 2201; PX0206-0010-0015; Heber, Tr. at 1948-50, 2056, 2166; PX0149-0006-0007; Burnett, Tr. 2272-74, 2303; PX0189-0003; Goldstein, Tr. 2600-02, 2611, 2620); deKernion, Tr. 3060; PX0025-0007). Dr. Miller testified that if a fruit juice were claiming to prevent prostate cancer and there was reliable scientific data to support that you could make that claim without a RCT. (RFF 1878; Miller, Tr. 2201).

Similarly, Dr. Heber testified that most experts in the field of nutrition consider competent and reliable science to support health claims for pomegranate juice based upon the totality of evidence, which does not necessarily include RCTs. (RFF 652; Heber, Tr. 1948-49, 2166, 2182).

Moreover, Respondents' prostate expert, Dr. deKernion, testified that in the case of fruit juice such as POM Juice, that has low or no toxicity, it is not necessary to have a RCT, placebo-controlled test. (RFF 1784; deKernion, Tr. 3060).

Respondents' erectile and nitric oxide experts, Drs. Goldstein and Burnett, also testified that urologist who treat men with erectile health concerns would not require that pomegranate juice be subjected to RCTs before concluding that pomegranate juice has a beneficial effect on preserving erectile function and erectile dysfunction. (RFF 650-651; 2122, 2123, 2164; PX0149-0006-0007; Burnett, Tr. 2272-74, 2303 (testifying that RCTs are not necessary to deal with studies of drinking pomegranate juice); PX0189-0003, 0014; PX0352 (Goldstein, Dep. at 50-52, 61); Goldstein, Tr. 2600-02, 2611, 2620 (testifying that pharmaceutical type trials should not be applied to nutraceuticals—"a natural food product [from a plant] with health benefits").

Furthermore, Respondents cardio expert, Dr. Ornish, opined in his expert report that "it is an extreme position to state that the therapeutic efficacy of a fruit juice or extract of pomegranate juice should be held to the same standard of evidence as a new drug." (RFF

1192; PX0025-0008). Dr. Ornish opined that the study of pomegranates or pomegranate juice is different than studying a new drug, in which harmful side-effects, both short-term and long-term, are the rule rather than the exception. (RFF 1195; PX0025-0008). Dr. Ornish opined that he is "not aware of any studies showing any harmful effects of consuming pomegranates or pomegranate juice." (RFF 1194; PX0025-0008). Dr. Ornish testified that a new drug needs to be held to a higher standard than a juice that has been around for thousands of years. (RFF 1196; Ornish, Tr. 2340). Dr. Ornish noted that RCTs, even when conducted perfectly, do not control for all sources of bias and may inject new ones unique to RCTs. (RFF 1190; PX0025-0008). Rather, Dr. Ornish noted that a more thoughtful way of analyzing therapeutic efficacy is to carefully examine the totality of scientific evidence, including but not limited to RCTs that are perfectly conducted. (RFF 1191; PX0025-0008).

In fact, much of what physicians provide patients in their clinical practices has not been proven to be beneficial in RCTs. (RFF 745-751; PX0025-0007; Sacks, Tr. 1559; PX0361 (Sacks Dep. at 111); CX1341 (Pantuck, Dep. at 276-277)). For example, Complaint Counsel's own expert, Dr. Eastham, admitted he has performed over 200 radical prostatectomies per year for a number of years before there were any RCTs showing that it worked. (RFF 746; Eastham Tr. 1331-32; PX0358 (Eastham, Dep. at 154-155)). Dr. Eastham performed these radical operations without RCTs despite the fact that the side-effects of this operation are significant and include impotence, incontinence, bleeding, embolisms, infection plus risks of general anesthetic. (RFF 747; Eastham, Tr. 1331-32). Also, Dr. Pantuck stated that clinicians remove kidneys without a RCT showing the benefits of nephrectomy. (RFF 748; CX1341 (Pantuck, Dep. at 276-277)).

Dr. Ornish also noted that randomized controlled trials have shown that angioplasties and stents do not prevent heart attacks or prolong life, yet the number of these procedures performed is greater than ever. (RFF 749; PX0025-0007). Dr. Miller indicated that

although health professionals, third party insurance carriers, and health related agencies highly recommend that eating 5 portions of fresh fruits and vegetables may prevent cancer, it is accepted without requiring controlled non-clinical or clinical trials. (RFF 750; PX0206-0012-0013).

Further, Complaint Counsel's experts, Professor Stampfer and Dr. Sacks, admitted that they have made public health recommendations that were not supported by RCTs. (RFF 751; Stampfer, Tr. at 810, 813-14; PX0300 (Stampfer, Dep. at 173); PX0361 (Sacks, Dep. at 35-38, 130-131)).

1112. Dr. Miller testified in this matter that a claim that fruit juice treated prostate cancer would not need to be supported by a randomized clinical trial. (Miller, Tr. 2201). This is directly contrary to his 2009 testimony in *Daniel Chapter One* : "Dr. Miller explained that in order to constitute competent and reliable scientific evidence that a product treats, cures, or prevents cancer, the products' efficacy and safety must be demonstrated through controlled clinical studies (tests on humans)." *In re Daniel Chapter One and James Feijo*, No. 9329, Commission Opinion at 18 (Dec. 24, 2009)[5]; *see also In re Daniel Chapter One and James Feijo*, No. 9329, Initial Decision at 55 (Aug. 5, 2009) (Dr. Miller's report stated that "[o]nly data from well-designed, controlled, clinical trials will substantiate a claim that a new therapy is safe and effective to treat, cure, or prevent cancer.")[6] Dr. Miller testified in *Daniel Chapter One* that such a cancer treatment claim for orange juice, for example, would require scientific evidence. (Miller, Tr. 2226).

Response to Finding No. 1112:

Respondents object to this proposed finding as contrary to the evidence in the record. There is no contradiction in Dr. Miller's testimony. Dr. Miller testified that "as it applied to the *Daniel Chapter One* ("DCO") products that statement is correct." (Miller, Tr. 2196). However, Dr. Miller distinguished his opinion in DCO from the instant matter for a number of reasons including: (1) "There was no reliable science supporting the claims that were made, nor were there any medical oncology/hematology experts that supported the position of DCO;" (Miller, Tr. 2193); (2) DCO "was making claims that their

[5] http://www.ftc.gov/os/adjpro/d9329/091224commissionopinion.pdf

[6] http://www.ftc.gov/os/adjpro/d9329/090811dcoinitialdecision.pdf

products could be taken in the place of and instead of conventional therapies to treat, prevent and cure cancer" (Miller, Tr. 2193); and (3) DCO's products, a conglomeration of different herbal and other materials, had side effects that were unsafe." (Miller, Tr. 2193-94). Furthermore, DCO's products were "not a food" they have not been "around for thousands of years where there are no safety concerns . . . there's a huge difference between all of the different products that were being offered and sold by [DCO] compared to [POM's] fruit juice . . .." (Miller, Tr. 2206). A food product, like the Challenged Products, don't "have to go through the same stringency of a randomized clinical trial" to establish safety. (Miller, Tr. 2207).

Respondents' experts and Complaint Counsel's experts all agree that RCTs are not required, nor even preferred to substantiate the health benefits of 100% natural, safe and healthy foods such as the Challenged Products. (RFF 569-744, 1184-1205, 1784-92, 2122, 2123; PX0149-0006-0007; Burnett, Tr. 2272-74, 2303 (testifying RCTs are not necessary to deal with studies of drinking pomegranate juice); PX0189-0003, 0014; PX0352 (Goldstein, Dep. at 50-52, 61); Goldstein, Tr. 2600-02, 2611, 2620 (testifying that pharmaceutical type trials should not be applied to nutraceuticals—"a natural food product [from a plant] with health benefits"); deKernion, Tr. 3060 (in the case of fruit juice such as POM Juice, that has low or no toxicity, it is not necessary to have a RCT, placebo-controlled test); Miller, Tr. 2194, 2201; PX0206-0010-0015; Heber, Tr. at 1948-50, 2056, 2166; PX0149-0006-0007; PX0025-0007; Sacks, Tr. 1545-46; PX0361 (Sacks, Dep. at 134-135) (Complaint Counsel's expert, Dr. Sacks, concedes that a casual influence can be demonstrated between and agent and its effects on humans without the use of RCTs); Stampfer, Tr. 830; CX1293_0029-0030; RX5007 to RPTB; PX0362 (Stampfer, Dep. at 73-79, 98) (Complaint Counsel's designated expert on this matter, Professor Stampfer, testified that RCTs are not required to conclude a causal link regarding a nutrient and disease)).

Additionally Dr. Miller's orange juice statement dealt with a hypothetical situation in which orange juice was offered in place of conventional medical treatment – which is not the case with the Challenged Products. (PX0354 (Miller, Dep. at103).

1113. Dr. Miller conceded in his report that "[t]he regulatory requirements are much more rigorous when crossing the boundary between making a general health benefit claim (low fat diets are healthier than high fat diets) and taking a general statement to the next level and claiming efficacy in the treatment of a specific type of cancer." (PX0206 (Miller, Report at 0006)).

Response to Finding No. 1113:

Respondents have no specific response.

1114. Dr. Miller also agreed that the claim being made about a product is relevant to the level of substantiation required, but he did not actually evaluate any of the advertising claims made regarding the health benefits of POM's products. (Miller, Tr. 2195, 2210).

Response to Finding No. 1114:

While Dr. Miller did not review all of POM's advertising he did testify generally that anytime you are talking about a food "which is not being offered as a substitute or a replacement for a conventional therapy, that is known to be safe, for which there are reliable data to support a claim that it may be beneficial to patients with a number of different disorders, one can relax the requirement for a randomized clinical trial if the food has a high benefit-risk ratio, a low or zero toxicity or safety profile, and has benefit to mankind." (Miller, Tr. 2200-01). In such a situation, Dr. Miller specifically testified that a fruit juice claiming to treat, or even prevent, prostate cancer would not require RCTs. (Miller, Tr. 2200).

1115. Although Dr. Miller testified that his views have "evolved" since testifying in *Daniel Chapter One*, the only citation in his expert report for his opinion that the level and rigor of substantiation for a food is quite different from that for a drug is a paper that he concedes is not a medical article or review. The paper is entitled, "In Defense of the Pfizer Factors," by Howard Beales, Timothy Muris, and Robert Pitofsky ("Beales paper"). (Miller, Tr. 2221; PX0206 (Miller, Report at 0015, 0019-20)). Dr. Miller did not know the background of the authors or whether they had medical backgrounds. (Miller, Tr. 2222).

Response to Finding No. 1115:

Respondents' object to and deny this finding of fact as false and contrary to the evidence in the record. Dr. Miller did not base his expert opinion, regarding substantiation for a food, on the Beales' paper as alleged by Complaint Counsel. That was but one out of twenty references mentioned at the end of Dr. Miller's expert report. Moreover, Dr. Miller's expert opinion is based on his experience a practicing clinician, his year of experience in treating patients and his expertise as a preeminent research scientist. Dr. Millers has, for over 40 years, directed clinical care, education, laboratory and clinical research, and administration, and lead divisions or departments at University of Rochester Medical Center, New York Hospital-Cornell Medical Center, Memorial Sloan Kettering Cancer Center ("MSKCC"), and Northwestern University Medical School. (PX0206 at 000; Miller Tr. 2190). Dr. Miller is a board certified pediatrician and pediatric hematologist/oncologist. (PX0206 at 0001; PX0354 (Miller, Dep. at 16)). Dr. Miller is a Clinical Professor of Pediatrics at Robert Wood Johnson School of Medicine in New Brunswick, New Jersey. (PX0206 at 0001; PX0354 (Miller, Dep. at 12); Miller Tr. 2189). Dr. Miller is familiar with pharmacology (pharmacokinetics, pharmacodynamics), mechanisms of action, safety, and therapeutic efficacy, including clinical benefit, of most, if not all, agents used to treat or provide supportive care in cancer and blood diseases. This knowledge comes from a professional life devoted to patient care and involvement in the various processes, phases, and stages of clinical drug development. (PX0206 at 0005). Dr. Miller's major area of clinical and laboratory research in academic medicine was focused on hematopoietic malignancies but clinically, he was directly involved in and cared for patients with both solid tumors and blood cancers. (PX0206 at 0002).

If a product is a 100% whole food, for example, or a derivative of a 100% whole food and obviously safe, like the Challenged Products, and that product is not offered in place

of conventional medical care or treatment then as a practicing clinician Dr. Miller believes that the public should be made aware of the potential or probable benefits of consuming that product. (PX0206-0007; Miller, Tr. 2194). "This is a flexible standard that must include input by practicing clinicians in the specific areas of health at issue. It is preferred, for example, that to accurately examine the desirability of getting information to the public, that input is given by practicing physicians in the relevant affected fields, who have firsthand knowledge regarding the needs and risks faced by their patients and options (or lack thereof) that are available to their patients." (PX0206 at 0008; *See* Miller, Tr. 2010). Dr. Miller's has a vast amount of experience in dealing with patients and treatment options. (RFF 658-700). Alternatively, Complaint Counsel's expert, Professor Stampfer is not even a practicing physician who treats patients. (RFF 868).

1116. The Beales paper that Dr. Miller relied upon is in fact a legal advocacy paper urging the application of a different substantiation standard for foods versus conventional treatments. Dr. Miller concedes this describes the entire scope of his opinion. (PX0209; Miller, Tr. 2222). Dr. Miller was not familiar with the Beales paper before he was asked to give his opinion in this matter, had not come across the paper in his independent literature review in this case, and was provided the Beales paper by Respondents. (Miller, Tr. 2223).

Response to Finding No. 1116:

Respondents' object to and deny this finding of fact as false and contrary to the evidence in the record. Dr. Miller did not base his expert opinion, regarding substantiation for a food, on the Beales' paper as alleged by Complaint Counsel. That was but one out of twenty references mentioned at the end of Dr. Miller's expert report. Moreover, Dr. Miller's expert opinion is based on his experience a practicing clinician, his year of experience in treating patients and his expertise as a preeminent research scientist. Dr. Millers has, for over 40 years, directed clinical care, education, laboratory and clinical research, and administration, and lead divisions or departments at University of Rochester Medical Center, New York Hospital-Cornell Medical Center, Memorial Sloan Kettering Cancer Center ("MSKCC"), and Northwestern University Medical School.

(PX0206 at 000; Miller Tr. 2190). Dr. Miller is a board certified pediatrician and pediatric hematologist/oncologist. (PX0206 at 0001; PX0354 (Miller, Dep. at 16)). Dr. Miller is a Clinical Professor of Pediatrics at Robert Wood Johnson School of Medicine in New Brunswick, New Jersey. (PX0206 at 0001; PX0354 (Miller, Dep. at 12); Miller Tr. 2189). Dr. Miller is familiar with pharmacology (pharmacokinetics, pharmacodynamics), mechanisms of action, safety, and therapeutic efficacy, including clinical benefit, of most, if not all, agents used to treat or provide supportive care in cancer and blood diseases. This knowledge comes from a professional life devoted to patient care and involvement in the various processes, phases, and stages of clinical drug development. (PX0206 at 0005). Dr. Miller's major area of clinical and laboratory research in academic medicine was focused on hematopoietic malignancies but clinically, he was directly involved in and cared for patients with both solid tumors and blood cancers. (PX0206 at 0002).

If a product is a 100% whole food, for example, or a derivative of a 100% whole food and obviously safe, like the Challenged Products, and that product is not offered in place of conventional medical care or treatment then as a practicing clinician Dr. Miller believes that the public should be made aware of the potential or probable benefits of consuming that product. (PX0206-0007; Miller, Tr. 2194). "This is a flexible standard that must include input by practicing clinicians in the specific areas of health at issue. It is preferred, for example, that to accurately examine the desirability of getting information to the public, that input is given by practicing physicians in the relevant affected fields, who have firsthand knowledge regarding the needs and risks faced by their patients and options (or lack thereof) that are available to their patients." (PX0206 at 0008; *See* Miller, Tr. 2010). Dr. Miller's has a vast amount of experience in dealing with patients and treatment options. (RFF 658-700). Alternatively, Complaint Counsel's expert, Professor Stampfer is not even a practicing physician who treats patients. (RFF 868).

1117. Dr. Miller is not an expert in the role of foods in prevention and treatment of disease; nor is he a nutritionist or a lawyer. (Miller, Tr. 2215, 2222; CCFF ¶ 757).

Response to Finding No. 1117:

Respondents dispute this proposed finding of fact to the extent Complaint Counsel seek to diminish the value of Dr. Miller's years of experience treating patients as a practicing clinician and his expertise as a preeminent research scientist. For example, Dr. Denis Miller is a board certified pediatrician and pediatric hematologist and oncologist. (RFF 110). Dr. Miller has, for over 40 years, directed clinical care, education, laboratory and clinical research, and administration, and led departments at some of the most prestigious hospitals in the world. (RFF 111). Dr. Miller has authored or co-authored over 300 book chapters, peer-reviewed articles, and abstracts mostly on cancer and blood disorders. (RFF 114). He directs one of the largest pediatric oncology/hematology programs in the world and holds an endowed chair. (PX0206 at 3; RFF 112). Dr. Miller has designed, managed, and directed many different research studies calculated to develop new anti-cancer agents. (RFF 113). Because of his expertise, Complaint Counsel have retained Dr. Miller on several matters, and he testified for Complaint Counsel previously in *Daniel Chapter One*. (RFF 115).

As a practicing clinician Dr. Miller provided general health care advice to cancer patients including advising patients on lifestyle and dietary changes. (PX0354 (Miller, Dep. at 52-53)). In addition, Dr. Miller has been involved in clinical trials examining the role of foods and cancer treatments such as mushrooms. (PX0354 (Miller, Dep. at 54)). As the Clinical Director of the Cancer Treatment Research Foundation, he funded a study designed by nutritionists and urological oncologists at Harvard University. The study evaluated the potential efficacy of a low fat diet in which patients' caloric intake was only 20 percent or less from fat in men diagnosed with prostate cancer. (PX0354 (Miller, Dep. at 66-67)).

Dr. Miller offered his expert opinion, on what the standard of substantiation should be, based on his 50 years of practicing medicine and being involved in clinical research both from the academic side as well as from the industry side. (Miller, Tr. 2217). Dr. Miller's experience in clinical practice, treating patients, and as a leading research scientist far exceeds the narrow scope of Complaint Counsel's expert Professor Stampfer who is not a practicing physician and who does not treat patients.. (Stampfer, Tr. 868).

1118. Dr. Heber and Dr. Miller's attempts to minimize the necessity of RCTs to support claims that a product will treat, prevent, or reduce the risk of a specific disease are not credible; Respondents' own heart expert, Dr. Ornish, directly contradicts Dr. Heber and Dr. Miller in this regard. Dr. Ornish testified that not only did he *not* recall telling the Resnicks that they did not need to sponsor randomized, controlled human trials before they could claim that pomegranate juice helps reduce the risk of heart disease, but that he was the "one who actually encouraged the Resnicks to do these studies when the Resnicks first proposed them. I thought it was a wonderful idea. I think that's the kind of behavior that the FTC should be encouraging[.]" (Ornish, Tr. 2386; *see also* CCFF ¶ 822 (Ornish conducted two RCTs on Respondents' behalf attempting to link pomegranate juice to a preventative for heart disease)).

Response to Finding No. 1118:

Respondents dispute this finding as contrary to the evidence in the record and as being nonsensical. While Dr. Ornish has opined that RCTs are not necessary for safe, pure fruit juice or whole foods, he is not testifying that RCTs are bad, just not the most effective means to determine a causal link between a 100% derived fruit product and a health benefit. (RFF 1190-92, 1194-96; PX0025-0008; Ornish, Tr. 2340). Rather, Dr. Ornish believes that most experts would consider the totality of the scientific evidence, including but not limited to RCTs, to support health claims for pomegranate juice. (RFF 1191; PX0025-0008; Ornish, Tr. 2386) (testifying that scientific studies regarding fruits are "the kind of behavior the FTC should be encouraging, rather than discouraging.") (emphasis added). The mere fact that Dr. Ornish has engaged in RCT studies or encouraged such robust human studies does not contradict this belief.

Moreover, Dr. Ornish's position regarding RCTs is confirmed repeatedly by both Complaint Counsel's and Respondents' experts, including Drs. Heber and Miller. (RFF 569-744, 1184-1205, 1784-92, 2122, 2123; PX0149-0006-0007; Burnett, Tr. 2272-74, 2303 (testifying that RCTs are not necessary to deal with studies of drinking pomegranate juice); PX0189-0003, 0014; PX0352 (Goldstein, Dep. at 50-52, 61); Goldstein, Tr. 2600-02, 2611, 2620 (testifying that pharmaceutical type trials should not be applied to nutraceuticals—"a natural food product [from a plant] with health benefits"); deKernion, Tr. 3060 (in the case of fruit juice such as POM Juice, that has low or no toxicity, it is not necessary to have a RCT, placebo-controlled test); Miller, Tr. 2194, 2201; PX0206-0010-0015; Heber, Tr. at 1948-50, 2056, 2166; PX0149-0006-0007; PX0025-0007; Sacks, Tr. 1545-46; PX0361 (Sacks, Dep. at 134-135); Stampfer, Tr. 830; CX1293_0029-0030; RX5007 to RPTB; PX0362 (Stampfer, Dep. at 73-79, 98)).

Complaint Counsel's designated expert on this matter, Professor Stampfer, testified that RCTs are not required to conclude a causal link regarding a nutrient and disease. (RFF 624-644; Stampfer, Tr. 830; PX0362 (Stampfer, Dep. at 73-79, 98)). Professor Stampfer further testified that in a nutritional context, a hypothesis about disease causation can, rarely, if ever, be directly tested in humans using the RCT design. (RFF 640; Stampfer, Tr. 832-33; PX0362 (Stampfer, Dep. at 73, 98); RX5007 to RPTB).

In his expert report, Professor Stampfer also admitted that he "believe[s] that it may be appropriate to use evidence short of randomized clinical trials for crafting public health recommendations regarding nutrient guidelines even when causality cannot be established, <u>because everyone eats and the public should be given advice based on the best evidence available</u>." (RFF 628; CX1293_0029-0030) (emphasis added).

Also, in a recently published article entitled "*Evidence-based criteria in the nutritional context*," Professor Stampfer opined that the general principles of evidence-based

nutrition "can provide a sufficient foundation for establishing nutrient requirements and dietary guidelines in the absence of RCTs for every nutrient and food group." (RFF 630; Stampfer, Tr. 831; RX5007 to RPTB) (opining that because RCT study designs may not be "available" (economically or scientifically) for nutrients, "nutrient related decisions could be made at a level of certainty somewhat below that required for drugs.") Professor Stampfer also noted that some of the intellectual fathers of evidence based medicine "stressed" that evidence based medicine was "'not restricted to randomized trials and meta-analyses.'" (RFF 643; RX5007 to RPTB). In the article, Professor Stampfer stated that "certain features of [evidence-based medicine] seem ill-suited to the nutrition context." (RFF 631; RX5007 to RPTB). He also opined that "to fail to act in the absence of conclusive RCT evidence increases the risk of forgoing benefits that might have been achieved with little risk and at low cost." (RFF 644; RX5007 to RPTB).

Professor Stampfer noted that some of the differences between the evaluation of drugs and nutrients are:

> "(i) medical interventions are designed to cure a disease not produced by their absence, while nutrients prevent dysfunction that would result from their inadequate intake; (ii) it is usually not plausible to summon clinical equipoise for basic nutrient effects, thus creating ethical impediments to many trials; (iii) drug effects are generally intended to be large with limited scope of action, while nutrient effects are typically polyvalent in scope and, in effect size, are typically within the "noise" range of biological variability; (iv) drug effects are tend to be monotonic, with response varying in proportion to dose, while nutrient effects are often of a sigmoid character, with useful response occurring only across a portion of the intake range; (v) drug effects can be tested against a non-exposed (placebo) contrast group, whereas it is impossible and/or unethical to attempt a zero intake group for nutrients; and (vi) therapeutic drugs are intended to be efficacious within a relatively short term while the impact of nutrients on the reduction of risk of chronic disease may require decades to

> demonstrate – a difference with significant implications for the feasibility of conducting pertinent RCTs."

(RFF 634; RX5007 to RPTB; PX0362 (Stampfer, Dep. at 78)) (emphasis added).

Additionally, Complaint Counsel's expert, Dr. Sacks, concedes that a causal influence can be demonstrated between an agent and its effect on humans without the use of RCTs. (RFF 647; PX0361 (Sacks, Dep. at 134-135)). Dr. Sacks testified that you do not need RCT trials to test the benefit of food categories that are included in a diet already tested, like the DASH diet, which includes pomegranates. (RFF 648; Sacks, Tr. 1545-46). Dr. Ornish noted that most of Dr. Sacks' published studies have been epidemiological and observational in nature, rather than RCTs, and include relatively small numbers of patients. (RFF 1186; PX0025-0007).

Respondents' expert, Dr. Miller, confirms that when a food product is safe, and where the claim or advertisement does not suggest that the product be used as a substitute for conventional medical care or treatment, then it is appropriate to look at the totality of the science (and in some cases, only basic science), and not require only RCTs, to substantiate health claims. (RFF 657-744; Miller, Tr. 2194, 2201; PX0206-0010-0015; Heber, Tr. at 1948-50, 2056, 2166; PX0149-0006-0007; Burnett, Tr. 2272-74, 2303; PX0189-0003; Goldstein, Tr. 2600-02, 2611, 2620); deKernion, Tr. 3060; PX0025-0007). Dr. Miller testified that if a fruit juice were claiming to prevent prostate cancer and there was reliable scientific data to support that you could make that claim without a RCT. (RFF 1878; Miller, Tr. 2201).

Similarly, Dr. Heber testified that most experts in the field of nutrition consider competent and reliable science to support health claims for pomegranate juice based upon the totality of evidence, which does not necessarily include RCTs. (RFF 652; Heber, Tr. 1948-49, 2166, 2182).

Moreover, Respondents' prostate expert, Dr. deKernion, testified that in the case of fruit juice such as POM Juice, that has low or no toxicity, it is not necessary to have a RCT, placebo-controlled test. (RFF 1784; deKernion, Tr. 3060).

Respondents' erectile and nitric oxide experts, Drs. Goldstein and Burnett, also testified that urologist who treat men with erectile health concerns would not require that pomegranate juice be subjected to RCTs before concluding that pomegranate juice has a beneficial effect on preserving erectile function and erectile dysfunction. (RFF 650-651; 2122, 2123, 2164; PX0149-0006-0007; Burnett, Tr. 2272-74, 2303 (testifying that RCTs are not necessary to deal with studies of drinking pomegranate juice); PX0189-0003, 0014; PX0352 (Goldstein, Dep. at 50-52, 61); Goldstein, Tr. 2600-02, 2611, 2620 (testifying that pharmaceutical type trials should not be applied to nutraceuticals—"a natural food product [from a plant] with health benefits").

In fact, much of what physicians provide patients in their clinical practices has not been proven to be beneficial in RCTs. (RFF 745-751; PX0025-0007; Sacks, Tr. 1559; PX0361 (Sacks Dep. at 111); CX1341 (Pantuck, Dep. at 276-277)). For example, Complaint Counsel's own expert, Dr. Eastham, admitted he has performed over 200 radical prostatectomies per year for a number of years before there were any RCTs showing that it worked. (RFF 746; Eastham Tr. 1331-32; PX0358 (Eastham, Dep. at 154-155)). Dr. Eastham performed these radical operations without RCTs despite the fact that the side-effects of this operation are significant and include impotence, incontinence, bleeding, embolisms, infection plus risks of general anesthetic. (RFF 747; Eastham, Tr. 1331-32). Also, Dr. Pantuck stated that clinicians remove kidneys without a RCT showing the benefits of nephrectomy. (RFF 748; CX1341 (Pantuck, Dep. at 276-277)).

Dr. Ornish also noted that randomized controlled trials have shown that angioplasties and stents do not prevent heart attacks or prolong life, yet the number of these procedures

performed is greater than ever. (RFF 749; PX0025-0007). Dr. Miller indicated that although health professionals, third party insurance carriers, and health related agencies highly recommend that eating 5 portions of fresh fruits and vegetables may prevent cancer, it is accepted without requiring controlled non-clinical or clinical trials. (RFF 750; PX0206-0012-0013).

Further, Complaint Counsel's experts, Professor Stampfer and Dr. Sacks, admitted that they have made public health recommendations that were not supported by RCTs. (RFF 751; Stampfer, Tr. at 810, 813-14; PX0300 (Stampfer, Dep. at 173); PX0361 (Sacks, Dep. at 35-38, 130-131)).

3. Respondents' Own Statements About and Use of RCTs Establish Their Important Role

1119. Mr. Resnick stated that human research is the most important type of study. (CX1360 (S. Resnick, Dep. at 93, 116, 121-22) (acknowledging early mechanistic research is different from human trials); *see also* S. Resnick, Tr. at 1758 (human research needed to reinforce *in* vitro and animal studies); CX1372 (S. Resnick, Trop. Dep. at 90) (Respondents conducted human research to reinforce *in* vitro and animal studies)).

Response to Finding No. 1119:

Respondents dispute this proposed finding of fact because Complaint Counsel have misstated testimony and mischaracterized evidence. Mr. Resnick never said that human research is the most important type of study. When asked about POM doing human research he said "in some instances [POM] can't; in some instances [POM] can. And we try – wherever we believe we really can do it and [it] make[s] sense . . . I mean we're not in a position to do a program where we have 6,000 people, as they do with, you know, some of these drugs. . . ." (CX1360 (S. Resnick, Dep. at 94)). Mr. Resnick does believe that human clinical research may be useful to reinforce findings in animal and *in vitro* studies. (S. Resnick, Tr. 1758). However Mr. Resnick also believes that basic research is enough to support claims, especially when the information is important for people to have, without conducting human clinical research. (S. Resnick, Tr. 1758). A position

that is in line with the consensus among competent and reliable scientists that when you are dealing with a safe 100% whole food product and that product is not offered as a substitute for conventional medical treatment, then it is appropriate to favor disclosure, and you may rely on basic science for substantiation and RCTs are not required. (Miller, Tr. 2194; PX0206-007, 0015).

Complaint Counsel's own nutrition expert, Professor Stamper, agreed stating that the general principles of evidence-based nutrition "can provide a sufficient foundation for establishing nutrient requirements and dietary guidelines in the absence of RCTs for every nutrient and food group." (Stamper, Tr. 831; RX5007 to RPTB). Additionally, Professor Stamper testified that when there is little risk and little cost involved and a potential benefit, that we should "definitely" make that information available to the public rather than withhold it. (Stamper, Tr. 838).

1120. Mr. Resnick testified that Respondents' human research distinguished POM from its competitors. (CX1360 (S. Resnick, Dep. at 94-95)).

Response to Finding No. 1120:

Respondents add the following explanatory facts to this proposed finding. Mr. Resnick does believe that POM's human research distinguishes POM from its competitors. Beyond that POM has done human research in situations where it is reasonable. (CX1360 (S. Resnick, Dep. at 95)). However, there are situations where human studies are not reasonable or feasible. (CX1360 (S. Resnick, Dep. at 94-95). If you are studying cardiovascular disease "where the end result is death" it may be unethical to conduct a human study. (CX1360 (S. Resnick, Dep. at 94-95)). Complaint Counsel's own expert, Professor Stampfer, agrees with Mr. Resnick's position for two reasons. First, Professor Stampfer testified that a major problem in using RCTs to study a food is that ethical principles do not permit randomizing individuals to diets that may have negative health effect. (RFF 636). Second, Professor Stampfer, testified that in a nutritional context, a

hypothesis about disease causation can, rarely, if ever, be directly tested in humans using an RCT design. (RFF 640). Respondent's expert, Dr. Heber, agreed testifying that most experts in the field of nutrition believe that RCTs have some significant drawbacks when it comes to the study of nutrient substances like pomegranates. (RFF653). Respondents do not dispute the value of human studies but they agree with Complaint Counsel's expert, Dr. Sacks, that there is value in conducting *in vitro* and animal studies because you can isolate mechanisms of action and such studies and be competent and reliable evidence of an agent's effect on a particular mechanism. (RFF 576, 577). Plus in an animal study, researchers can examine a specific mechanism by taking out their organs and cells, which you cannot do in humans. (RFF 578; CX1360 (S. Resnick, Dep. at 93-94)).

1121. Mr. Tupper stated in the "POM's Health Benefits: Fact or Fiction?" section of the www.pomwonderful.com website, that "[w]hen you look at the medical research that has been conducted on POM and compare it to research that's been done on other foods and beverages, what's been done on POM is . . . more akin to research being done on pharmaceutical drugs." (CX0336_0001; Tupper, Tr. 918).

Response to Finding No. 1121:

Respondents object to this proposed finding because Complaint Counsel selectively quote and mischaracterized statements made by Mr. Tupper. Respondents dispute Complaint Counsel's insinuation that Respondents believe that a research protocol, based on drug approval standards, is necessary to substantiate health benefit claims for a 100% whole food product. It is obvious when reading the full quote, without Complaint Counsel's selective edits, that Mr. Tupper did not say anything about POM using a drug research protocol. Mr. Tupper said, "When you look at the medical research that has been conducted on POM and compare it to research that's been done on other foods and beverages, what's been done on POM is way, way more extensive. It's almost more akin to research being done on pharmaceutical drugs." (CX0336_001) (emphasis added). In this context Mr. Tupper was merely distinguishing POM's vast body of research from the

limited research done by POM's competitors. Mr. Tupper never said POM's research was based on a drug approval protocol rather he used pharmaceutical research generally as reference point to illustrate the scope and breadth of POM's own research program. Mr. Tupper testified that POM's goal is to "distinguish ourselves from most of the other food and supplement companies that do one or two simple studies and stop there. That's very different than how we've approached our program, where, you know, over the past decade-plus we've funded and provided support for dozens upon dozens of studies with the intention of probing the frontiers of knowledge about pomegranates." (Tupper, Tr. 2997-98).

1122. Mr. Tupper further explained on the website that this "is why we go beyond the test tube and do all this clinical research. It isn't until you see an effect in humans with measurements that are medically meaningful that you know you've got something going on." (CX0336_0010; Tupper, Tr. 918, 1041; *see also* CCFF ¶ IX.B.6.272, ("[I]t really comes down to what happens in the human body.")).

Response to Finding No. 1122:

Respondents object to this proposed finding as contrary to the evidence in the record and dispute Complaint Counsel's insinuation that Respondents believe that RCTs are necessary to substantiate health benefit claims for a safe 100% whole food product like the Challenged Products.

Complaint Counsel selectively quote and mischaracterize statements made by Mr. Tupper. When read in context, the evidence does not support Complaint Counsel's proposition. Mr. Tupper wrote in full:

> "It's fine to say a product works as an antioxidant in a test tube but that's just scratching the surface. What you really have to do is make sure that your product and the antioxidants – end up being absorbed by your body, get transported through your blood stream, and make it to your vital organs, because that's really where the benefit occurs. Which is why we go beyond the test tube and do all this clinical research. It isn't until you see an effect in humans

> with measurements that are medically meaningful that you know you've got something going on." (CX0336_0010) (emphasis added)

Mr. Tupper was not, in fact, saying that human research is necessary to show a specific health benefit. Instead Mr. Tupper was advocating the importance of human studies showing the bioavailability and absorption of antioxidants – which POM has. POM has conducted three human clinical studies that showed that the Challenged Products are bioavailable and are absorbed into the blood stream. (RFF 882-902).

Moreover, Mr. Tupper's statement is taken from a webpage wherein the opening sentence states, "Antioxidants are all the rage. Every product on the supermarket shelves seems to tout its antioxidant benefits, whether or not the producer has done any research to back its claims." (CX0336_0009). The purpose of this webpage, and Mr. Tupper's comments regarding human research, was to distinguish POM's research from the research of competitors and was not meant to imply that POM believes human clinical trial are necessary to substantiate health claims for 100% whole food products like pomegranate juice.

1123. Mr. Tupper reiterated this position when he testified in federal court that Respondents worked with scientists to explore health benefits of POM and "pursued a very rigorous approach to science" starting with test tube research, then animal studies, followed by human clinical trials, which was the "gold standard in the scientific research community." (CX1406 (Tupper, Trop. Tr. at 130); *see also* CX1406 (Tupper, Trop. Tr. at 34-35) (Respondents' research on various areas of health "included very basic lab science, test tube science, and progressed over time into human studies[.]")).

Response to Finding No. 1123:

Respondents object to this proposed finding as contrary to the evidence in the record to the extent Complaint Counsel insinuate that Respondents believe that RCTs are necessary to substantiate health benefit claims for a safe 100% whole food product like the Challenged Products.

First, Mr. Tupper has an MBA and a bachelor's degree in political science he is not a doctor or research scientist and is not qualified to speak to standards in the scientific community. (Tupper, Tr. 889). That being said POM has conducted and published seventeen peer-reviewed human clinical trials. (RFF 269). Regardless of that Complaint Counsel has presented no evidence to prove that Mr. Tupper was using the term "human clinical trials" interchangeably with "RCTs" or that POM in general, separate and apart from Mr. Tupper, believes RCTs to be the best or even necessary scientific evidence. Therefore it is deceptive for Complaint Counsel to presume as much. Particularly in this case where Mr. Tupper was speaking generally about a general scientific process and the fact PETA was concerned because POM's research, in part, was done using animal models. (CX1406 (Tupper, Trop. Tr. at 130)).

Nevertheless, Respondents do believe that human clinical research may be useful to reinforce findings in animal and *in vitro* studies. (S. Resnick, Tr. 1758). However Respondents also believe that basic research is enough to support claims, especially when the information is important for people to have, without conducting human clinical research. (S. Resnick, Tr. 1758). A position that is in line with the consensus among competent and reliable scientists that when you are dealing with a safe 100% whole food product and that product is not offered as a substitute for conventional medical treatment, then it is appropriate to favor disclosure, and you may rely on basic science for substantiation and RCTs are not required. (Miller, Tr. 2194; PX0206-007, 0015).

While data from RCTs may provide the best evidence of a causal relationship between a treatment and a disease outcome in a pharmaceutical drug, Respondents' experts and Complaint Counsel's experts agree that RCTs are not required, nor even preferred to substantiate the health benefits of 100% natural, safe and healthy foods such as the Challenged Products. (RFF 569-744, 1184-1205, 1784-92, 2122, 2123; PX0149-0006-0007; Burnett, Tr. 2272-74, 2303 (testifying RCTs are not necessary to deal with studies

of drinking pomegranate juice); PX0189-0003, 0014; PX0352 (Goldstein, Dep. at 50-52, 61) (testifying that pharmaceutical type trials should not be applied to nutraceuticals—"a natural food product [from a plant] with health benefits"); Goldstein, Tr. 2600-02, 2611, 2620; deKernion, Tr. 3060 (in the case of fruit juice such as POM Juice, that has low or no toxicity, it is not necessary to have a RCT, placebo-controlled test); Miller, Tr. 2194, 2201; PX0206-0010-0015; Heber, Tr. at 1948-50, 2056, 2166; PX0149-0006-0007; PX0025-0007; Sacks, Tr. 1545-46; PX0361 (Sacks, Dep. at 134-135) (Complaint Counsel's expert, Dr. Sacks, concedes that a casual influence can be demonstrated between and agent and its effects on humans without the use of RCTs); Stampfer, Tr. 830; CX1293_0029-0030; RX5007 to RPTB; PX0362 (Stampfer, Dep. at 73-79, 98) (Complaint Counsel's designated expert on this matter, Professor Stampfer, testified that RCTs are not required to conclude a causal link regarding a nutrient and disease)).

1124. Steve Henig, one of POM's in-house scientific advisors, stated in an email that was copied to Mr. Tupper and MS. Resnick that "we [POM] and our collaborators are using a proven process to test [sic] health benefits of naturally occurring active components. A process that test the hypothesis *in vitro* first, then scales it up to a biological model using test animals . . . and then to human clinical. This process is used for functional foods, nutritional supplements, and medical drugs." (CX0038_0001; *see also* CX0780_0001 (outside scientists suggesting that "the juice must be tested in a large placebo-controlled trial . . . [to] finally answer the pomegranate question in a fashion that would be publishable in a major journal and sufficiently powered to convince clinicians and the media.")).

Response to Finding No. 1124:

Respondents dispute this proposed finding as contrary to the evidence in the record to the extent Complaint Counsel insinuate that Respondents believe that RCTs are required to substantiate health benefit claims for a 100% whole food product like the Challenged Products.

Complaint Counsel has presented no evidence to prove that Mr. Henig was using the term "human clinical" studies interchangeably with "RCTs" or that POM in general, separate

and apart from Mr. Henig, believes RCTs to be the best or even necessary scientific evidence. Therefore it is deceptive for Complaint Counsel to presume as much.

Regardless, Respondents do believe that human clinical research may be useful to reinforce findings in animal and *in vitro* studies. (S. Resnick, Tr. 1758). In fact Respondents have conducted seventeen human clinical studies all of which are published in peer-reviewed journals. (RFF 269). However, Respondents also believe that basic research is enough to support claims, especially when the information is important for people to have, without conducting human clinical research. (S. Resnick, Tr. 1758). A position that is in line with the consensus among competent and reliable scientists that when you are dealing with a safe 100% whole food product and that product is not offered as a substitute for conventional medical treatment, then it is appropriate to favor disclosure, and you may rely on basic science for substantiation and RCTs are not required. (Miller, Tr. 2194; PX0206-007, 0015).

While data from RCTs may provide the best evidence of a causal relationship between a treatment and a disease outcome in a pharmaceutical drug, Respondents' experts and Complaint Counsel's experts agree that RCTs are not required, nor even preferred to substantiate the health benefits of 100% natural, safe and healthy foods such as the Challenged Products. (RFF 569-744, 1184-1205, 1784-92, 2122, 2123; PX0149-0006-0007; Burnett, Tr. 2272-74, 2303 (testifying RCTs are not necessary to deal with studies of drinking pomegranate juice); PX0189-0003, 0014; PX0352 (Goldstein, Dep. at 50-52, 61) (testifying that pharmaceutical type trials should not be applied to nutraceuticals—"a natural food product [from a plant] with health benefits"); Goldstein, Tr. 2600-02, 2611, 2620; deKernion, Tr. 3060 (in the case of fruit juice such as POM Juice, that has low or no toxicity, it is not necessary to have a RCT, placebo-controlled test); Miller, Tr. 2194, 2201; PX0206-0010-0015; Heber, Tr. at 1948-50, 2056, 2166; PX0149-0006-0007; PX0025-0007; Sacks, Tr. 1545-46; PX0361 (Sacks, Dep. at 134-135) (Complaint

Counsel's expert, Dr. Sacks, concedes that a casual influence can be demonstrated between and agent and its effects on humans without the use of RCTs); Stampfer, Tr. 830; CX1293_0029-0030; RX5007 to RPTB; PX0362 (Stampfer, Dep. at 73-79, 98) (Complaint Counsel's designated expert on this matter, Professor Stampfer, testified that RCTs are not required to conclude a causal link regarding a nutrient and disease)).

1125. Mrs. Resnick testified that the company protocol was to require animal studies as prerequisites to human studies, which were essential for the company to make marketing claims about heart or prostate health. (L. Resnick, Tr. 276-77).

Response to Finding No. 1125:

Complaint Counsel's proposed finding of fact is completely disingenuous and is based on statements taken out of context and a blatant mischaracterization of the record evidence.

At trial Complaint Counsel cited to *Rubies in the Orchard* wherein Mrs. Resnick wrote about PETA protesting POM because POM's research program included animal studies. In addressing PETA's concerns Mrs. Resnick wrote, "Animal tests were necessary for the kind of rigorous, peer-reviewed science we were financing. Animal studies are generally a prerequisite for human studies and human studies are considered essential. (We didn't invent this protocol; but for the science to be considered sound we had to follow it)." (CX0001_0033). From this Complaint Counsel insinuate that POM's believes human studies are necessary to substantiate health benefit claims. For many reasons, Complaint proposition is absurd.

First, Mrs. Resnick is not a scientist and is not qualified to speak to standards in the scientific community. Nor has Complaint Counsel presented any evidence to prove that Mrs. Resnick was using the term "human studies" interchangeably with "RCTs" or that POM in general, separate and apart from Mrs. Resnick, believed RCTs to be the best or even necessary scientific evidence. Therefore, it is deceptive for Complaint Counsel to

presume as much. Beyond that POM has conducted, and published in peer-reviewed journals, seventeen humans studies. (RFF 269).

Second, and more importantly, Mrs. Resnick made is clear at trial that she was referring to a drug approval protocol in her book, "this is a drug protocol, and drugs are a single -- and I'm not a scientist, so I may not make a lot of sense here, but this is the way I understand it -- that drugs are a single action usually and therefore easier to study in humans, but fresh fruits and vegetables act systemically throughout the body, and maybe it is better to do test tube studies on those than actual human studies, is what I've been told. And it makes sense to me." (L. Resnick, Tr. 277) (emphasis added).

Mrs. Resnick's comments, in *Rubies in the Orchard*, were based on her understanding of drug protocol and not what competent and reliable scientists would consider sufficient scientific substantiation for a health claim made for a 100% whole food product. Respondents' experts and Complaint Counsel's experts agree that RCTs are not required, nor even preferred to substantiate the health benefits of 100% natural, safe and healthy foods such as the Challenged Products. (RFF 569-744, 1184-1205, 1784-92, 2122, 2123; PX0149-0006-0007; Burnett, Tr. 2272-74, 2303 (testifying RCTs are not necessary to deal with studies of drinking pomegranate juice); PX0189-0003, 0014; PX0352 (Goldstein, Dep. at 50-52, 61) (testifying that pharmaceutical type trials should not be applied to nutraceuticals—"a natural food product [from a plant] with health benefits"); Goldstein, Tr. 2600-02, 2611, 2620; deKernion, Tr. 3060 (in the case of fruit juice such as POM Juice, that has low or no toxicity, it is not necessary to have a RCT, placebo-controlled test); Miller, Tr. 2194, 2201; PX0206-0010-0015; Heber, Tr. at 1948-50, 2056, 2166; PX0149-0006-0007; PX0025-0007; Sacks, Tr. 1545-46; PX0361 (Sacks, Dep. at 134-135) (Complaint Counsel's expert, Dr. Sacks, concedes that a casual influence can be demonstrated between and agent and its effects on humans without the use of RCTs); Stampfer, Tr. 830; CX1293_0029-0030; RX5007 to RPTB; PX0362 (Stampfer, Dep. at

73-79, 98)) (Complaint Counsel's designated expert on this matter, Professor Stampfer, testified that RCTs are not required to conclude a causal link regarding a nutrient and disease)).

If you are talking about a pure food product or its derivative, and that product is not offered as a substitute for proper medical treatment, you may rely on basic science and RCTs are not required for substantiation. (Miller, Tr. 2194; PX0206-0007, 00015).

1126. Mrs. Resnick states in her book, "[W]e had invested millions in medical research to understand the efficacy of Wonderful pomegranates in treating a host of medical issues. Animal tests were necessary for the kind of rigorous, peer-reviewed science we were financing. Animal studies are generally a prerequisite for human studies and human studies are considered essential. (We didn't invent this protocol; but for the science to be considered sound, we had to follow it.)" (CX0001_0033).

Response to Finding No. 1126:

Complaint Counsel's proposed finding of fact is completely disingenuous and is based on statements taken out of context and a blatant mischaracterization of the record evidence.

At trial Complaint Counsel cited to *Rubies in the Orchard* wherein Mrs. Resnick wrote about PETA protesting POM because POM's research program included animal studies. In addressing PETA's concerns Mrs. Resnick wrote, "Animal tests were necessary for the kind of rigorous, peer-reviewed science we were financing. Animal studies are generally a prerequisite for human studies and human studies are considered essential. (We didn't invent this protocol; but for the science to be considered sound we had to follow it)." (CX0001_0033). From this Complaint Counsel insinuate that POM's believes human studies are necessary to substantiate health benefit claims. For many reasons, Complaint proposition is absurd.

First, Mrs. Resnick is not a scientist and is not qualified to speak to standards in the scientific community. Nor has Complaint Counsel has presented no evidence to prove that Mrs. Resnick was using the term "human studies" interchangeably with "RCTs" or

that POM in general, separate and apart from Mrs. Resnick, believed RCTs to be the best or even necessary scientific evidence. Therefore, it is deceptive for Complaint Counsel to presume as much. Beyond that POM has conducted, and published in peer-reviewed journals, seventeen humans studies. (RFF 269).

Second, and more importantly, Mrs. Resnick made is clear at trial that she was referring to a drug approval protocol in her book, "this is a drug protocol, and drugs are a single -- and I'm not a scientist, so I may not make a lot of sense here, but this is the way I understand it -- that drugs are a single action usually and therefore easier to study in humans, but fresh fruits and vegetables act systemically throughout the body, and maybe it is better to do test tube studies on those than actual human studies, is what I've been told. And it makes sense to me." (L. Resnick, Tr. 277) (emphasis added).

Mrs. Resnick's comments, in *Rubies in the Orchard*, were based on her understanding of drug protocol and not what competent and reliable scientists would consider sufficient scientific substantiation for a health claim made for a 100% whole food product. (L. Resnick, Tr. 277). Respondents' experts and Complaint Counsel's experts agree that RCTs are not required, nor even preferred to substantiate the health benefits of 100% natural, safe and healthy foods such as the Challenged Products. (RFF 569-744, 1184-1205, 1784-92, 2122, 2123; PX0149-0006-0007; Burnett, Tr. 2272-74, 2303 (testifying RCTs are not necessary to deal with studies of drinking pomegranate juice); PX0189-0003, 0014; PX0352 (Goldstein, Dep. at 50-52, 61) (testifying that pharmaceutical type trials should not be applied to nutraceuticals—"a natural food product [from a plant] with health benefits"); Goldstein, Tr. 2600-02, 2611, 2620; deKernion, Tr. 3060 (in the case of fruit juice such as POM Juice, that has low or no toxicity, it is not necessary to have a RCT, placebo-controlled test); Miller, Tr. 2194, 2201; PX0206-0010-0015; Heber, Tr. at 1948-50, 2056, 2166; PX0149-0006-0007; PX0025-0007; Sacks, Tr. 1545-46; PX0361 (Sacks, Dep. at 134-135) (Complaint Counsel's expert, Dr. Sacks, concedes that a casual

influence can be demonstrated between and agent and its effects on humans without the use of RCTs); Stampfer, Tr. 830; CX1293_0029-0030; RX5007 to RPTB; PX0362 (Stampfer, Dep. at 73-79, 98) (Complaint Counsel's designated expert on this matter, Professor Stampfer, testified that RCTs are not required to conclude a causal link regarding a nutrient and disease)).

If you are talking about a pure food product or its derivative, and that product is not offered as a substitute for proper medical treatment, you may rely on basic science and RCTs are not required for substantiation. (Miller, Tr. 2194; PX0206-0007, 00015).

1127. Indeed, Respondents have commissioned at least ten randomized, controlled human trials to study the effects of pomegranate products on endpoints relating to heart disease, prostate cancer, and erectile dysfunction. (*See* CCFF ¶¶ C.2.b.822, C.2.b(2)(a)855, C.2.c(1)(a)879, C.2.c(2)(a)912, C.3.a(2)929-30, C.3.b(2)946, D.3.1026, E.1.b(b)1065-64)).

Response to Finding No. 1127:

Respondents dispute this proposed finding as contrary to the evidence in the record to the extent Complaint Counsel insinuate that Respondents believe that RCTs are required to substantiate health benefit claims for a 100% whole food product like the Challenged Products. Complaint Counsel make astounding leaps of questionable logic when arguing that because Respondents did in fact conduct RCTs studies that Respondents have effectively acknowledged that only RCTs are reasonably reliable and scientifically accurate measures of substantiation.

This is simply untrue. Respondents commissioned studies because of their sincere desire to discover the truth about the health benefits of the pomegranate. (S. Resnick, Tr. 1859-60). RCTs are a useful piece, but not the entire scope of competent and reliable scientific discovery. Moreover, Respondents have never disputed the validity or importance of RCTs. Rather, Respondents dispute Complaint Counsels contention that RCTs are the

sole and only means by which competent and reliable scientific support must be measured – a position that is not supported by the scientific community.

Respondents' experts and Complaint Counsel's experts agree that RCTs are not required, nor even preferred to substantiate the health benefits of 100% natural, safe and healthy foods such as the Challenged Products. (RFF 569-744, 1184-1205, 1784-92, 2122, 2123; PX0149-0006-0007; Burnett, Tr. 2272-74, 2303 (testifying RCTs are not necessary to deal with studies of drinking pomegranate juice); PX0189-0003, 0014; PX0352 (Goldstein, Dep. at 50-52, 61) (testifying that pharmaceutical type trials should not be applied to nutraceuticals—"a natural food product [from a plant] with health benefits"); Goldstein, Tr. 2600-02, 2611, 2620; deKernion, Tr. 3060 (in the case of fruit juice such as POM Juice, that has low or no toxicity, it is not necessary to have a RCT, placebo-controlled test); Miller, Tr. 2194, 2201; PX0206-0010-0015; Heber, Tr. at 1948-50, 2056, 2166; PX0149-0006-0007; PX0025-0007; Sacks, Tr. 1545-46; PX0361 (Sacks, Dep. at 134-135) (Complaint Counsel's expert, Dr. Sacks, concedes that a casual influence can be demonstrated between and agent and its effects on humans without the use of RCTs); Stampfer, Tr. 830; CX1293_0029-0030; RX5007 to RPTB; PX0362 (Stampfer, Dep. at 73-79, 98) (Complaint Counsel's designated expert on this matter, Professor Stampfer, testified that RCTs are not required to conclude a causal link regarding a nutrient and disease)).

1128. In addition, Respondents have sponsored various human clinical trials on pomegranate products related to other diseases and areas of health, including two large unpublished RCTs on cold and flu, urinary tract infection, an RCT on cognitive function, an RCT on sports health, and skincare. (S*ee, e.g.,* CX01029_0008-09, 0011, 0015-16). For example, Respondents' Research Portfolio describes an RCT on the effect of POM Juice/POMx Beverage on 80 HIV/AIDS patients. (CX1029_0009). This document indicates that the "end game scenario" of the HIV/AIDS research was to "[p]ublicize results of current study (if positive)." (CX1029_0009).

Response to Finding No. 1128:

Respondents dispute this proposed finding as contrary to the evidence in the record to the extent Complaint Counsel insinuate that Respondents believe that RCTs are required to substantiate health benefit claims for a 100% whole food product like the Challenged Products. Complaint Counsel make astounding leaps of questionable logic when arguing that because Respondents did in fact conduct RCT studies that Respondents have effectively acknowledged that only RCTs are reasonably reliable and scientifically accurate measures of substantiation.

This is simply untrue. Respondents commissioned studies because of their sincere desire to discover the truth about the health benefits of the pomegranate. (S. Resnick, Tr. 1859-60). RCTs are a useful piece, but not the entire scope of competent and reliable scientific discovery. Moreover, Respondents have never disputed the validity or importance of RCTs. Rather, Respondents dispute Complaint Counsels contention that RCTs are the sole and only means by which competent and reliable scientific support must be measured – a position that is not supported by the scientific community.

Respondents' experts and Complaint Counsel's experts agree that RCTs are not required, nor even preferred to substantiate the health benefits of 100% natural, safe and healthy foods such as the Challenged Products. (RFF 569-744, 1184-1205, 1784-92, 2122, 2123; PX0149-0006-0007; Burnett, Tr. 2272-74, 2303 (testifying RCTs are not necessary to deal with studies of drinking pomegranate juice); PX0189-0003, 0014; PX0352 (Goldstein, Dep. at 50-52, 61) (testifying that pharmaceutical type trials should not be applied to nutraceuticals—"a natural food product [from a plant] with health benefits"); Goldstein, Tr. 2600-02, 2611, 2620; deKernion, Tr. 3060 (in the case of fruit juice such as POM Juice, that has low or no toxicity, it is not necessary to have a RCT, placebo-controlled test); Miller, Tr. 2194, 2201; PX0206-0010-0015; Heber, Tr. at 1948-50, 2056,

2166; PX0149-0006-0007; PX0025-0007; Sacks, Tr. 1545-46; PX0361 (Sacks, Dep. at 134-135) (Complaint Counsel's expert, Dr. Sacks, concedes that a casual influence can be demonstrated between and agent and its effects on humans without the use of RCTs); Stampfer, Tr. 830; CX1293_0029-0030; RX5007 to RPTB; PX0362 (Stampfer, Dep. at 73-79, 98) (Complaint Counsel's designated expert on this matter, Professor Stampfer, testified that RCTs are not required to conclude a causal link regarding a nutrient and disease)).

1129. Given the overwhelming evidence of Respondents' understanding and use of RCTs, they are well aware that their randomized, controlled human clinical trials have failed to support their treatment, prevention and reduction of risk claims for heart disease, prostate cancer, or erectile dysfunction. (*See* CCFF ¶¶ 966-73, 1044-51, 1098-99). Nevertheless, POM continues to maintain that anything it has said in any of its ads is more than adequately backed up by published research over the past 10 to 15 years. Mr. Tupper testified that POM is comfortable that every advertisement it has run, with one or two exceptions, have been more than adequately supported by the body of science. (Tupper, Tr. 2985-86, 3015).

Response to Finding No. 1129:

Respondents dispute this proposed finding as contrary to the evidence in the record. Respondents' believe that the all of the ads that POM has run are "more than adequately supported by the body of science." (Tupper, Tr. 3015; RFF 569-2196). POM, where feasible, has conducted RCTs. (CX1360 (S. Resnick, Dep. at 94)). Respondents do believe that human clinical research may be useful to reinforce findings in animal and *in vitro* studies. (S. Resnick, Tr. 1758). However, Respondents also believe that basic research is enough to support claims, especially when the information is important for people to have, without conducting human clinical research. (S. Resnick, Tr. 1758). RCTs are sometimes a useful piece, but not the entire scope of competent and reliable scientific discovery. Moreover, Respondents have never disputed the validity or importance of RCTs. Rather, Respondents dispute Complaint Counsel's contention that RCTs are the sole and only means by which competent and reliable scientific support must be measured – a position that is not supported by the scientific community.

The consensus among competent and reliable scientists is that if you are talking about a pure food product or its derivative, and that product is not offered as a substitute for proper medical treatment, you may rely on basic science and RCTs are not required for substantiation. (Miller, Tr. 2194; PX0206-0007, 00015). In fact both Respondents' experts and Complaint Counsel's experts agree that RCTs are not required, nor even preferred to substantiate the health benefits of 100% natural, safe and healthy foods such as the Challenged Products. (RFF 569-744, 1184-1205, 1784-92, 2122, 2123; PX0149-0006-0007; Burnett, Tr. 2272-74, 2303 (testifying RCTs are not necessary to deal with studies of drinking pomegranate juice); PX0189-0003, 0014; PX0352 (Goldstein, Dep. at 50-52, 61) (testifying that pharmaceutical type trials should not be applied to nutraceuticals—"a natural food product [from a plant] with health benefits"); Goldstein, Tr. 2600-02, 2611, 2620; deKernion, Tr. 3060 (in the case of fruit juice such as POM Juice, that has low or no toxicity, it is not necessary to have a RCT, placebo-controlled test); Miller, Tr. 2194, 2201; PX0206-0010-0015; Heber, Tr. at 1948-50, 2056, 2166; PX0149-0006-0007; PX0025-0007; Sacks, Tr. 1545-46; PX0361 (Sacks, Dep. at 134-135) (Complaint Counsel's expert, Dr. Sacks, concedes that a casual influence can be demonstrated between and agent and its effects on humans without the use of RCTs); Stampfer, Tr. 830; CX1293_0029-0030; RX5007 to RPTB; PX0362 (Stampfer, Dep. at 73-79, 98) (Complaint Counsel's designated expert on this matter, Professor Stampfer, testified that RCTs are not required to conclude a causal link regarding a nutrient and disease)).

1130. Respondents' expert testimony dismissing the need for RCTs to support Respondents' claims is revisionist history, as best exposed by Mrs. Resnick's trial testimony when she attempted to distance herself from her own prior statements about the proper scientific method, such as in CCFF ¶ 1126. (L. Resnick, Tr. 276-77). She testified: "I've recently been educated to the fact that" studies on fruits were better done in test tube studies rather than human studies. (L. Resnick, Tr. 277).

Response to Finding No. 1130:

Complaint Counsel's proposed finding of fact is completely disingenuous and is based on statements taken out of context and an out-and-out mischaracterization of the record evidence.

In *Rubies in the Orchard,* Mrs. Resnick wrote about PETA protesting POM because POM's research program included animal studies. In addressing PETA's concerns Mrs. Resnick wrote, "Animal tests were necessary for the kind of rigorous, peer-reviewed science we were financing. Animal studies are generally a prerequisite for human studies and human studies are considered essential. (We didn't invent this protocol; but for the science to be considered sound we had to follow it)." (CX0001_0033). From this Complaint Counsel extrapolate a broad, unqualified, and unsupported proposition that Respondents' have always and unequivocally agreed that the only "proper scientific method" for the substantiation of health claims is RCTs and therefore any testimony offered by Respondents' experts in this matter amounts to nothing more than revisionist history. Complaint Counsel is wrong for a myriad of reasons.

First, Mrs. Resnick is not a scientist and is not qualified to speak to standards in the scientific community. Additionally, POM does have 17 peer-reviewed and published human studies. (RFF 269). Regardless Complaint Counsel has presented no evidence to prove that Mrs. Resnick was using the term "human studies" interchangeably with "RCTs" or that POM in general, separate and apart from Mrs. Resnick, believes RCTs to be the best or even necessary scientific evidence. Therefore it is deceptive for Complaint Counsel to presume as much.

More importantly, the second sentence in Complaint Counsel's proposed finding of fact is a partial quote taken out of context. When quoted in full it is clear Complaint Counsel's argument is facially incorrect. The full quote reads:

> "I've recently been educated to the fact that -- and it makes sense -- that this is a drug protocol, and drugs are a single -- and I'm not a scientist, so I may not make a lot of sense here, but this is the way I understand it -- that drugs are a single action usually and therefore easier to study in humans, but fresh fruits and vegetables act systemically throughout the body, and maybe it is better to do test tube studies on those than actual human studies, is what I've been told. And it makes sense to me." (L. Resnick, Tr. 277) (emphasis added).

Mrs. Resnick made it clear that her comments were based on her understanding of drug protocol and not what competent and reliable scientists would consider sufficient scientific substantiation for a health claim made for a 100% whole food product. Respondent's expert Dr. Miller testified that the consensus among competent and reliable scientists is that if you are talking about a pure food product or its derivative, and that product is not offered as a substitute for proper medical treatment, you may rely on basic science and RCTs are not required for substantiation. (Miller, Tr. 2194; PX0206-0007, 00015). Complaint Counsel's own expert, Professor Stampfer, testified that is appropriate to rely upon evidence short of RCTs for claims regarding nutrients in food. (Stampfer, Tr. 830; PX0362 (Stampfer, Dep. at 73-79)).

Complaint Counsel alone attempts to revise history by claiming that RCTs are always required to substantiate health claims – a proposition that is both legally baseless and scientifically unsound.

I. COMPLAINT COUNSEL'S PROPOSED CONCLUSIONS OF LAW

A. Burden of Proof

1. The parties' burdens of proof are governed by Federal Trade Commission ("FTC") Rule 3.43(a), Section 556(d) of the Administrative Procedure Act ("APA"), and case law. FTC Rules of Practice, Interim rules with request for comments, 66 Fed. Reg. 17,622, 17,626 (Apr. 3, 2001). Pursuant to Commission Rule 3.43(a), "[c]ounsel representing the Commission . . . shall have the burden of proof, but the proponent of any factual proposition shall be required to sustain the burden of proof with respect thereto." 16 C.F.R. § 3.43(a).

Response to Conclusion 1:

Respondents do not disagree. (*See* RCL ¶¶ 13-14).

2. "It is well established that the preponderance of the evidence standard governs FTC enforcement actions." *Daniel Chapter One*, Docket No. 9329, 2009 FTC LEXIS 157, at *134-35 (Aug. 5, 2009) (initial decision) (citing *Telebrands Corp.*, 140 F.T.C. 278, 426 (2004) (initial decision), *aff'd.*, 140 F.T.C. 278 (2005), *aff'd.*, 457 F.3d 354 (4th Cir. 2006); *Automotive Breakthrough Sciences, Inc.*, 126 F.T.C. 229, 306 n.45 (1998)) (other citations omitted), *aff'd*, FTC Commission Decision (Dec. 24, 2009), available at http://www.ftc.gov/os/adjpro/d9329/091224commissionopinion.pdf, *aff'd.*, 405 F. App'x. 505 (D.C. Cir. 2010), *cert. denied*, 131 S. Ct. 2917 (2011).

Response to Conclusion 2:

Respondents do not disagree. (*See* RCL ¶¶ 13-14).

B. Jurisdiction

1. Jurisdiction over Respondents

3. The acts and practices charged in the Complaint in this matter took place in or affecting commerce within the meaning of the Federal Trade Commission Act, as amended. 15 U.S.C. § 41 et seq. (2012); (PX0364-0002 (Answer ¶ 8)). Nationwide advertising, marketing, or sales activity of the sort that Respondents engaged in constitutes "commerce" under the FTC Act. *See, e.g.*, *P.F. Collier & Son Corp. v. FTC*, 427 F.2d 261, 272 (6th Cir. 1970); *Ford Motor Co. v. FTC*, 120 F.2d 175, 183 (6th Cir. 1941) (noting that commerce also includes the actions, communications, and other acts or practices that are incident to those activities).

Response to Conclusion 3:

This Conclusion of Law is potentially misleading. Respondents agree that the acts and practices charged in the Complaint took place in or affecting commerce within the meaning of the FTC Act. Respondents do not agree that the acts or practices charged in the Complaint constitute actionable acts or practices under Sections 5(a) or "advertisements" under Section 12 of the FTC Act.

4. The Commission has jurisdiction over persons, partnerships, and corporations. 15 U.S.C. § 45(a)(2). A "corporation" is defined in Section 4 of the FTC Act as "any company . . . which is organized to carry on business for its own profit or that of its members[.]" 15 U.S.C. § 44. If individuals direct and control the acts and practices of a corporation amenable to the FTC's jurisdiction, then they too may be made subject to the FTC's jurisdiction. *Ohio Christian Coll.*, 80 F.T.C. 815, 845 (1972); *see also FTC v. Amy*

Travel Serv., Inc., 875 F.2d 564, 573 (7th Cir. 1989) (holding that an individual who either participated directly in or had the authority to control deceptive acts or practices may be held liable under the FTC Act for the violations of his corporation). Therefore, the Commission has jurisdiction over Corporate Respondents POM and Roll and Individual Respondents Stewart Resnick, Lynda Resnick, and Matthew Tupper.

Response to Conclusion 4:

This Conclusion of Law is potentially misleading. Respondents do not disagree with Complaint Counsel's statement of the relevant law. The Conclusion is incorrect as to Mr. Tupper for the reasons discussed in RCL ¶¶ 135-38.

5. The Complaint charges Respondents with violating Sections 5 and 12 of the FTC Act. Section 5(a) provides that "unfair or deceptive acts or practices in or affecting commerce are hereby declared unlawful." 15 U.S.C. § 45(a)(1). Section 12 prohibits the dissemination of "any false advertisement" in order to induce the purchase of "food, drugs, devices, services, or cosmetics." 15 U.S.C. § 52(a)(2). For the purposes of Section 12, the POM Products are "food" or "drugs." 15 U.S.C. § 55(b), (c) (defining "food" as, among other things, "articles used for food or drink for man," and defining "drug" as, among other things, "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man"). For the purposes of Section 12, "false advertisement" is defined as "an advertisement, other than labeling, which is misleading in a material respect[.]" 15 U.S.C. § 55(a).

Response to Conclusion 5:

This Conclusion of Law is potentially misleading. Respondents do not disagree with Complaint Counsel's statement of the relevant law, however Complaint Counsel have not shown in this proceeding that any POM Products are "drugs" as defined under Section 15(c) of the FTC Act.

2. All of Respondents' Challenged Marketing Is Advertising Subject to the FTC Act

6. "Advertisement" is not defined in the FTC Act and the "ordinary meaning of the word is: The act or process of calling something to the attention of the public; or a public notice, especially one published in the press or broadcast over the air." *Daniel Chapter One*, 2009 FTC LEXIS 157, at *168 (initial decision). Respondents promoted the POM Products through various means, including print advertisements in magazines, freestanding inserts in newspapers, out of home media such as billboards and bus shelters, posters in health clubs and doctors' offices, advertising on prescription drug bags, Internet websites, online banner advertisements, medical outreach, radio advertisements, television advertisements, press releases, and press interviews. (*See* CCFF ¶¶ 175-77).

Response to Conclusion 6:

This proposed Conclusion of Law is potentially misleading. Complaint Counsel's broad set of accusations includes many types of material that are not actionable "advertising." (*See* RCL ¶¶ 30-43). Furthermore, Complaint Counsel has conceded that it does not challenge certain types of marketing identified in this proposed Conclusion of Law, such as billboard advertisements. The proposed Conclusion of Law therefore contradicts its subject heading by including such extraneous statements.

7. Neither Section 5 nor 12 limits the FTC's reach to a specific type of advertising or even to paid-for advertising. *See* 15 U.S.C. § 55(a)(1) (defining "false advertisement" without requiring that the ad be paid for); *see also Daniel Chapter One*, 2009 FTC LEXIS 157, at *168 (initial decision). Rather, the Commission's authority to regulate advertising is circumscribed only by its statutory authority and the limits of the commercial speech doctrine. *See R.J. Reynolds Tobacco Co., Inc.*, 111 F.T.C. 539, 542 (1988) ("The more limited protection accorded commercial speech permits the FTC to act when necessary to challenge false or deceptive advertising.") (citing *Thompson Med. Co. v. FTC*, 791 F.2d 189 (D.C. Cir. 1986); *Sears, Roebuck & Co. v. FTC*, 676 F.2d 385 (9th Cir. 1982); *Warner-Lambert Co. v. FTC*, 562 F.2d 749 (D.C. Cir. 1977); *Beneficial Corp. v. FTC*, 542 F.2d 611 (3d Cir. 1976)). Public relations was a critical component of POM's marketing scheme and Respondents' challenged promotional materials include press releases and press interviews. (*See* CCFF ¶¶ 175-77, 261-80, 541-78). Respondents admitted in their Answer that the Lynda Resnick and Matthew Tupper interviews excerpted in the Complaint were "advertisements and promotional materials" that they disseminated or caused to be disseminated. (*See* CCFF ¶ 578).

Response to Conclusion 7:

Respondents agree that the Commission's authority to regulate advertising is circumscribed by its statutory authority and the commercial speech doctrine. Respondents disagree that this principle reaches to all the conduct challenged by Complaint Counsel. (*See* RCL ¶¶ 30-43). Respondents further disagree that these two doctrines are the "only" limits on the FTC's authority; for example, like any other federal agency, the FTC is subject to all of the various limitations that the U.S. Constitution imposes on government action – not just the commercial speech doctrine.

8. Although the Commission observed in *R.J. Reynolds Tobacco Co.* that "commercial speech frequently takes the form of paid-for advertising" and that "paid-for advertising [] is typical of commercial speech," it did not declare that payment is a necessary element of commercial speech. *R.J. Reynolds Tobacco Co., Inc.*, 111 F.T.C. at 545, 547 (emphasis added). The Commission merely pointed to payment as one of five non- dispositive indicia of commercial speech. *Id*. at 544. The other four were whether the speech (1) "contain[s] a message promoting the demand for a product;" (2) "refers to a specific product or service;" (3) conveys "information about attributes of a product or service offered for sale, such as type, price, or quality" or "health effects associated with the use of a product;" and (4) "benefit[s] or seek[s] to benefit the economic interests of the speaker by promoting sales of its products." *Id*. at 544-56. POM's challenged public relations carried the latter four indicia of commercial speech and fit comfortably into the commercial speech factors that the Commission considered in *R.J. Reynolds Tobacco Co*.

Response to Conclusion 8:

This Conclusion of Law is incorrect. In *R.J. Reynolds* the Commission held that they "understand [an advertisement] to mean a notice or announcement that is publicly published or broadcast and is paid-for," because such a communication embraces all of the enumerated characteristics and signifies that the speech is motivated primarily by commercial concerns. *In re R.J. Reynolds*, 111 F.T.C. 539, 547 (1988). Moreover, where the general purpose of the materials is not to promote a commercial transaction, it is not appropriate to classify select portions of the materials as commercial speech. Importantly, "where the main purpose of the work is non-commercial, and the commercial and non-commercial component parts of a 'single speech are inextricably intertwined, we cannot parcel out the speech, applying one test to one phrase and another test to another phrase.'" *Oxycal Labs., Inc. v. Jeffers*, 909 F. Supp. 719, 724-25 (S.D. Cal. 1995) (quoting *Riley v. Nat'l Fed. of the Blind*, 487 U.S. 781, 795-96 (1988)).

9. Respondents' challenged public relations materials, as well as Respondents' other challenged forms of marketing, constitute "advertisements" within the scope of Section 12 of the FTC Act, 15 U.S.C. § 52, and alleged deceptive acts or practices within the scope of Section 5 of the FTC Act, 15 U.S.C. § 45.

Response to Conclusion 9:

This Conclusion of Law is incorrect. (*See* RCL ¶¶ 36-40).

C. Respondents' Advertising is Deceptive or Misleading

1. Respondents' Advertisements Make the Claims Alleged in the Complaint

10. As alleged in Paragraphs 12 through 18 of the Complaint, Respondents' challenged advertisements make false and misleading representations that clinical studies, research, and/or trials prove that daily use of the POM Products treats, prevents, and/or reduces the risk of heart disease, prostate cancer, and/or erectile dysfunction ("establishment claims"). As alleged in Paragraphs 19 through 21 of the Complaint, Respondents' challenged advertisements make false and misleading representations that Respondents had substantiation that daily use of the POM Products treats, prevents, and/or reduces the risk of heart disease, prostate cancer, and/or erectile dysfunction ("efficacy claims"). These deceptive misrepresentations violate Sections 5 and 12 of the FTC Act.

Response to Conclusion 10:

This Conclusion of Law is not supported by the record in this proceeding.

11. An "advertisement is deceptive under the FTC Act if it is likely to mislead consumers, acting reasonably under the circumstances, in a material respect." *Daniel Chapter One*, 2009 FTC LEXIS 157, at *173 (initial decision) (quoting *Kraft, Inc. v. FTC*, 970 F.2d 311, 314 (7th Cir. 1992)); *see also FTC v. Direct Mktg. Concepts, Inc.*, 569 F. Supp. 2d 285, 297 (D. Mass. 2008), *aff'd*, 624 F.3d 1 (1st Cir. 2010); *Telebrands Corp.*, 140 F.T.C. at 290; *Thompson Med. Co.*, 104 F.T.C. 648, 788 (1984), *aff'd*, 791 F.2d 189 (D.C. Cir. 1986); *Cliffdale Assocs., Inc.*, 103 F.T.C. 110, 164-66 (1984); Federal Trade Commission Policy Statement on Deception, 103 F.T.C. 174, 175-76 (1984) (appended to *Cliffdale Assocs., Inc.*) ("Deception Policy Statement").

Response to Conclusion 11:

Respondents have no specific response.

12. "The primary evidence of the claims an advertisement conveys to reasonable consumers is the advertisement itself." *Daniel Chapter One*, 2009 FTC LEXIS 157, at *176 (initial decision) (citing *Telebrands Corp.*, 140 F.T.C. at 290; *Novartis Corp.*, 127 F.T.C. 580, 680 (1999), *aff'd*, 223 F.3d 783 (D.C. Cir. 2000); *Kraft, Inc.*, 114 F.T.C. 40, 121 (1991), *aff'd*, 970 F.2d 311 (7th Cir. 1992)).

Response to Conclusion 12:

Respondents have no specific response.

13. The FTC may use its own reasoned analysis to determine what claims an advertisement conveys. *See Kraft, Inc. v. FTC*, 970 F.2d at 318 ("[i]n determining what claims are conveyed by a challenged advertisement, the [FTC] relies on . . . its own viewing of the ad"); *FTC v. Colgate-Palmolive Co.*, 380 U.S. 374, 385 (1965).

Response to Conclusion 13:

This Conclusion of Law is potentially misleading because it is incomplete and ambiguous. Although the FTC may rely on "its own viewing of the ad" with respect to specific claims that are explicitly stated, *see* CCCL ¶ 13, the FTC cannot determine claims that are not conspicuous and clear from an ad without extrinsic evidence. (*See* RCL ¶¶ 19-21).

14. In determining whether an advertisement conveys a claim, the Commission looks to the overall, net impression created by the advertisement, through the interaction of different elements in the advertisement, rather than focusing on the individual elements in isolation. *See Am. Home Prods. Corp. v. FTC*, 695 F.2d 681, 687-88 (3d Cir. 1982); *Stouffer Foods Corp.*, 118 F.T.C. 746, 798-99 (1994); *Kraft, Inc.*, 114 F.T.C. at 122; Deception Policy Statement, 103 F.T.C. at 179; *see also FTC v. Sterling Drug, Inc.*, 317 F.2d 669, 674 (2d Cir. 1963) ("The entire mosaic should be viewed rather than each tile separately. 'The buying public does not ordinarily carefully study or weigh each word in an advertisement. . . .'") (quoting *Aronberg v. FTC*, 132 F.2d 165, 167 (7th Cir. 1942)).

Response to Conclusion 14:

Respondents have no specific response.

15. This Court has the authority to rule as to the conveyed meaning of advertisements and promotional materials based on a facial analysis of these advertisements or promotional materials. *Auto. Breakthrough Scis., Inc.*, Docket Nos. 9275-77, 1996 FTC LEXIS 252, at *44 (partial summary decision May 22, 1996) (citing *Kroger Co.*, 98 F.T.C. 684, 726, 729 n.12 (1981); *Ford Motor Co.*, 87 F.T.C. 756, 794-97 (1976)).

Response to Conclusion 15:

This Conclusion of Law is potentially misleading because it is incomplete and ambiguous. Although the FTC may rely on "its own viewing of the ad" with respect to specific claims that are explicitly stated, *see* CCCL ¶ 13, the FTC cannot determine claims that are not conspicuous and clear from an ad without extrinsic evidence. (*See* RCL ¶¶ 19-21).

16. Assessing the overall net impression of an advertisement includes examining the interaction of such elements as language and visual images. *See Kraft, Inc. v. FTC*, 970 F.2d at 322; *Telebrands Corp.*, 140 F.T.C. at 290; *see also Thompson Med. Co.*, 104 F.T.C. at 793, 811-12.

Response to Conclusion 16:

Respondents have no specific response.

17. Advertising claims may be express or implied. *See Kraft, Inc. v. FTC*, 970 F.2d at 318. Express claims directly state the representation at issue, while implied claims make representations without direct statements. *Id*. at 319 n.4; *Thompson Med. Co.*, 104 F.T.C. at 788-89.

Response to Conclusion 17:

Respondents have no specific response.

18. "The courts and the FTC have recognized consistently that implied claims fall along a continuum, from those which are so conspicuous as to be virtually synonymous with express claims, to those which are barely discernible." *FTC v. Febre*, No. 94 C 3625, 1996 U.S. Dist. LEXIS 9487, at *14 (N.D. Ill. July 3, 1996) (citing *Kraft, Inc. v. FTC*, 970 F.2d at 319) (magistrate judge's recommendation), adopted by 1996 U.S. Dist. LEXIS 14297 (N.D. Ill. Sept. 25, 1996), *aff'd*, 128 F.3d 530 (7th Cir. 1997); *see also FTC v. Bronson Partners*, LLC, 564 F. Supp. 2d 119, 127-28 (D. Conn. 2008) (an advertisement's statements were "so clear, repetitive, and unambiguous that they constitute[d] the functional equivalent of express claims"), *aff'd*, 654 F.3d 359 (2d Cir. 2011).

Response to Conclusion 18:

Respondents have no specific response.

19. "If the advertisement explicitly states or clearly and conspicuously implies a claim, the court need not look to extrinsic evidence to ascertain whether the advertisement made the claim." *FTC v. Nat'l Urological Group, Inc.*, 645 F. Supp. 2d 1167, 1189 (N.D. Ga. 2008), *aff'd*, 356 F. App'x 358 (11th Cir. 2009); *see also FTC v. Colgate-Palmolive Co.*, 380 U.S. at 391-92 (stating that the FTC is not required to conduct consumer surveys before determining that a commercial has a tendency to mislead); *Kraft, Inc. v. FTC*, 970 F.2d at 320 ("[W]hen confronted with claims that are implied, yet conspicuous, extrinsic evidence is unnecessary because common sense and administrative experience provide the Commission with adequate tools to make its findings. [citations omitted]. The implied claims Kraft made are reasonably clear from the face of the advertisements, and hence the Commission was not required to utilize consumer surveys in reaching its decision.").

Response to Conclusion 19:

Respondents have no specific response.

20. "[R]eferences to clinical testing, research and case studies are express claims that the respondents' representations are supported by scientific evidence." *Removatron Int'l Corp.*, 111 F.T.C. 206, 298 (1988), *aff'd*, 884 F.2d 1489 (1st Cir. 1989). *See also*

Thompson Med. Co., 104 F.T.C. at 814 (finding that "references to tests by a medical specialist, or 'clinical tests,' are an express reference to the type of test acceptable to the medical scientific community" and it would be "reasonable for consumers to expect that the claims . . . would be substantiated in a manner acceptable to the medical scientific community.")

Response to Conclusion 20:

Complaint Counsel's proposed *Removatron* quotation is erroneous because it decapitalizes the word "Respondents," thereby incorrectly implying that the quoted language is a general statement of the law as it applies to *all* respondents. The *Removatron* holding was limited to the respondents' representations in that specific case. The true and correct quotation is "We hold that references to clinical testing, research and case studies are express claims that the Respondents' representations are supported by scientific evidence." 111 F.T.C. 206, 298 (1988). This is not the generalized holding that Complaint Counsel present through selective decapitalization. Likewise, Complaint Counsel omits the word "The" from the beginning of their quotation from *Thompson Med. Co.*, implying that the holding was a legal finding that extends to all such tests references. The actual quotation makes clear that the holding was case-specific, following a fact-specific discussion of advertising by stating that "The references to tests by a medical specialist, or 'clinical tests,' are an express reference to the type of test acceptable to the medical scientific community." 104 F.T.C. at 814. Respondents object to Complaint Counsel deleting and modifying text in these quotations.

21. "Common examples of establishment claims include statements such as 'tests prove,' 'doctors recommend,' or 'studies show.'" *Daniel Chapter One*, 2009 FTC LEXIS 157, at *225-26 (initial decision) (citing *FTC v. Direct Mktg. Concepts*, 569 F. Supp. 2d at 298-99).

Response to Conclusion 21:

Respondents have no specific response.

22. "Although an establishment claim may be made by such words and phrases as 'established,' 'here's proof' and 'medically proven' …, it may also be made through the use of visual aids (such as scientific texts or white-coated technicians) which clearly suggest that the claim is based upon a foundation of scientific evidence." *Bristol-Myers Co.*, 102 F.T.C. 21, 321 (1983) (internal citations omitted), *aff'd*, 738 F.2d 554 (2d Cir. 1984). The net impression of such advertisements is that "respondents' claims were based on competent scientific proof." *Removatron Int'l Corp.*, 111 F.T.C. at 298 (citing *Bristol-Myers Co.*, 102 F.T.C. at 321; *Porter & Dietsch, Inc.*, 90 F.T.C. 770, 865 (1977), *aff'd* 605 F.2d 294 (7th Cir. 1979)).

Response to Conclusion 22:

This Conclusion of Law is potentially misleading. Mere inclusion of a scientific reference is not sufficient to make a claim an establishment claim. Rather, an establishment claim is a statement "to the effect that scientific tests establish that a product works." *Removatron Int'l Corp. v. FTC*, 884 F.2d 1489, 1492 n.3 (1st Cir. 1989). Respondents have not made unqualified "proven" health claims in any of their advertisements.

23. The following are examples of the types of advertising statements from which courts have found "clinically proven" claims to have been made either expressly or by implication:

- *FTC v Nat'l Urological Group, Inc.*, 645 F. Supp. 2d at 1201 (finding challenged claim that "Spontane-ES is clinically proven to be effective in treating 90% of men with erectile dysfunction" was made by the combination of an advertising statement that "in preliminary testing, Spontane-ES's active components have been shown to be effective in nearly 90% of all men who have taken it" combined with a reference to "research and development" conducted by "pharmacological staff at Warner Laboratories" and a letter from a doctor positively reviewing the product).

- *Bristol-Myers Co.*, 102 F.T.C. at 32, 322-23 (finding a challenged establishment claim that "tests or studies prove claims that Bufferin is twice as fast . . . as aspirin in relieving pain" from statements that "[s]cientific tests show," "[t]ests show," and "Bufferin laboratory tests show" faster relief than aspirin and noting that although "[n]one of Bristol-Myers' ads actually uses the word 'established' . . . this is immaterial because the ads create the impression that the claims have been established.");

- *FTC v. QT, Inc.*, 448 F. Supp. 2d 908, 929-32 (N.D. Ill. 2006) (finding the challenged establishment claim that "tests proved the Q-Ray bracelet relieves pain" from an ad in which a medical doctor said the bracelet worked for him, that he "did a little bit more research on it and then I decided to give the bracelet a try on some of my patients . . . and I was absolutely amazed at the response"; finding it from infomercials which emphasized the connection between the Q-Ray bracelet and alternative treatments such as acupuncture; finding it from a brochure in which a doctor described before and after thermographic imaging of one person as "a convincing piece of evidence for it's [sic] effectiveness"; and finding it from another brochure "that included the following statements: 'Only Q-Ray has Passed the Critical Yin-Yang Test; No other bracelets can pass these Natural Power tests.'"), *aff'd*, 512 F.3d 858 (7th Cir. 2008); *Metagenics, Inc.*, Docket No. 9267, 1996 FTC LEXIS 459, at *39-41 (Oct. 11, 1996) (initial decision) (finding challenged claim that "scientific research proves that Bone Builder or MCHC halts, prevents or treats osteoporosis" was made by an ad which stated, "Important and exciting research demonstrates that osteoporosis can safely and effectively be treated with a specially processed bone concentrate from young cattle . . ." and by an ad which stated, "[w]here there is evidence [of osteoporosis risk to an individual] [t]his safe, reliable, inexpensive, scientifically tested preventive is his/hers to take as they choose and not dependent upon the whim of another;" also finding challenged claim that "scientific research proves that Bone Builder or MCHC reduces or eliminates pain associated with bone ailments" from an ad which stated, "MCHC has been reported to improve fracture healing and relieve back pain in women with post menopausal bone loss").

Response to Conclusion 23:

Respondents have no specific response.

24. Here, the vast majority of Respondents' challenged advertisements contain indicia of "clinically proven" claims: express language (e.g., "Medical studies have shown" that POM Juice "minimizes factors that lead to atherosclerosis"; "Pomegranate juice consumption resulted in significant reduction in IMT (thickness of arterial plaque) by up to 30% after one year"), references to specific clinical studies, bold headlines (e.g., "24 SCIENTIFIC STUDIES NOW IN ONE EASY-TO-SWALLOW PILL," "Real Studies. Real Results."; "Science, not fiction"), statements touting their medical research expenditures (e.g., "backed by $32 million in medical research at the world's leading universities"), and/or medical imagery (e.g., a picture of POM Juice bottle used as an intravenous bottle, hooked to an electrocardiogram; or enclosed in a blood pressure cuff). (*See, e.g.*, CCFF ¶¶ 326, 344, 357, 368, 398, 415, 419, 425, 468).

Response to Conclusion 24:

Whether an advertisement makes an establishment claim "is a question of fact," *see Thompson Medical Co. v. FTC*, 791 F.2d 189, 194 (D.C. Cir. 1986), and therefore needs to be addressed with respect to particular ads. A general conclusion of law of this type is inappropriate, particularly when phrased in argumentative terminology like "the vast majority," where it is not supported by numerical data. Respondents possess substantiation for the specific claims made in specific advertisements. Furthermore, rather than the vague term "indicia," the issue turns on whether establishment claims are actually communicated by a specific advertisement. *Id.*

25. "Disclaimers or qualifications in any particular ad are not adequate to avoid liability unless they are sufficiently prominent and unambiguous to change the apparent meaning of the claims and to leave an accurate impression. Anything less is only likely to cause confusion by creating contradictory double meanings." *Daniel Chapter One*, 2009 FTC LEXIS 157, at *213 (initial decision) (quoting *Removatron Int'l Corp. v. FTC*, 884 F.2d 1489, 1497 (1st Cir. 1989)).

Response to Conclusion 25:

This Conclusion is an accurate quotation but may be misleading. The Commission has recognized that disclaimers or qualifications in a particular ad may be effective to negate potentially inaccurate impressions consumers may otherwise draw from an advertisement, and that an advertisement is not deceptive where it contains a conspicuous and unambiguous disclaimer in a form that consumers are likely to notice and understand. *Removatron Int'l Corp.*, 884 F.2d at 1496; *see also Thompson Med. Co.,* 104 F.T.C. at 842-843. Moreover, the Commission has never specified particular formats for disclaimers and qualifications (e.g. typeface size, proximity to other parts of an ad), opting instead for a flexible standard requiring analysis of each particular advertisement.

26. Qualifier words such as "can help" that appear in some of the challenged ads do not negate the net impressions of those ads that daily use of the POM Products prevents, and/or reduces the risk of heart disease, prostate cancer, and/or erectile dysfunction.

Similarly, words such as "preliminary" and "pilot" that appear in some of the challenged ads do not negate the establishment claims in those ads. *See Daniel Chapter One*, 2009 FTC LEXIS 157, at *204 (initial decision) ("Even though the language of the product description . . . attempts to relegate GDU's claimed effectiveness to a supporting role in 'helping' or 'aiding' the body, . . . the entire mosaic of the advertisement belies a merely 'supporting' role for GDU.").

Response to Conclusion 26:

Complaint Counsel has produced no evidence relating to (and has therefore not met its burden of showing) either the nature of the claims referred to in this Conclusion or the effect on any such claims of other language used in the relevant ads. The proposed Conclusion does not specify what advertisements it refers to, instead vaguely alluding to "some of the challenged ads," and to qualifier language and terms at a general level. This Conclusion is therefore incorrect and incomplete.

27. Small print disclaimers at the bottom of advertisements are insufficient as disclaimers. *See FTC v. Medlab, Inc.*, 615 F. Supp. 2d 1068, 1077 (N.D. Cal. 2009) ("Defendants cannot innoculate [sic] themselves from the representations that appear in the body of the text by including cautionary statements at the foot of the advertisements."). To be effective, disclosures must be clear and conspicuous. *See, e.g.*, *Thompson Med. Co.*, 104 F.T.C. at 842-43.

Response to Conclusion 27:

This Conclusion contains categorical conclusions that do not reflect Commission law, and are a patent overgeneralization of the cited authority, which does not state such categorical conclusions. (*See* RCL ¶ 25).

28. Moreover, "persons reading a print ad often will read only the headline, and will take their sole impression of the ad from it. The special significance of headlines has previously been recognized in Commission cases, which hold that even an express disclosure in the text of an ad may not be enough to change the ad's net impression upon consumers." *Thompson Med. Co.*, 104 F.T.C. at 799. Here, some of Respondents' bold headlines and sub-headlines conveyed specific health benefit claims, e.g., "Floss your arteries. Daily," "Heart Therapy," "Drink to prostate health," "I'm off to save PROSTATES!", "One small pill for mankind. 'Findings from a small study suggest that pomegranate juice may one day prove an effective weapon against prostate cancer,'" "NEW RESEARCH OFFERS FURTHER PROOF OF THE HEART-HEALTHY BENEFITS OF POM WONDERFUL JUICE. . . . 30% DECREASE IN ARTERIAL PLAQUE . . . 17% IMPROVED BLOOD FLOW . . . PROMOTES HEALTHY BLOOD VESSELS," and "NEW POMEGRANATE RESEARCH OFFERS HOPE TO

PROSTATE CANCER PATIENTS." (capitalization in originals). (*See* CCFF ¶¶ 336, 363, 368, 372, 397, 435-37, 440).

Response to Conclusion 28:

Respondents have no specific response to the first sentence of this Conclusion. Complaint Counsel has failed to offer any evidence whatsoever as to the meaning or net impression of the material quoted in the second sentence, and it is therefore incorrect. For example, the headline "Floss your arteries. Daily." does not, by itself, "convey a specific health benefit claim," because it is manifest puffery; arteries are not flossed, and even if they were, the headline itself is an imperative command to the reader to floss daily, not a specific claim. Indeed, the headline does not even mention a product. Any specific claims would have to be determined by net impression analysis of the advertisement, which Complaint Counsel failed to present – not just from looking at this headline by itself. The other examples are similarly defective.

29. In considering the net impression of an advertisement, the Commission does "not require that all consumers reading or viewing it be sophisticated experts in interpreting the nuances of the English language." *Thompson Med. Co.*, 104 F.T.C. at 792 ("We look at how such individuals actually interpret advertisements in a real-life situation, not at how they would if they had sufficient time and incentives attentively to review the ads so as to come up with the most semantically correct interpretation of them.").

Response to Conclusion 29:

Respondents have no specific response.

30. If an ad is targeted at a particular audience, the Commission analyzes ads from the perspective of that audience. *See Telebrands Corp.*, 140 F.T.C. at 291-92 ("Different target audiences come to an ad with different perceptions. Consumers cannot understand an ad – or any communication – without applying their own knowledge, associations, or cultural understandings that are external to the ad itself. For that reason, the purpose of ad interpretation is to determine the claims that consumers – particularly the target audience – take away from an ad, whether or not an advertiser intended to communicate those claims."); Deception Policy Statement, 103 F.T.C. at 179. Here the target audiences for ads for the POM Products were consumers who were very concerned about health or who already have health problems. (*See* CCFF ¶¶ 302-05).

Response to Conclusion 30:

Respondents have no specific response to the first sentence of this Conclusion, except that Complaint Counsel has omitted the important qualification from *Telebrands* that "ad interpretation focuses on the impact of the particular ad on *reasonable consumers* in the target group; an advertiser is not liable for an interpretation of an ad that a consumer may have based on an idiosyncratic perspective." *In re Telebrands Corp.*, 140 F.T.C. 278, 292 (2005) (emphasis added). The last sentence of this Conclusion is not supported by the record in this case. (*See* RRFF ¶¶ 302-05).

31. Commission law recognizes that advertisements may be susceptible to more than one reasonable interpretation. *Kraft, Inc.*, 114 F.T.C. at 120-21 n.8; *Thompson Med. Co.*, 104 F.T.C. at 789 n.7. "[S]tatements susceptible of both a misleading and a truthful interpretation will be construed against the advertiser." *FTC v. Bronson Partners, LLC*, 564 F. Supp. 2d at 127 n.6 (quoting *Country Tweeds, Inc. v. FTC*, 326 F.2d 144, 148 (2d Cir. 1964)).

Response to Conclusion 31:

Respondents have no specific response.

32. "Moreover, an ad need not mislead a majority of reasonable consumers. An ad is misleading if at least a significant minority of reasonable consumers are likely to take away the misleading claim." *Telebrands Corp.*, 140 F.T.C. at 291 (citing *Kraft, Inc.*, 114 F.T.C. at 122; Deception Policy Statement, 103 F.T.C. at 177 n.20).

Response to Conclusion 32:

Respondents have no specific response.

33. The Bovitz Survey provides evidence that at least a significant minority of consumers took away relevant health messages from the headlines and images used in several of the challenged ads. For example, a significant minority of consumers took from the images and headlines of the challenged "Decompress" print ad a message that drinking POM Juice lowers blood pressure; from the image and headline/subheadline of the challenged "I'm off to save PROSTATES!" print and banner ads a message that drinking POM Juice is good for prostate health; and from the headline "Holy Health! $25 million in medical research!" a message that "$25 million [was] spent on research/research based." (*See* CCFF ¶ 588). It also shows that a significant minority of those who saw the image and headline of the challenged "Heart Therapy" print and banner ads, together with the headlines of other challenged print ads, took away a message that a benefit of drinking POM Juice is that it is good for the heart. (*See* CCFF ¶ 590).

Response to Conclusion 33:

This is not a Conclusion of Law, but rather a defective proposed Finding of Fact. The Bovitz Survey does not provide such evidence, as discussed in the Responses to Complaint Counsel's proposed Findings of Fact regarding the Bovitz Survey.

34. These conclusions are based upon responses to open-ended questions. (*See* CCFF ¶¶ 587, 589). The Commission has held that credible evidence as to advertising communication can be obtained from responses to open-ended questions without controls. *See Telebrands Corp.*, 140 F.T.C. at 318 ("Marketing experts have found that credible evidence can be obtained from the responses to open-ended questions. We agree with the ALJ that it is appropriate to consider the open-ended responses without netting out any controls.") (citation omitted).

Response to Conclusion 34:

The proposed Conclusion misstates the citation and misstates the law. The Commission did not hold that open-ended responses are "credible evidence," but rather that the open-ended question *in that particular case* could be *considered as evidence*. An open-ended question is simply a question where the answers are not listed for the respondent. Open-ended questions may be just as biased or leading as closed-end questions (e.g., "what disease claims did the advertisement communicate?" is an open-ended question, if respondents can give any answer to it). Finally, although such data may be considered under appropriate circumstances, courts have consistently given little to no weight to ad perception survey data when that data was not obtained with the use of controls. "A survey that fails to use a control may be given less weight or even excluded all together." 6 J. Thomas McCarthy, *McCarthy on Trademarks and Unfair Competition*, § 32:187. As the Reference Manual on Scientific Evidence states, "[w]ithout the control group, it is not possible to determine how much of the 40% [deceptive response rate] is due to respondents' preexisting beliefs or other background noise (e.g., respondents who misunderstand the question or misstate their responses." Reference Manual on Scientific

Evidence, 257 (Federal Judicial Center 2d Ed. 2000); *see also* M. Rappeport, *Litigation Surveys: Social Science as Evidence*, 92 Trademark Rptr. 957, 986 (2002) ("Just as in most circumstances, no one would trust the results of a 'lineup' in which witnesses were shown only the suspect, the results in a litigation survey, without any controls, are strongly suspect.").

35. In fact, the Commission has held that results from open-ended ad communication questions understate communication. *Telebrands Corp.*, 140 F.T.C. at 318-19. In *Telebrands Corp.*, survey respondents were asked, "[w]hat did the commercial say, show, or imply about" the product at issue followed by, "[a]nything else?" to elicit additional responses, and the Commission held that this "likely understated the consumer take-away because consumers are unlikely to volunteer all of the messages they glean from an ad." *Id*.; *see also Stouffer Foods Corp.*, 118 F.T.C. at 805 (noting that "even . . . one of Stouffer's experts testified that often a researcher must rely on open-ended responses in the magnitude of 8 percent to 10 percent as being meaningful"); *Thompson Med. Co.*, 104 F.T.C. at 697 (initial decision) ("[O]pen-ended questions lead most respondents to play back only one theme or point. They do not draw out a complete or exhaustive list of all the things respondents may have on their minds. Rather, respondents will play back the dominant theme or primary impression and, having done that, will probably stop.").

Response to Conclusion 35:

The proposed Conclusion of Law inaccurately suggests that responses from open-ended ad communications "understate communication." That is not what *Telebrands* held, nor is it consistent with survey research. Open-ended questions may not include all of the more minor messages that an ad may convey, instead focusing on the dominant and primary messages – which is different than Complaint Counsel's inaccurate general paraphrase, "understate communication." *Telebrands* held that the specific open-ended data at issue in that case "*if anything, likely* understate the consumer take-away because consumers are unlikely to volunteer all of the messages they glean from an ad." 140 F.T.C. 278, 319 (2005) (emphasis added). Complaint Counsel's proposed Conclusion of Law improperly omits the "if anything, likely" introduction to this statement,

mischaracterizing the partial and rhetorical quotation as if it were a general holding about survey research, which it is not.

36. In the Bovitz Survey, a majority of consumers exposed to the images and headlines of POM print ads, one of which referred to $25 million in medical research," said in response to a closed-ended question that, based on the ads they saw, POM Juice had "proven health benefits." (*See* CCFF ¶ 592-93). Even after using another attribute as a control for noise and yea-saying, 43% or more thought that POM Juice had "proven health benefits." (*See* CCFF ¶ 594).

Response to Conclusion 36:

This is not a Conclusion of Law, but rather a proposed Finding of Fact, which Respondents have disputed and refuted in their responses to the cited proposed Findings of Fact.

37. "Marketing experts also rely upon the results to closed-ended questions as indicative of consumer responses to ads. Closed-ended questions, however, have the potential to direct participants to certain aspects of an ad. Consequently, participants may respond to such questions based upon yea-saying, inattention, pre-conceptions, or other 'noise.' Thus, closed-ended questions require the use of some type of control mechanism. An appropriate control can involve the use of a control ad, or a control question. The use of both is not required." *Telebrands Corp.*, 140 F.T.C. at 319-20 (citations omitted).

Response to Conclusion 37:

Respondents have no specific response, except that this quotation constitutes a limited and partial discussion of the use and analysis of control functions in advertisement perception surveys.

38. "The Commission does not require methodological perfection before it will rely on a copy test or other type of consumer survey, but looks to whether such evidence is reasonably reliable and probative." *Stouffer Foods Corp.*, 118 F.T.C. at 799. Thus, the Bovitz Survey provides additional reliable evidence of how consumers interpreted various elements of Respondents' challenged ads.

Response to Conclusion 38:

The proposed first sentence is a partial quotation, and is deeply misleading. The full quotation from the case includes material that is critically important, but which Complaint Counsel omits:

> Extrinsic evidence includes, but is not limited to, reliable results from methodologically sound consumer surveys. *Kraft*, 114 F.T.C. at 121; *Cliffdale*, 103 F.T.C. at 164-66. In determining whether a consumer survey is methodologically sound, the Commission will look to whether it "draws[s] valid samples from the appropriate population, ask[s] appropriate questions in ways that minimize bias, and analyze[s] results correctly." *Thompson Medical*, 104 F.T.C. at 790. The Commission does not require methodological perfection before it will rely on a copy test or other type of consumer survey, but looks to whether such evidence is reasonably reliable and probative. *See Bristol-Myers Co.*, 85 F.T.C. 688, 743-44 (1975). Flaws in the methodology may affect the weight that is given to the results of the copy test or other consumer survey.

Stouffer Foods Corp., 118 F.T.C. 746, 799 (1994). Complaint Counsel's selective excerpt from this discussion fails to address the fact that the Commission must determine that the survey is methodologically sound before relying upon it, and must determine that it is methodologically sound by looking at whether it draws valid samples from the appropriate population, asks appropriate questions in ways that minimize bias, and analyzes results correctly. Even if, after considering such factors, the survey is determined sufficiently reliable to be considered extrinsic evidence, the flaws may affect its weight. Complaint Counsel simply ignores these points of law. The Bovitz Survey does not come close to satisfying this test for reliability. Complaint Counsel's proposed second sentence is contrary to law and unsupported by the evidence.

39. There is abundant evidence in the record that Respondents intended to communicate the Challenged Claims. (*See, e.g.*, CCFF ¶¶ 281-318, 334, 337-38, 350, 354, 359-60, 369, 373-74). Making the specific health claims at issue was the business strategy for Respondents from the outset. (*See* CCFF ¶¶ 153-57; 159-60). Respondents have highlighted the medical research in POM Product advertising and marketing materials because the research lends credibility to the claims and gives consumers a "reason to believe." (*See* CCFF ¶ 306). Although intent is not required to find liability, a showing of intent is powerful evidence that the alleged claims in fact were conveyed to

consumers. *See Telebrands Corp.*, 140 F.T.C. at 304; *Novartis Corp.*, 127 F.T.C. at 683; *see also Thompson Med. Co.*, 104 F.T.C. at 791.

Response to Conclusion 39:

This Conclusion consists of factual assertions that Respondents strongly contest. (*See, e.g.* RRFF ¶¶ 153-57, 159-60).

40. Respondents' challenged advertisements convey expressly or strongly imply the challenged claims:

a. Clinical studies, research, and/or trials prove that daily use of POM Juice treats, prevents, and/or reduces the risk of heart disease. (*See* CCFF ¶¶ 328, 335, 340, 348, 361, 367, 388, 414, 418, 424, 429, 434, 441, 471, 494, 500, 535, 548, 555, 562, 573).

b. Clinical studies, research, and/or trials prove that daily use of POM Juice treats, prevents, and/or reduces the risk of prostate cancer. (*See* CCFF ¶¶ 371, 376, 384, 388, 405, 414, 418, 424, 429, 434, 441, 471, 494, 500, 535, 562, 573, 575, 577).

c. Clinical studies, research, and/or trials prove that daily use of POM Juice treats, prevents, and/or reduces the risk of erectile dysfunction. (*See* CCFF ¶¶ 388, 429, 471, 494, 500, 535, 567, 577).

d. Clinical studies, research, and/or trials prove that daily use of POMx Pills or POMx Liquid treats, prevents, and/or reduces the risk of heart disease. (*See* CCFF ¶¶ 414, 418, 424, 429, 434, 441, 535, 562).

e. Clinical studies, research, and/or trials prove that daily use of POMx Pills or POMx Liquid treats, prevents, and/or reduces the risk of prostate cancer. (*See* CCFF ¶¶ 405, 414, 418, 424, 429, 434, 441, 535, 562).

f. Daily use of POM Juice treats, prevents, and/or reduces the risk of heart disease. (*See* CCFF ¶¶ 328, 335, 340, 343, 348, 356, 361, 367, 388, 414, 418, 424, 429, 434, 441, 471, 494, 500, 535, 538, 548, 555, 562, 573).

g. Daily use of POM Juice treats, prevents, and/or reduces the risk of prostate cancer. (*See* CCFF ¶¶ 371, 376, 384, 388, 405, 414, 418, 424, 429, 434, 441, 471, 494, 500, 535, 540, 562, 571, 573, 575, 577).

h. Daily use of POM Juice treats, prevents, and/or reduces the risk of erectile dysfunction. (*See* CCFF ¶¶ 388, 429, 471, 494, 500, 535, 567, 577).

i. Daily use of POMx Pills or POMx Liquid treats, prevents, and/or reduces the risk of heart disease. (*See* CCFF ¶¶ 414, 418, 424, 429, 434, 441, 535, 562).

j. Daily use of POMx Pills or POMx Liquid treats, prevents, and/or reduces the risk of prostate cancer. (*See* CCFF ¶¶ 405, 414, 418, 424, 429, 434, 441, 535, 562).

k. Daily use of POMx Pills or POMx Liquid treats, prevents, and/or reduces the risk of erectile dysfunction. (*See* CCFF ¶¶ 429, 535).

Response to Conclusion 40:

This Conclusion consists of factual assertions that Respondents strongly contest.

Complaint Counsel have failed to meet their burden of establishing that Respondents' advertising makes any of the listed claims.

2. Respondents' Advertising Claims Are Material

41. A "material" misrepresentation is one that involves information important to consumers and that is therefore likely to affect the consumer's choice of, or conduct regarding, a product. Deception Policy Statement, 103 F.T.C. at 182.

Response to Conclusion 41:

Respondents have no specific response.

42. To be material, "a claim does not have to be the only factor or the most important factor likely to affect a consumer's purchase decision, it simply has to be an important factor." *Novartis Corp.*, 127 F.T.C. at 695.

Response to Conclusion 42:

Respondents have no specific response.

43. Materiality is a test of the likely effect of the claim on the conduct of a consumer who has been reached by the claim. *Novartis Corp.*, 127 F.T.C. at 691 ("Materiality turns upon whether those consumers who have drawn the claim from the advertisement" are "likely to have their conduct affected by the [alleged] misrepresentation."); Deception Policy Statement, 103 F.T.C. at 182.

Response to Conclusion 43:

Respondents have no specific response.

44. Certain categories of information are presumptively material. Claims significantly involving health are presumptively material. *Kraft, Inc. v. FTC*, 970 F.2d at 323; *accord Novartis Corp. v. FTC*, 223 F.3d 783, 786 (D.C. Cir. 2000) (quoting Deception Policy Statement, 103 F.T.C. at 182; *see also Daniel Chapter One*, 2009 FTC LEXIS 157, at *245 (initial decision) ("Health-related efficacy claims are consistently held to involve information that is important to consumers"); *FTC v. Direct Mktg. Concepts, Inc.*, 569 F. Supp. 2d at 300 (holding that claims that dietary supplements could prevent or treat cancer and other diseases were health-related efficacy claims which were "clearly material"); *FTC v. Nat'l Urological Group, Inc.*, 645 F. Supp. 2d at 1190-91 (applying presumption of materiality to claims that dietary supplements were effective to treat weight loss and sexual dysfunction); *FTC v. QT, Inc.*, 448 F. Supp. 2d at 965-66 (stating that claims that the Q-Ray bracelet provides immediate, significant, or complete relief

from various types of pain were "[w]ithout question" medical, health-related claims that were material to consumers).

Response to Conclusion 44:

Respondents have no specific response.

45. Express representations are presumed material because "the willingness of a business to promote its products reflects a belief that consumers are interested in the advertising." Deception Policy Statement, 103 F.T.C. at 182 (quoting *Cent. Hudson Gas & Elec. Co. v. Pub. Serv. Comm'n*, 447 U.S. 557, 567 (1980)); *see also FTC v. 1st Guar. Mortg. Corp.*, No. 09-cv-61840, 2011 U.S. Dist. LEXIS 38152, at *46 (S.D. Fla. Mar. 30, 2011); *FTC v. Nat'l Urological Group, Inc.*, 645 F. Supp. 2d at 1190; *Medical Billers Network, Inc.*, 543 F. Supp. 2d 283, 304 (S.D.N.Y. 2008). Also presumed as material are implied claims that are made "by such strong implication that they are the functional equivalent of an express claim." *See FTC v. Bronson Partners, LLC*, 564 F. Supp. 2d at 135.

Response to Conclusion 45:

Respondents have no specific response.

46. "The Commission presumes that claims are material if . . . they pertain to the 'central characteristics of a product * * * such as those relating to its purpose * * * [or] efficacy.'" *Telebrands Corp.*, 140 F.T.C. at 292 (quoting *Thompson Med. Co.*, 104 F.T.C. at 816-17) (alteration in original); *see also Novartis Corp.*, 127 F.T.C. at 687 (agreeing with the ALJ that "the challenged superior efficacy claim relates to central characteristic of the product, that is, Doan's ability to relieve back pain."); *Brake Guard Prods., Inc.*, 125 F.T.C. 138, 210-11 (1997) (initial decision) ("The Commission also presumes claims to be material if they pertain to the 'central characteristics of a product . . . such as those relating to its purpose . . . [or] efficacy,' or to safety. The majority of the challenged claims made for the product directly involved its purpose, efficacy and safety. The central theme of respondents' ads was that the Brake Guard device was an antilock brake system that provided certain braking and stopping distance improvements, and that installing an antilock brake system like Brake Guard would make the vehicle safer.") (alteration in original) (citation omitted), *aff'd*, 125 F.T.C. 138 (1998).

Response to Conclusion 46:

Respondents have no specific response.

47. The Commission will also infer materiality where the record shows that Respondent intended to make an implied claim. *Novartis Corp.*, 127 F.T.C. at 686-89 (explaining that the ALJ correctly presumed implied superior efficacy claims were material because Novartis had intended to make such claims) (citing Deception Policy Statement, 103 F.T.C. at 182); *see also FTC v. 1st Guar. Mortg. Corp.*, 2011 U.S. Dist. LEXIS 38152, at *46 ("[D]eliberately-implied claims used to induce the purchase of a product or service are presumed to be material to consumers as a matter of law."); *FTC v. Bronson Partners, LLC*, 564 F. Supp. 2d at 135 ("The underlying rationale for finding [an intended] claim to be presumptively material . . . is 'the assumption that the willingness

of a business to promote its product reflects a belief that the consumers are interested in the advertising.'"); *FTC v. Nat'l Urological Group, Inc.*, 645 F. Supp. 2d at 1190 ("[D]eliberately made implied claims, used to induce the purchase of a particular product or service are presumptively material.").

Response to Conclusion 47:

This Conclusion confuses an evidentiary "inference" with the traditional presumption of materiality, which indeed may arise in situations — unlike this case — in which there is evidence that the seller intended to make the claim at issue. *Kraft, Inc. v. FTC*, 970 F.2d 311, 322 (7th Cir. 1992); *see also In the Matter of Novartis Corp.*, 127 F.T.C. 580, 686 (1999). Like other rebuttable presumptions, this presumption is not "an inflexible rule that eliminates [the] need to look at materiality on a case-by-case basis." *Thompson Med. Co.*, 104 F.T.C. at n.45. Rather, the FTC "will always consider relevant and competent evidence to rebut presumptions of materiality." *Novartis Corp.*, 127 F.T.C. at 686 (quoting *In the Matter of Cliffdale Assocs., Inc.*, 103 F.T.C. 110, 182 n.47 (1984)). Specifically, the FTC will consider evidence such as expert opinion and consumer surveys for this purpose. *Thompson Med. Co., Inc.*, 104 F.T.C. at 788-89.

48. In this case, Respondents' challenged claims unquestionably relate to health concerns (*see* CCFF ¶ 625), were often made expressly or so strongly implied as to be virtually express (*see* CCFF ¶ 627), and were intended (*see* CCFF ¶ 628), so they are presumed material. The claims are also presumptively material because they relate to the central characteristic and purpose of using POMx Pills or POMx Liquid and a central characteristic of POM Juice as it was advertised. (*See* CCFF ¶ 626).

Response to Conclusion 48:

The phrase "Respondents' challenged claims" is unclear because it does not specify whether it refers to Respondents' express claims or the implied claims that Complaint Counsel alleges were communicated by certain advertisements. Respondents agree that some of the advertising in dispute relates to health concerns, but other aspects do not. The proposed statement that the challenged claims "were often made expressly or so

strong implied as to be virtually express" is an argumentative statement that Respondents contest, rather than a Conclusion of Law. Respondents contend that to the extent the Commission is entitled to any presumption of materiality in this case for whatever reason, that presumption was rebutted by the testimony of Professor Reibstein as well as Matthew Tupper, and Complaint Counsel failed to provide affirmative evidence of materiality beyond such a presumption.

49. The Commission has also relied upon other evidence of materiality. Studies Respondents commissioned in the ordinary course of business demonstrate the importance of the challenged claims. (*See* CCFF ¶¶ 639-50). In the 2009 A&U study, 85% of then-current POM Juice drinkers said they personally drank pomegranate juice because it is "healthy/good for my health." (*See* CCFF ¶¶ 640-41). "[H]elps promote heart health" (57%), and "helps protect against prostate cancer" (47% of males) were the second and third ranked of nine or ten specific health benefits motivating drinkers of POM Juice. (*See* CCFF ¶¶ 642-43). Heavy pomegranate drinkers in the August 2007 Zoomerang online study ranked cardiovascular health and prostate health as the top two (out of six) health benefits of drinking pomegranate juice in importance to them. (*See* CCFF ¶¶ 648-49). Among a larger sample population, which included drinkers of other juices, 18% of males ranked erectile dysfunction as the first or second most important health benefit to them. (*See* CCFF ¶ 650).

Response to Conclusion 49:

These statements are not conclusions of law, but rather a reiteration of the cited proposed findings of fact. Complaint Counsel has mischaracterized the results of the A&U and Zoomerang surveys, and Respondents have set forth their positions on these issues in their responses to the cited findings of fact. (*See* RFF ¶¶ 2721-51). For example, Complaint Counsel's own survey expert, Michael Mazis, criticized the A&U survey, testifying that it has myriad flaws including the fact that it "primed" respondents' answers, was not directed at materiality, lacked a true control, was not a causal survey, and found high health benefits answers that could not have come from Pom's advertising. (*See* RFF ¶¶ 2735-50). The Zoomerang survey was similarly flawed, inflated, and unreliable. (*See* RFF ¶¶ 648-50). This Conclusion is therefore defective.

50. In *Kraft*, the Commission relied upon the responses to a similar closed-ended survey question as evidence of materiality. *Kraft, Inc.*, 114 F.T.C. at 135. In that matter, survey respondents were asked to rate the importance of nine factors in the decision to buy a challenged product. *Id*. at 86. The critical factor at issue was ranked only seventh out of nine characteristics, but the Commission still viewed the survey as evidencing materiality because a high percentage rated the factor as "extremely" or "very important." *Id*. at 138 n.30. *See also Novartis Corp.*, 127 F.T.C. at 690 (relying upon the closed-ended ratings of characteristics of pain relief products).

Response to Conclusion 50:

The questions are not similar. Over 71% of all the survey respondents in *Kraft* rated the response "a source of calcium" as "extremely" or "highly" important to their purchasing decision. 114 F.T.C. at 86. Even if Complaint Counsel's assertions about the A&U and Zoomerang surveys were correct, and they were reliable surveys, neither of those surveys asked respondents to assess the degree of importance of the stated factors in the manner addressed by the *Kraft* survey. The A&U survey did not ask about importance of the factors at all; it simply asked, via a leading, closed-end question without controls, if the listed factors were a factor in the purchase. Moreover, neither survey got the type of massive response cited by *Kraft*.

51. The survey conducted by Respondents' marketing expert, Dr. Reibstein, also shows the importance of health benefits to past POM purchasers. (*See* CCFF ¶ 655).

Response to Conclusion 51:

This is a proposed finding of fact, not a conclusion of law, and it is not accurate. Dr. Reibstein found that 35.2% of Pom purchasers said they bought or would repurchase Pom because it was "healthy," which, even as a finding of fact, should not be argumentatively rephrased as "shows the importance of health benefits."

52. Moreover, Dr. Reibstein testified that consumers in POM's target audience who were concerned about heart disease, prostate cancer, or erectile dysfunction would likely find the challenged claims to be important. (*See* CCFF ¶ 638). Expert testimony that a

challenged claim would motivate the target audience to purchase a product has been a basis for finding materiality. *Novartis Corp.*, 127 F.T.C. at 689-90.

Response to Conclusion 52:

The first sentence is not a conclusion of law, but rather a misleadingly phrased proposed finding of fact. (*See* RFF ¶¶ 2623-57). The first sentence is also vague and ambiguous in its reference to "the challenged claims." Respondents have no specific response to the second sentence.

53. Materiality is also shown by a willingness to pay a price premium for a product with a claimed attribute. Deception Policy Statement, 103 F.T.C. at 183 & n.57 ("there is a reason to believe consumers are willing to pay a premium for a product believed to contain a special analgesic ingredient, but not for a product whose analgesic is ordinary aspirin") (quoting *Am. Home Prods. Corp.*, 98 F.T.C. 136, 369-70 (1981), *aff'd* as modified, 695 F.2d 681 (3d Cir. 1982)). Respondents' marketing strategy for the POM Products was premised on convincing consumers that the claimed health benefits are the reason to buy their expensive products. (*See* CCFF ¶ 629).

Response to Conclusion 53:

Although a presumption of materiality may be "buttressed" by a demonstrated willingness to pay a price premium for a product with a claimed attribute, the Commission must establish a linkage between the two. *Kraft, Inc.*, 970 F.2d at 323-24. The Commission meets this burden where an increase in sales "correspond[s] directly with the ad campaign" and "indisputably reverse[s] sagging sales and market share." *Id*. This economic argument is most persuasive where a consumer purchases the product at issue over a less expensive, comparable product. *See* F.T.C. Policy Statement on Deception *appended to In re Cliffdale Assocs.*, 103 F.T.C. 182, 189 (1984). As to the last sentence, it refers to an argumentative assertion in CCFF ¶ 629 that lacks any supporting evidentiary citation. Complaint Counsel has offered no evidence whatsoever on any of these points. This Conclusion is therefore misleading and irrelevant.

54. Materiality is also shown by evidence that the challenged advertising led to increased sales. *Kraft, Inc. v. FTC*, 970 F.2d at 324 (Kraft's "increase in sales corresponded directly with the ad campaign . . . . [and] Kraft's increase in market share came at a time when Singles were priced roughly 40% higher than imitation slices. Thus, the Commission reasonably inferred that the [challenged] imitation superiority message, as a central theme in the ads, contributed to increased sales and market share."). Here, Respondents, themselves, assert that through their investment of millions of dollars to research and promote the health benefits associated with pomegranate juice, they largely created the market for pomegranate juice. (*See* CCFF ¶ 176). Sales went from nothing to $165 million in just four years. (*See* CCFF ¶ 137).

Response to Conclusion 54:

As with Conclusion of Law 53, Complaint Counsel failed to offer any evidence and has failed to meet its burden of demonstrating that the advertising of POM products had any specific effect on sales. *Cf. Kraft, Inc.*, 970 F.2d at 323-24. This Conclusion is therefore unsubstantiated, irrelevant, and incorrect.

55. Another basis to infer materiality is persistence in using challenged claims in the face of warnings that a deceptive message is conveyed. *Kraft, Inc. v. FTC*, 970 F.2d at 323; *Kraft, Inc.*, 114 F.T.C. at 137. Here, Respondents persisted in conveying the challenged claims despite numerous third parties warning them of the deceptive nature of their claims. (*See* CCFF ¶ 685).

Response to Conclusion 55:

Respondents have no specific response to the first sentence of Conclusion 55. The second sentence contains factual assertions that have not been proven and that Respondents deny. (*See* RFF ¶¶ 456-85, 2453-58). The Conclusion is therefore incorrect.

56. In order to rebut the presumption of materiality Respondents must come forward with sufficient evidence to support a finding that the claim at issue is not material. *Novartis Corp.*, 127 F.T.C. at 686. Materiality is a test of the likely effect of the claim on the conduct of a consumer who has been reached by the claim. Deception Policy Statement, 103 F.T.C. at 182-83; *Novartis Corp.*, 127 F.T.C. at 691 ("Materiality turns upon whether those consumers who have drawn the claim from the advertisement" are "likely to have their conduct affected by the [alleged] misrepresentation."). Respondents' rebuttal evidence, the Reibstein Survey, fails to provide such evidence. (*See* CCFF ¶¶ 654-55, 657-59). *See Kraft, Inc. v. FTC*, 970 F.2d at 323 (concluding that Respondent's consumer surveys were insufficient to rebut the presumption of materiality that had properly been presumed because the challenged calcium content and benefit claims involved a significant health concern to consumers).

Response to Conclusion 56:

Respondents have no specific response to the statements of law in the first, second, and fourth sentences of this Conclusion. The third sentence is incorrect. The Reibstein Survey demonstrated definitively that no meaningful number of consumers had purchased POM products in the belief that the product would have any specific effect on a disease state, therefore proving that the alleged claims, even if made, were not material to purchasing decisions by any cognizable group of consumers. (*See* RFF ¶¶ 2623-2679).

57. The Reibstein survey should have but did not ask survey respondents to evaluate the importance of the challenged claims in terms of whether those claims were likely to have an effect on their decision to purchase or to use POM Juice. (*See* CCFF ¶ 658). The survey failed to even expose consumers to the challenged ads or the challenged claims, so it did not provide a proper measure of materiality. (*See* CCFF ¶¶ 654-55, 657-59).

Response to Conclusion 57:

These are not conclusions of law, but rather recitations of proposed findings of fact which are defective for the reasons stated in Respondents' responses to the cited proposed findings of fact.

58. In *Novartis Corp.*, the Commission concluded that a study by respondents' expert "understated the number of respondents to whom the [challenged] superiority claims were material by failing to ask directly whether the superiority claim was important to them." *Novartis Corp.*, 127 F.T.C. at 695; *see also Kraft, Inc.*, at 90 (initial decision) (faulting Respondent's survey for not mentioning that the ads made the challenged claim and that "therefore it did not provide a basis for a conclusion as to the impact of the claims on consumer behavior").

Response to Conclusion 58:

Respondents have no specific response.

59. Even as a study of the purchase motivations of past purchasers, the Reibstein survey was flawed by its reliance on broad open-ended questions with no probing as to what survey respondents who said they bought POM Juice because it was "healthy" meant. (*See* CCFF ¶¶ 660-61). In *Novartis Corp.*, even when survey respondents had been exposed to a challenged ad, the Commission found that responses to an open-ended question about materiality were "almost certainly understated" because Respondents' expert "failed to ask follow-up questions to determine all of the aspects of the

commercial that made consumers more likely to buy Doan's in the future." *Novartis Corp.*, 127 F.T.C. at 695.

Response to Conclusion 59:

This criticism about insufficient probing is defective for the reasons set forth in RRFF ¶¶ 660-61. Respondents have no specific response to the second sentence.

60. Even if the Court were to give the Reibstein survey some weight, the predicate facts that gave rise to the presumption of materiality are not negated and remain evidence from which materiality can be inferred. *Novartis Corp.*, 127 F.T.C. at 686-89. The vast, overwhelming evidence on this issue in the record supports a finding that the challenged claims are material. (*See* CCFF ¶¶ 625-61).

Response to Conclusion 60:

In this proposed conclusion of law, Complaint Counsel argues that the totality of the evidence supports a finding of materiality. For the reasons set forth at length by Respondents in their briefs and in their responses to the cited proposed findings of fact, Complaint Counsel are incorrect.

3. Respondents' Advertising Claims Are Deceptive or Misleading

61. The Commission may prove an advertisement is deceptive or misleading by showing that a claim is false, or by showing that a claim is unsubstantiated because Respondents lacked a reasonable basis for asserting that the claim was true. *FTC v. Pantron I Corp.*, 33 F.3d 1088, 1096 (9th Cir. 1994); *FTC v. Sabal*, 32 F. Supp. 2d 1004, 1007 (N.D. Ill. 1998). The Complaint in this case makes allegations under both theories. (*See* Complaint ¶¶ 12-21).

Response to Conclusion 61:

Respondents have no specific response.

62. To prevail under the "falsity" theory, Complaint Counsel must prove that the express or implied claims conveyed by an advertisement are false. *Daniel Chapter One*, 2009 FTC LEXIS 157, at *222 n.4 (initial decision).

Response to Conclusion 62:

Respondents have no specific response.

63. In an advertising case, "the advertiser has the burden of establishing the substantiation it relied on for its claim." *Daniel Chapter One*, 2009 FTC LEXIS 157, at *137 (initial decision) (citing *FTC v. QT, Inc.*, 448 F. Supp. 2d at 959). The Commission then has the burden of proving that Respondents' purported substantiation is inadequate, but is not required to conduct or present clinical studies showing that the products do not perform as claimed. *See FTC v. QT, Inc.*, 448 F. Supp. 2d at 959 (citing *FTC v. Sabal*, 32 F. Supp. 2d at 1008-09).

Response to Conclusion 63:

Respondents have no specific response.

64. The vast majority of Respondents' challenged advertisements contain establishment claims, referencing clinical testing or medical research or otherwise suggesting that Respondents' claims are based upon a foundation of scientific evidence. (*See* CCFF ¶¶ 328, 335, 340, 348, 361, 367, 371, 376, 384, 388, 405, 414, 418, 424, 429, 434, 441, 471, 494, 500, 535, 548, 555, 562, 567, 573, 575, 577; CCCL ¶ 40).

Response to Conclusion 64:

This Conclusion states an unsubstantiated and vague factual generalization. (*See* RCL ¶ 24). The phrase "the vast majority" is undefined, as is the reference to "Respondents' claims," which could mean any claim communicated by the advertisement.

65. "If an advertisement represents that a particular claim has been scientifically established, the advertiser must possess a level of proof sufficient to satisfy the relevant scientific community of the claim's truth." *Removatron Int'l Corp.*, 111 F.T.C. at 297. In other words, the advertiser must possess "competent scientific proof." *Id*. at 298-99.

Response to Conclusion 65:

This Conclusion is potentially misleading. Respondents agree that the "competent and reliable scientific evidence" standard is appropriate for evaluating certain health claims, and that the application of that standard to individual cases will be informed by testimony from experts in the relevant field. Respondents submit that the credible expert testimony in this matter, including the testimony on cross-examination of Complaint Counsel's experts, confirms that under the standard applicable to Respondents' products, Respondents did possess adequate substantiation for their advertisements. In *Removatron*, only one expert testified on the standard of substantiation applicable to the

products and claims at issue in that litigation, and the Commission therefore largely, but not entirely, relied on that testimony. 111 F.T.C. at 299, 311.

66. In affirming the Commission's *Removatron* decision, the 1st Circuit stated that "a 'reasonable basis,' when one makes establishment claims, means well-controlled scientific studies. Without such a study, petitioners could not, as a matter of law, have a reasonable basis for their establishment claims." *Removatron Int'l Corp. v. FTC*, 884 F.2d 1489, 1498 (1st Cir. 1989).

Response to Conclusion 66:

This Conclusion also is potentially misleading. (*See* RCL ¶ 65). The record in *Removatron* on the standard for substantiation with regard to the product at issue consisted solely of the one expert proffered by Complaint Counsel, who testified in that context that the efficacy of the respondents product could only be established through a controlled, blinded clinical study. 111 F.T.C. at 299, 311. The record in this case, in contrast, abundantly demonstrates that for the products at issue here that standard is inappropriate and indeed largely infeasible. The discussion of this issue in the decisions of the Commission and the Court of Appeals in *Removatron* is inapplicable to this case. Furthermore, Complaint Counsel has selectively omitted important aspects of the discussions in those opinions. As the Commission itself acknowledged, its ruling in *Removatron* in no way altered the long-standing Commission general rule for establishment claims, like other claims, that the required level of substantiation for a claim depends on the nature and substance of the claim itself, and Respondents must "have at least the advertised level of substantiation" communicated to consumers. FTC's Statement on Advertising Substantiation at 3; *Removatron*, 111 F.T.C. at 297, 306; *Thompson Med. Co.*, 104 F.T.C. at 821 n.59; *Bristol-Myers Co.,* 102 F.T.C. 21, 231 (1983), *aff'd*, 738 F.2d 554 (2d Cir. 1984). This is a flexible, fact-specific inquiry. There is no short-cut in the law for Complaint Counsel to jump from alleging the existence of "establishment" claims to an imposition of a multiple "well-controlled" clinical trial requirement. The latter requirement, in any event, does

not exist in the FTC Act, *see, e.g. FTC v. QT, Inc.*, 512 F.3d 858, 861 (7th Cir. 2008), and is contrary to prevailing scientific standards. *See Matrixx Initiatives, Inc. v. Siracusano*, 131 S. Ct. 1309, 1320 (2011). Such a requirement cannot therefore be imposed indirectly and surreptitiously by Complaint Counsel's intricate proposed approach.

67. Moreover, if advertisements "expressly or impliedly promise a scientific level of substantiation," then a Pfizer analysis is not required and the ads' claims must be supported by scientific proof. *Removatron Int'l Corp.*, 111 F.T.C. at 297-98, 306 (when evaluating ads "the net impression" of which was "that respondents' claims were based on competent scientific proof . . . . we need not apply the Pfizer analysis in determining the reasonable basis for respondents' claims.").

Response to Conclusion 67:

This Conclusion is misleading. (*See* RCL ¶ 66). Once again, Complaint Counsel have selectively omitted relevant references from the *Removatron* decision. In that case the Commission actually held that "application of the Pfizer factors . . . [is] not required in cases such as this where a specific type of substantiation is claimed." 111 F.T.C. at 306, n.20. In such instances, the advertiser need only have the advertised level of substantiation. *See* Statement on Advertising Substantiation, 49 Fed. Reg. 30,999 (FTC Aug. 2, 1984), *reprinted in* 6 Trade Reg. Rep. (CCH) ¶ 39,060.

68. Courts have consistently found or upheld that double-blind, placebo-controlled studies are required to provide adequate substantiation for the truthfulness of the health-related efficacy claims challenged by the Commission. *See FTC v. Direct Mktg. Concepts, Inc.*, 569 F. Supp. 2d at 303 ("While it seems well-accepted that double-blind, placebo- controlled studies are necessary to substantiate health-related efficacy claims, it is not firmly accepted how many such studies must be offered"; requiring double-blind, placebo controlled human studies for claims of multiple health benefits for coral calcium supplement); *see also Removatron Int'l Corp. v. FTC*, 884 F.2d at 1499-1500 (upholding requirement for double-blind clinical test to substantiate performance claims for hair removal device); *Schering Corp.*, 118 F.T.C 1030, 1080, 1115-16 (1991) (initial decision) (weight-loss and generalized health benefit claims for a high fiber supplement required "substantiation by two well controlled clinical trials," which were described as double-blind, placebo controlled); *FTC v. Nat'l Urological Group, Inc.*, 645 F. Supp. 2d at 1202-03 (accepting undisputed expert testimony that erectile dysfunction claims require well-designed, placebo-controlled, randomized, double-blind clinical trials for substantiation); *FTC v. Braswell*, CV 03-3700 DT, 2005 U.S. Dist. LEXIS 42976, at *35 (C.D. Cal. Sept. 26, 2005) (by offering unrefuted evidence that the standard to

substantiate claims for various health-related products should be double-blind, placebo-controlled tests, Commission offered sufficient evidence to withstand summary judgment); *FTC v. SlimAmerica, Inc.*, 77 F. Supp. 2d 1263, 1274 (S.D. Fla. 1999) ("Scientific validation of the defendants' product claims requires a double blind study of the combination of ingredients used in" the defendants' weight loss product); *FTC v. Sabal*, 32 F. Supp. 2d at 1008-09 (rejecting a study as inadequate substantiation, in part, because it was not blinded or placebo-controlled); *FTC v. Pantron I Corp.*, 33 F.3d at 1097-98 (finding that use of a placebo-control is required to substantiate efficacy claims for a hair growth product); *FTC v. Cal. Pac. Research, Inc.*, No. CV-N-88-602, 1991 U.S. Dist. LEXIS 12967, at *12-13 (D. Nev. Aug. 27, 1991) (only placebo-controlled, double-blind clinical studies meet "the most basic and fundamental requirements for scientific validity and reliability").

Response to Conclusion 68:

This Conclusion is incorrect. *See* Respondents Reply Brief at 73-88. Complaint Counsel improperly attempts to substitute an administrative legal rule, taken from the FDA's pharmaceutical regulation scheme, in place of the "competent and reliable scientific evidence" standard that actually governs this proceeding and constrains the Commission's authority.

69. The need for double-blind, placebo-controlled studies is even clearer in cases which involve establishment claims. *See FTC v. QT, Inc.*, 448 F. Supp. 2d at 962 ("[W]ith medical, health-related claims, a well-conducted, placebo-controlled, randomized, double-blind study, the gold standard, should have been conducted. . . . Defendants would not be required to have a gold-standard study to substantiate the Q-Ray bracelet if they did not make such a strong, medical claim"). Here, Respondents, themselves, have asserted that one does not know that an antioxidant product is efficacious until one finds "measurements that are medically meaningful" through clinical testing on humans. (*See* CCFF ¶¶ 491, 1122).

Response to Conclusion 69:

This Conclusion is incorrect. *See* Respondents Reply Brief at 73-88. Not only does the quoted language from the district court opinion not support Complaint Counsel's sweeping assertion, the court of appeals that reviewed that opinion specifically noted that "[n]othing in the Federal Trade Commission Act . . . requires placebo-controlled, double-blind studies." *QT, Inc.*, 512 F.3d at 861. *See generally Matrixx Initiatives, Inc.*, 131 S.

Ct. at 1320 (medical researchers and the FDA do not limit themselves to the results of double-blind placebo-controlled studies).

70. A well-conducted, placebo-controlled, randomized, double-blind clinical trial:

> must (a) include patients who fulfill criteria for the type of pain to be treated; (b) be randomized so that each individual has the same probability of being in either the treatment or the placebo group; (c) be a double-blind study so that neither the investigator conducting the study nor the participants know who is receiving the placebo; (d) utilize [an endpoint, e.g.,] a pain rating instrument that has been demonstrated to be valid, reliable, and responsive for that disease and population; (e) subject its data to appropriate statistical analysis; and (f) show a statistically significant and clinically significant improvement in the treatment group, when compared to the control group, at the end of the trial.

FTC v. QT, Inc., 448 F. Supp. 2d at 938 (citing the Federal Judicial Center Reference Guide on Statistics and the Federal Judicial Center Reference Manual on Scientific Evidence).

Response to Conclusion 70:

This Conclusion is irrelevant. (*See* RCL ¶¶ 68-69).

71. "Randomized controlled experiments are ideally suited for demonstrating causation. . . . A good study design compares outcomes for subjects who are exposed to some factor (the treatment group) with outcomes for other subjects who are not exposed (control group). . . . In summary, data from a treatment group without a control group generally reveal very little and can be misleading." Federal Judicial Center, Reference Manual on Scientific Evidence 218-20, (3d ed. 2011); *see also id*. at 230 ("It is randomness in the technical sense that provides assurance of unbiased estimates from a randomized controlled experiment or a probability sample.").

Response to Conclusion 71:

This Conclusion is irrelevant. (*See* RCL ¶¶ 68-69).

72. One court has noted that "[i]n a randomized, placebo-controlled, clinical study, the appropriate statistical analysis is one that statistically compares the change observed in the treatment group to the change in the same measure observed in the placebo group"

and that "it is not scientifically appropriate to rely on a 'within group' statistical analysis; that is, an analysis of only the change in a measured parameter in the treatment group from the beginning to the end of the study, because the result may be due to other factors such as regression to the mean or the placebo effect." *See FTC v. QT, Inc.*, 448 F. Supp. 2d at 939.

Response to Conclusion 72:

This Conclusion is irrelevant. (*See* RCL ¶¶ 68-69). In addition, Complaint Counsel continues to cite to a district court opinion rather than the opinion of the court of appeals in the same case.

73. "If statistical significance is not achieved, [a] treatment cannot be said to have had an effect." *FTC v. QT, Inc.*, 448 F. Supp. 2d at 939 (citing the Federal Judicial Center Reference Guide on Statistics, the court wrote that "statistical significance is achieved if the statistical analysis shows that there is a 0.05 or less likelihood that the difference measured is due to chance ($p \leq 0.05$)").

Response to Conclusion 73:

This Conclusion is irrelevant and would be incorrect if applied in this case. (*See* RCL ¶¶ 68-69); *see generally Matrixx Initiatives, Inc.*, 131 S. Ct. at 1320.

74. Clinical studies, research, and/or trials do not prove that:

a. Daily use of POM Products treats, prevents, and/or reduces the risk of heart disease. (*See* CCFF Section VII.C, ¶¶ 784-973).

b. Daily use of POM Products treats, prevents, and/or reduces the risk of prostate cancer. (*See* CCFF Section VII.D, ¶¶ 974-1054).

c. Daily use of POM Products treats, prevents, and/or reduces the risk of erectile dysfunction. (*See* CCFF Section VII.E, ¶¶ 1055-1101).

Accordingly, Respondents' challenged establishment claims are false and misleading and Respondents did not possess competent and reliable scientific evidence for the challenged efficacy claims presented in these advertisements.

Response to Conclusion 74:

This Conclusion contains factual assertions that Complaint Counsel have failed to establish at trial. The Conclusion is contrary to the record and evidence from the hearing in this case.

75. A minority of the challenged ads only make non-establishment, efficacy claims. (*See* CCFF ¶¶ 343, 356, 538, 540, 571; CCCL ¶ 40). For those advertisements, the Court must determine the appropriate level of substantiation.

Response to Conclusion 75:

Respondents dispute the factual assertions stated in the first sentence. Respondents have no specific response to the second sentence.

76. "For non-establishment claims, what constitutes sufficient substantiation may depend on multiple factors, such as the type of claim, the type of product, the consequences of a false claim, the benefits of a truthful claim, the cost of developing substantiation for the claim, and the amount of substantiation that experts in the field believe is reasonable." *Daniel Chapter One*, 2009 FTC LEXIS 157, at *226-27 (initial decision) (citing *FTC v. Direct Mktg. Concepts*, 569 F. Supp. 2d at 299); *see also Removatron Int'l Corp.*, 111 F.T.C. at 306-07 n.20; *Thompson Med. Co.*, 104 F.T.C. at 821 (citing FTC Policy Statement Regarding Advertising Substantiation, 104 F.T.C. at 839-40 (1984) (appended to *Thompson Med. Co.*).

Response to Conclusion 76:

Respondents have no specific response.

77. Courts have consistently found that for health and safety claims, advertisers must possess "competent and reliable scientific evidence" substantiating their claims in order to have a "reasonable basis" for such claims. *See FTC v. Nat'l Urological Group, Inc.*, 645 F. Supp. 2d at 1202 (granting the FTC's motion for summary judgment and finding that since all of defendants' "claims regard the safety and efficacy of dietary supplements; [] they must be substantiated with competent and reliable scientific evidence"); *FTC v. Natural Solution, Inc.*, 2007 U.S. Dist. LEXIS 60783, at *11-13 (granting the FTC's motion for summary judgment and applying the "competent and reliable scientific evidence" standard to defendants' claims that their product prevents and treats cancer); *FTC v. QT, Inc.*, 448 F. Supp. 2d at 961 ("Reasonable basis" required defendants to have "competent and reliable scientific evidence" when they made the claim that the Q-Ray bracelet provides immediate, significant, or complete pain relief).

Response to Conclusion 77:

Respondents have no specific response.

78. Claims that are difficult or impossible for consumers to evaluate for themselves require a high level of substantiation, such as scientific tests. *Removatron Int'l Corp.*, 111 F.T.C. at 306 n.20; *Thompson Med. Co.*, 104 F.T.C. at 822-23. "The 'placebo' effect of consumer expectations when taking a purported remedy makes it difficult for consumers to verify product effectiveness for themselves." *Daniel Chapter One*, 2009 FTC LEXIS 157, at *230 (initial decision) (citing *FTC v. Pantron I Corp.*, 33 F.3d at 1090 n.1; *Removatron Int'l Corp.*, 111 F.T.C. at 306 n.20; *Thompson Med. Co.*, 104 F.T.C. at 822-23). Consumers cannot effectively determine for themselves the accuracy of the challenged claims.

Response to Conclusion 78:

This Conclusion of Law is potentially misleading and contains several unsubstantiated contentions. For example, Complaint Counsel's inclusion of the phrase "scientific tests" is vague and misleading. Moreover, Complaint Counsel fails to explain that the circumstances in which the Commission has referred to a "high level" of substantiation exclude situations in which the claims are express (e.g., "a pilot study showed"). In those instances, the advertiser need only have the advertised level of substantiation. *See Removatron Int'l Corp.,* 111 F.T.C. at 306 n.20; Statement on Advertising Substantiation, 49 Fed. Reg. 30,999 (FTC Aug. 2, 1984), *reprinted in* 6 Trade Reg. Rep. (CCH) ¶ 39,060.

79. Claims referring to specific facts and figures of a product's capabilities require a high level of substantiation, such as scientific tests. *Removatron Int'l Corp.*, 111 F.T.C. at 306 n.20; *Thompson Med. Co.*, 104 F.T.C. at 822.

Response to Conclusion 79:

This Conclusion is potentially misleading, and does not accurately reflect the quoted authority. (*See* RCL ¶ 78).

80. The inquiry into the "type of product" has consistently called for a "high level of substantiation, such as scientific tests," when a product is related to consumer health. *Daniel Chapter One*, 2009 FTC LEXIS 157, at *230 (initial decision); *Removatron Int'l Corp.*, 111 F.T.C. at 306 n.20; *Thompson Med. Co.*, 104 F.T.C. at 822.

Response to Conclusion 80:

This Conclusion is potentially misleading. Respondents do not challenge the traditional "competent and reliable scientific evidence" standard for health claims, but the

application of that standard to particular cases is a flexible one dependent on the circumstances and generally characterizing the required level of substantiation as "high" is inaccurate. Such a generalization is not possible.

81. The Commission stated in its May 1994 FTC Enforcement Policy Statement On Food Advertising: "The Commission's standard for substantiation of health claims in food advertising shares many elements with FDA's approach to such claims in labeling. Like FDA, the Commission imposes a rigorous substantiation standard for claims relating to the health or safety of a product, including health claims for food products. The Commission's standard that such claims be supported by 'competent and reliable scientific evidence' has been more specifically defined in Commission orders addressing health claims for food products to mean: tests, analyses, research, studies or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results." Enforcement Policy Statement On Food Advertising, 59 Fed. Reg. 28,388, 28,393 (FTC June 1, 1994)), *also available at* CX0002_0006 (footnotes omitted).

Response to Conclusion 81:

Respondents have no specific response.

82. "When no specific claim about the level of support is made, the evidence needed depends on the nature of the claim. . . . As a general rule, well-controlled human clinical studies are the most reliable form of evidence." Dietary Supplements: An Advertising Guide for Industry at 10 (FTC Apr. 2001), *available at* http://www.ftc.gov/bcp/edu/pubs/business/adv/bus09.pdf, also available at CX1014_0019.

Response to Conclusion 82:

Respondents have no specific response.

83. The sufficiency of the evidence to support efficacy claims for both food and dietary supplements must be evaluated in light of the entire body of scientific evidence. Respondents cannot simply rely upon studies that they quoted in their ads, while discounting research that does not support their claims. *See* Dietary Supplements: An Advertising Guide for Industry at 14 (FTC Apr. 2001), *available at* http://www.ftc.gov/bcp/edu/pubs/business/adv/bus09.pdf, also available at CX1014_0019 ("Studies cannot be evaluated in isolation. The surrounding context of the scientific evidence is just as important as the internal validity of individual studies. Advertisers should consider all relevant research relating to the claimed benefit of their supplement and should not focus only on research that supports the effect, while discounting research that does not. . . . Wide variation in outcomes of studies and inconsistent or conflicting results will raise serious questions about the adequacy of an advertiser's substantiation. . . . If a number of studies of different quality have been conducted on a specific topic,

advertisers should look first to the results of the studies with more reliable methodologies.").

Response to Conclusion 83:

Respondents have no specific response to the first sentence of this Conclusion. The second sentence is a defective argumentative contention that is not supported by the record in this case.

84. "[T]he Commission, like FDA, evaluates substantiation for health claims in the context of the surrounding body of evidence, and does not look to isolated studies, especially if those studies are unrepresentative of the larger body of evidence. . . . [T]he Commission believes that qualified claims based on evidence that is inconsistent with the larger body of evidence have the potential to mislead consumers, and, therefore, are likely to violate section 5." Enforcement Policy Statement On Food Advertising, 59 Fed. Reg. 28,388, 28,393-94 (FTC June 1, 1994), also available at CX0002_0006-07.

Response to Conclusion 84:

Respondents have no specific response.

85. Despite Respondents' contentions that developing competent and reliable scientific evidence is too costly for foods and that foods should be held to a lower standard, the Commission has consistently required in settlements that health claims for foods be supported by competent and reliable scientific evidence. *See The Dannon Co., Inc.*, 151 F.T.C. 62 (2011) (consent order) (challenging claims that Activia yogurt relieved temporary irregularity and helped with "slow intestinal transit time," and claims that DanActive dairy drink helped prevent colds and flu); *Kellogg Co.*, Docket No. C-4262, 2009 WL 2402679 (F.T.C. July 27, 2009) (consent order) (challenging claims that Frosted Mini-Wheats cereal was clinically shown to improve children's attentiveness by nearly 20%); *Tropicana Prods., Inc.*, 140 F.T.C. 176 (2005) (consent order) (challenging unsubstantiated representations that drinking 2-3 glasses a day of "Healthy Heart" orange juice would produce dramatic effects on blood pressure, cholesterol, and homocysteine levels, thereby reducing the risk of heart disease and stroke); *Unither Pharma, Inc.*, 136 F.T.C. 145 (2003) (consent order) (challenging claims that food bar containing amino acid reduces the risk of heart disease and reverses damage to the heart); *Interstate Bakeries Corp.*, 133 F.T.C. 687 (2002) (consent order) (challenging claims that calcium in Wonder Bread could improve children's brain function and memory); *Conopco, Inc.*, 123 F.T.C. 131 (1997) (consent order) (challenging heart-health claims for Promise margarine); *U.S. v. Eggland's Best, Inc.*, No. 96 CV-1983 (E.D. Pa. Mar. 12, 1996) (stipulated permanent injunction) (challenging claims about product's effect on cholesterol); *Eggland's Best, Inc.*, 118 F.T.C. 340 (1994) (consent order) (challenging claims about product's effect on cholesterol); *The Isaly Klondike Co.*, 116 F.T.C. 74 (1993) (consent order) (challenging claims about effect of Klondike Lite frozen dessert bars on consumers' serum cholesterol levels); *Bertolli USA, Inc.*, 115 F.T.C. 774 (1992) (consent order) (challenging claims that olive oil had been medically proven to reduce cholesterol, blood pressure, and blood sugar).

Response to Conclusion 85:

This Conclusion misstates Respondents' contentions and is misleading. Respondents do not challenge the Commission's traditional "competent and reliable scientific evidence" standard, but rather Complaint Counsel's novel interpretation of that standard to require multiple randomized, placebo-controlled clinical trials reaching a .95 confidence level of statistical significance for the types of claims made in POM advertisements. The settlements listed in this Conclusion by Complaint Counsel all refer only to the traditional, general, "competent and reliable scientific evidence" standard with the exception of the recent *Dannon* settlement, which does require "two adequate and well-controlled human clinical trials" if Dannon chooses to make claims that its yogurt product relieves temporary irregularity or helps with slow intestinal transit time. The *Dannon* settlement is one of the recent events that Respondents have pointed to as evidence of the new and unwarranted position the Commission is asserting against food manufacturers. As noted elsewhere, however, the present case is the first opportunity for judicial scrutiny of this position. For the reasons Respondents have identified, Respondents urge the Court to make clear to Complaint Counsel that this new position is contrary to existing law and the record in this case and is wholly inappropriate. Respondents further maintain and object that the Commission has improperly shifted its position in this manner without complying with the formal rulemaking procedures that were required under Section 18 of the FTC Act, 15 U.S.C. § 57(a), as well as under the Administrative Procedure Act, 5 U.S.C. § 553.

86. Moreover, Respondents have demonstrated their ability to fund a scientific research program to ascertain the health benefits of their products. As they told consumers, Respondents spent $34 million in medical research regarding the POM Products. (*See* CCFF ¶ 309). For example, the cost for the two well-conducted, placebo-controlled, randomized, double-blind clinical trials commissioned by Respondents to

determine any benefits of POM Juice in treating and preventing cardiovascular disease (the Davidson studies) was approximately $3 million. (*See* CCFF ¶ 878).

Response to Conclusion 86:

This is an argumentative proposed finding of fact, not a conclusion of law. As the testimony at trial established, Respondents have conducted an extensive, responsible, and scientifically valid research program that substantiates their claims for POM products. The record in this proceeding is also clear that a research program comparable to that required for FDA drug approval, which is the implication of Complaint Counsel's theory of this case, would be prohibitively expensive and infeasible for foods. (*See* RFF ¶¶ 346-377, 1222-26).

87. The POM Products are expensive for consumers to purchase. A one-year supply of POM Juice cost approximately $780 (buying 16-ounce bottles), a one-year supply of POMx Pills cost approximately $315 (buying 90-count bottles), and a one-year supply of POMx Liquid cost approximately $360. (*See* CCFF ¶¶ 127-28, 133, 135, 140, 145-46). Spending money on an expensive and unproven preventative or treatment causes economic injury which also weighs in favor of requiring a higher level of substantiation. *See Daniel Chapter One*, 2009 FTC LEXIS 157, at *234 (initial decision) (citing *Schering Corp.*, 118 F.T.C. at 1115 (initial decision); *Removatron Int'l Corp.*, 111 F.T.C. at 306 n.20). Furthermore, the use of POM Products are not risk-free. (*See* CCFF ¶ 1020-21).

Response to Conclusion 87:

Pomegranate juice is not something that must be purchased in what Complaint Counsel calls a "one-year supply." Complaint Counsel's subjective characterization of the products at issue as "expensive" and "unproven" is not supported by record evidence. For example, Complaint Counsel has not compared the prices of POM juice to other 100% fruit juice products, nor has Complaint Counsel established what the cost of a "one-year supply" of such other products is. This Conclusion is inappropriate.

88. "The Court can look to what experts in the relevant area of study would consider to be adequate in determining the amount and type of evidence that is sufficient" to substantiate the advertisers' claims. *FTC v. Braswell*, 2005 U.S. Dist. LEXIS 42976, at *31 (citing *Thompson Med. Co.*, 104 F.T.C. at 821). The credible expert testimony

supports a finding that the challenged claims require substantiation in the form of competent and reliable scientific evidence consisting of double-blind, placebo-controlled studies. (*See* CCFF ¶ 1102).

Response to Conclusion 88:

Respondents have no specific response to the first sentence of this Conclusion. The second sentence of this Conclusion is contrary to the record in this proceeding. (*See* RFF ¶¶ 1215-48).

89. The appropriate level of substantiation for those challenged ads that do not make establishment claims is competent and reliable scientific evidence consisting of well-designed, well-conducted, randomized, placebo-controlled, and double-blinded human clinical trials. (*See* CCFF ¶ 1108).

Response to Conclusion 89:

This Conclusion is contrary to law and the record in this case. (*See* RFF ¶¶ 1215-48).

90. Respondents did not possess competent and reliable scientific evidence to substantiate claims that:

a. Daily use of POM Products treats, prevents, and/or reduces the risk of heart disease. (*See* CCFF Section VII.C, ¶¶ 784-973).

b. Daily use of POM Products treats, prevents, and/or reduces the risk of prostate cancer. (*See* CCFF Section VII.D, ¶¶ 974-1054).

c. Daily use of POM Products treats, prevents, and/or reduces the risk of erectile dysfunction. (*See* CCFF Section VII.E, ¶¶ 1055-1101).

Response to Conclusion 90:

Respondents have competent and reliable scientific evidence to support the claims actually made in their advertising. This Conclusion contains unsupported accusations by Complaint Counsel concerning other alleged claims and incorrect implicit assumptions concerning the relevant science supporting Respondents' claims.

91. Therefore, Respondents violated Sections 5 and 12 of the FTC Act, and Complaint Counsel is entitled to the proposed order against Respondents.

Response to Conclusion 91:

This Conclusion states Complaint Counsel's conclusion from the preceding 90 proposed Conclusions of Law and is unsupported for the reasons identified in Respondents' Responses to those Conclusions.

D. Remedy

1. Corporate Liability

92. A corporation is liable for violations of the FTC Act if the corporation "engaged in misrepresentations or omissions of a kind usually relied on by reasonably prudent persons and [] consumer injury resulted." *FTC v. Pantron I Corp.*, 33 F.3d at 1102 (citing *FTC v. Amy Travel Serv.*, 875 F.2d at 573).

Response to Conclusion 92:

The language quoted in this Conclusion relates to potential liability in a federal district court injunction action under FTC Act Section 13(b), and Complaint Counsel fails to explain its relevance or application to this matter. This Conclusion is therefore irrelevant and potentially misleading.

93. POM and Roll are each liable, under Sections 5 and 12 of the FTC Act, for their involvement in making the challenged claims. POM is liable for claims made in its advertisements for its products. Roll is liable because of its role in creating POM's advertisements, promoting POM products through its public relations employees, and sponsoring and funding research on POM products. (*See* CCFF ¶¶ 92-107).

Response to Conclusion 93:

Complaint Counsel have failed to meet their burden of showing any violation of the FTC Act by any respondent. Further, Complaint Counsel have failed to meet their burden of showing liability of any entity other than POM itself. (*See* RRFF ¶¶ 92-107).

94. Additionally, Roll and POM are also jointly liable under the common enterprise theory. (*See* CCFF ¶ 121). The common enterprise theory exists for "situations where corporations are so entwined that a judgment absolving one of them of liability would provide the other defendants with 'a clear mechanism for avoiding the terms of the order.'" *FTC v. Nat'l Urological Group, Inc.*, 645 F. Supp. 2d at 1182.

Response to Conclusion 94:

Complaint Counsel have failed to meet their burden of showing any violation of the FTC Act by any respondent. Further, Complaint Counsel have failed to meet their burden of showing liability of any entity other than POM itself. (*See* RRFF ¶¶ 92-107).

95. "Where one or more corporate entities operate in a common enterprise, each may be held liable for the deceptive acts and practices of the others." *FTC v. Bay Area Bus. Council, Inc.*, No. 02-C-5762, 2004 U.S. Dist. LEXIS 6192, at *33-34 (N.D. Ill. Apr. 8, 2004) (finding a common enterprise where the corporate defendants were owned by the same person, were operated by the same people, often shared offices, did business under each other's names and accessed the same customer databases, shared and transferred proceeds as needed, and were considered a collaborative effort by the owner); *Telebrands Corp.*, 140 F.T.C. at 451 (initial decision) ("Corporate respondents acting in concert to further a common enterprise are each liable for the acts and practices of the others in furtherance of the enterprise").

Response to Conclusion 95:

Respondents have no specific response.

96. To determine whether a common enterprise exists, courts will consider a variety of factors including: "common control; the sharing of office space and officers; whether business is transacted through a maze of interrelated companies; the commingling of corporate funds and failure to maintain separation of companies; unified advertising; and evidence that reveals that no real distinction exists between the corporate defendants." *FTC v. Nat'l Urological Group, Inc.*, 645 F. Supp. 2d at 1182. Courts look for vertical or horizontal commonality. *FTC v. Network Servs. Depot, Inc.*, 617 F.3d 1127, 1142-43 (9th Cir. 2010) (noting evidence showing that the companies pooled resources, staff, and funds; shared common owners and managers; and participated to some extent in a common venture).

Response to Conclusion 96:

Respondents have no specific response.

97. The common enterprise analysis is not an alter ego analysis. The entities formally may be separate corporations, but operate as a common enterprise. *FTC v. Grant Connect, LLC*, No. 2:09-CV-01349, 2011 U.S. Dist. LEXIS 123792, at *43 (D. Nev. Oct. 25, 2011).

Response to Conclusion 97:

Respondents have no specific response.

2. Individual Liability

98. Individual Respondents Stewart Resnick, Lynda Resnick, and Matthew Tupper are directly liable for the violations, under Sections 5 and 12 of the FTC Act, given that they participated directly in or had the authority to control the deceptive acts or practices. (*See* CCFF ¶¶ 9-86). It is well established that an individual can be held liable for a corporation's violations of Section 5 if the individual formulates, controls or directs corporate policy. *See Benrus Watch Co. v. FTC*, 352 F.2d 313, 324-25 (8th Cir. 1965); *Griffin Sys., Inc.*, 117 F.T.C. 515, 582 (1994); *see also Standard Educators, Inc. v. FTC*, 475 F.2d 401, 403 (D.C. Cir. 1973). The Commission has also held that where an individual participates in preparation of deceptive representations, he may "be held liable for his own actions in violation of Section 5." *Griffin Sys., Inc.*, 117 F.T.C. at 583.

> When both a corporation and an individual are named in the complaint, to obtain a cease and desist order against the individual, Complaint Counsel must prove violations of the FTC Act by the corporation and that the individual either directly participated in the acts at issue or had authority to control them.

Daniel Chapter One, 2009 FTC LEXIS 157, at *275-76 (initial decision) (citing *FTC v. Standard Educ. Soc'y*, 302 U.S. 112, 119-20 (1937) (finding it proper for Commission to include individuals who were in charge and control of the affairs of respondent corporations in the Commission's cease and desist order).

Response to Conclusion 98:

Complaint Counsel has failed to meet its burden to demonstrate the contentions in the first sentence of this Conclusion. Respondents have no specific response to the remainder of this Conclusion.

3. The Order Sets Forth Appropriate Relief

99. The Order sets forth relief appropriate for this case. In carrying out this function the Commission is not limited to prohibiting the illegal practice in the precise form in which it is found to have existed in the past. If the Commission is to attain the objectives Congress envisioned, it cannot be required to confine its "road block" to the narrow lane the transgressor traveled; it must be allowed effectively to close all roads to the prohibited goal, so that its order may not be "by-passed" with impunity. Moreover, the Commission has wide discretion in its choice of a remedy deemed adequate to cope with the unlawful practices disclosed. *FTC v. Ruberoid Co.*, 343 U.S. 470, 473, 475 (1952); *Removatron Int'l Corp. v. FTC*, 884 F.2d at 1498 ("Our role in reviewing a Commission order has been defined by the Supreme Court: It has been repeatedly held that the Commission has wide discretion in determining the type of order that is necessary to cope with unfair practices found, and that Congress has placed the primary responsibility for fashioning orders upon the Commission.").

Response to Conclusion 99:

Complaint Counsel has failed to meet its burden to demonstrate the contentions in the first sentence of this Conclusion. Respondents have no specific response to the remainder of this Conclusion.

100. The "wide discretion" described in *FTC v. Ruberoid Co*. is subject only to two constraints: the order must bear a "reasonable relation" to the unlawful practices, *Jacob Siegel Co. v. FTC*, 327 U.S. 608, 612-13 (1946), and it must be sufficiently clear and precise that its requirements can be understood, *FTC v. Colgate-Palmolive Co.*, 380 U.S. at 392. *See also Thompson Med. Co. v. FTC*, 791 F.2d 189 (1986) (affirming an order requiring at least two adequate and well-controlled, double-blinded clinical studies for future efficacy claims for a topical analgesic).

Response to Conclusion 100:

Complaint Counsel cites no authority holding that the Commission is subject to only two constraints in issuing injunctive relief, and in arguing that overreaching position Complaint Counsel emphasizes how far its radical position in this case departs from historical practice and precedent. The discretion of the Commission in crafting remedies is subject to many constraints, in addition to the two identified by Complaint Counsel. The remedy must also be rational, within the Commission's jurisdiction as provided by the FTC Act, and not in violation of other law or the Constitution. For example, a "blanket" order is unwarranted where the major claims for a product are valid and the misrepresentation pertains to the extent that a product is beneficial rather than the fact that it is beneficial. *See, e.g.*, *Standard Oil Co. v. FTC.*, 577 F.2d 653, 662-63 (9th Cir. 1978) (misrepresentations in the advertisements pertained to the extent of pollution reduction and did not amount to a wholly false claim). In addition, the Commission should consider whether it has adequately justified and provided adequate notice of changes in its enforcement standards before imposing such new standards in an Order.

101. In determining the appropriate scope of relief, the Commission considers the seriousness and deliberateness of the violations, the ease with which the unlawful conduct can be transferred to other products, and whether the respondents have a history of prior violations. *Telebrands Corp. v. FTC*, 457 F.3d 354, 358 (4th Cir. 2006); *Kraft, Inc. v. FTC*, 970 F.2d at 326; *Sears, Roebuck & Co. v. FTC*, 676 F.2d at 392; *Standard Oil Co. v. FTC*, 577 F.2d 653, 662 (9th Cir. 1978); *Thompson Med. Co.*, 104 F.T.C. at 832-33. All three elements need not be present to warrant fencing-in. *See Stouffer Foods Corp.*, 118 F.T.C. at 811; *Kraft, Inc.*, 114 F.T.C. at 142.

Response to Conclusion 101:

This Conclusion is potentially misleading. Although the Commission has indicated that not all three of these elements need be equally present in a particular case, the factors "operate[] on a sliding scale" so that the absence of one or more needs to be offset by a strong showing of other factors. *Telebrands Corp. v. F.T.C.*, 457 F.3d 354, 358-59 (4th Cir. 2006).

102. The size and duration of the deceptive advertising campaign also is considered in evaluating the seriousness of the violations. *Stouffer Foods Corp.*, 118 F.T.C. at 812-13; *Kraft, Inc.*, 114 F.T.C. at 140. For at least seven years, Respondents engaged in a marketing campaign, in multiple media (including print, Internet, public relations, and point of sale marketing) to promote the POM Products as having been proven to provide, or effectively providing, heart, prostate, and/or erectile function benefits. (*See* CCFF ¶¶ 325-578).

Response to Conclusion 102:

Respondents have no specific response, apart from disputing the factual assertions in the last sentence of this proposed conclusion of law.

103. The seriousness of the Respondents violations stems from several factors. First, "the overall health ramifications" of the claims makes them serious. *Stouffer Foods Corp.*, 118 F.T.C. at 812-13. Respondents are urging consumers to purchase and use their products to treat, prevent, or reduce the risk of disease without a reasonable basis for doing so. Second, where, as here, a consumer is unable to assess, on their own, the validity of the claim, the seriousness of the violation is enhanced. *Id*.

Response to Conclusion 103:

Complaint Counsel has failed to meet its burden to demonstrate the factual contentions supporting this Conclusion. In particular, the second and third sentences of this

Conclusion are contrary to the record in this proceeding, and include argumentative factual assertions without supporting citation to the record.

104. Third, violations also have been found to be "serious" where "claims were consciously made despite flaws in the studies relied upon by [the respondent]." *See Schering Corp.,* 118 F.T.C. at 1121 (initial decision). Respondents claimed that their products were not only effective, but that their benefits were clinically proven. (*See* CCFF ¶¶ 328, 335, 340, 348, 361, 367, 371, 376, 384, 388, 405, 414, 418, 424, 429, 434, 441, 471, 494, 500, 535, 548, 555, 562, 567, 573, 575, 577, CCCL ¶ 40). They did this despite the fact that their data consisted largely either of unblinded, uncontrolled studies on questionable endpoints —such as the prostate and Aviram studies — or well-controlled, double-blind, randomized, placebo-controlled trials with negative results — such as the Ornish CIMT Study, Davidson CIMT Study (2009), Davidson BART/FMD Study, San Diego Study, and Forest Erectile Dysfunction Study (2007). (*See* CCFF ¶¶ 795, 857-58, 882, 914-15, 942, 1002, 1076).

Response to Conclusion 104:

This Conclusion is incorrect. This Conclusion reflects an incorrect assumption of the relevant legal standard of substantiation, *see* RCL ¶¶ 47-67, and also a mischaracterization of the nature of the cited studies. (*See* RFF ¶¶ 1415-26, 1427-1504, 1505-13, 1548-53, 1971-87).

105. The deliberateness of the violations is evidenced by the Respondents' "ready willingness to flout the law." *See Sears, Roebuck & Co. v. FTC*, 676 F.2d at 392. Respondents persisted in making the challenged claims despite expressions of concern about misleading marketing from the New York State Attorney General's office, the Council for Better Business Bureau's National Advertising Division, Dr. Pantuck, several Institutional Review Boards, the FTC, and the Food and Drug Administration's ("FDA"). (*See* CCFF ¶¶ 402, 662-84, 686-88). In addition, Respondents have expressed no remorse for their actions, and in fact are comfortable with continuing to make the challenged claims. (*See* CCFF ¶¶ 618-19, 953, 971-72, 1054, 1098, 1100).

Response to Conclusion 105:

This Conclusion is incorrect. This Conclusion incorrectly equates the extensive and complex history of Respondents' research program with the groundless conduct described in *Sears*, and also mischaracterizes the nature of the cited communications. (*See* RFF ¶¶ 426-31, 456-82, 487-92, 619, 953, 971-72, 1690-94, 2254-95, 2453-58).

106. A violation is transferrable where other products could be sold using similar techniques. *FTC v. Colgate-Palmolive Co.*, 380 U.S. at 395; *Sears, Roebuck & Co. v. FTC*, 676 F.2d at 392. Respondents sell a variety of foods and supplements, such as POMx bars, POMx iced tea and iced coffee, a POMx sports recovery beverage, Wonderful Pistachios, Wonderful Almonds, Fiji Water, citrus fruit, and wine, that could also be promoted using the kinds of health related representations that were challenged in this matter. (*See* CCFF ¶¶ 12, 123). Indeed, they have a made a variety of additional representations, not challenged in the Commission's complaint, about the potential of their products for other conditions, such as Alzheimer's disease and sports recovery. (*See* CCFF ¶¶ 241, 308, 326, 341, 349, 495, 570, 668). Further, the Respondents have researched potential health benefits of Wonderful Pistachios and Fiji Water. (*See* CCFF ¶ 725).

Response to Conclusion 106:

Respondents have no specific response to the first sentence of this Conclusion. The remainder of this Conclusion consists of unsubstantiated and irrelevant factual allegations and is therefore incorrect.

107. The Commission has entered orders covering many of a company's products on the basis of violations as to a single product. *Litton Indus., Inc.*, 97 F.T.C. 1, 78-80 (1981), *aff'd* as modified, 676 F.2d 364 (9th Cir. 1982); *Sears Roebuck & Co.*, 95 F.T.C. 406, 515-22 (1980), *aff'd*, 676 F.2d 385 (9th Cir. 1982). Here, the Respondents made deceptive representations regarding three products – POM Juice, POMx Pills, and POMx Liquid. (CCCL ¶¶ 40, 74, 90-91).

Response to Conclusion 107:

Respondents have no specific response to the first sentence of this Conclusion. Complaint Counsel have not met their burden of establishing the accusations in the last sentence.

108. "The more egregious the facts with respect to a particular element, the less important it is that another negative factor be present." *Sears, Roebuck & Co. v. FTC*, 676 F.2d at 392; *see also Thompson Med. Co.*, 104 F.T.C. at 833.

Response to Conclusion 108:

Respondents have no specific response.

109. Part I of the Order addresses disease claims made for any POM Product (defined as any food, drug or dietary supplement containing pomegranate or its components). It provides that the necessary substantiation for future claims that any POM Product is effective in the diagnosis, cure, mitigation, treatment, or prevention of any disease –

including heart disease, prostate cancer, or erectile dysfunction – is approval by the FDA, which may be provided in the form of a tentative final or final over-the-counter drug monograph, a new drug application, or labeling approval under regulations promulgated pursuant to the Nutrition Labeling and Education Act of 1990 ("NLEA").

Response to Conclusion 109:

This Conclusion describes Part I of the proposed Order in this case. That provision is contrary to law for the reasons described in Respondents' Briefing in this matter. (*See* Respondents Pre-Trial Brief at 62; Post-Trial Brief at 98; Reply Brief at 209-18).

110. Deference to the FDA's standards and its evaluation of scientific evidence is consistent with prior Commission practice. "It is well settled that in establishing substantiation requirements, the Commission accords substantial weight to FDA regulations and proposed rules." *Removatron Int'l Corp.*, 111 F.T.C. at 305.

Response to Conclusion 110:

This Conclusion is potentially misleading. Although FDA actions, once taken, may be relevant to the analysis of a particular case, the Commission's analysis is a distinct one arising under the FTC Act and the Commission has acknowledged that FDA standards are not always applicable or useful in an FTC Act case. The Commission's Enforcement Policy Statement on Food Advertising, for example, carefully notes that the Commission does not require "scientific consensus" to support claims, and that there are certainly circumstances in which the Commission would approve a claim that would not meet FDA standards.

111. In *Thompson Med. Co.*, after determining, under a Pfizer analysis, that the proper level of substantiation for the company's advertising claims for the topical analgesic Aspercreme was two well-controlled clinical tests, the Commission went on to note, [w]e are additionally persuaded to use this level of substantiation because … this is the standard currently being required [by the FDA]. We believe that advertisers of drug products subject to the joint jurisdiction of the FTC and the FDA will benefit from greater regulatory certainty if they can act with reasonable assurance that the two agencies will accept the same evidence to demonstrate the safety and efficacy of a particular ingredient. *Thompson Med. Co.*, 104 F.T.C. at 821-26.

Response to Conclusion 111:

Respondents have no specific response. To the extent Complaint Counsel attempts to extend this discussion to this case, however, they are incorrect. (*See* Respondents Pre-Trial Brief at 63; Post-Trial Brief at 99; Reply Brief at 80, 214).

112. In two settlements, the Commission prohibited respondents from representing that a product promoted hair growth or prevented hair loss unless the product was the subject of a new drug application approved by the FDA for that purpose. *See Synchronal Corp.,* 117 F.T.C. 724, 743 (1994) (consent order); *Nature's Bounty, Inc.*, 120 F.T.C. 206, 237 (1995) (consent order).

Response to Conclusion 112:

Respondents have no specific response.

113. In the NLEA, Congress directed the FDA to promulgate regulations authorizing claims about diet-disease relationships only if the FDA determined, based on the totality of the publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence. 21 U.S.C. § 343(r)(3)(B)(i) (2012). The Commission stated in its May 1994 FTC Enforcement Policy Statement On Food Advertising: "The Commission regards the 'significant scientific agreement' standard, as set forth in the NLEA and FDA's regulations, to be the principal guide to what experts in the field of diet-disease relationships would consider reasonable substantiation for an unqualified health claim." Enforcement Policy Statement On Food Advertising, 59 Fed. Reg. 28,388, 28,393 (FTC June 1, 1994), also available at CX0002_0006.

Response to Conclusion 113:

Complaint Counsel has selectively quoted from this Enforcement Policy Statement, omitting, for example, the Commission's careful indication in the same part of the Policy that it does not require "scientific consensus" to support claims, and that there are certainly circumstances in which the Commission would approve a claim that would not meet FDA standards.

114. The Part I relief proposed is consistent with the relief approved in recent Commission settlements. *See The Dannon Co., Inc.*, 151 F.T.C. 62, 93 (2011) (consent order); Nestle HealthCare Nutrition, Inc., 151 F.T.C. 1, 12-13 (2011) (consent order); *FTC v. Iovate Health Sciences U.S.A., Inc.*, No. 10-CV-587 (W.D.N.Y. July 29, 2010) (stipulated final judgment and order), available at http://www.ftc.gov/os/caselist/0723187/100729iovatestip.pdf.

Response to Conclusion 114:

Respondents agree that the Commission has obtained relief similar to Part I of the proposed order in recent settlements, but reiterates that the present case is the first opportunity for judicial scrutiny of this new practice. Respondents have described in Pre- and Post-Trial briefing in this case why Part I exceeds the Commission's authority and is inappropriate. (*See* Respondents Pre-Trial Brief at 62; Post-Trial Brief at 98; Reply Brief at 209-18).

115. Part II of the Order prohibits, in connection with the marketing of any Covered Products (defined as any food, drug, or dietary supplement), misrepresentations about the existence, content, validity, results, conclusions or interpretations of any test, study, or research. This provision is appropriate in light of Respondents' deceptive establishment claims. (*See* CCCL ¶ 74).

Response to Conclusion 115:

Respondents have no specific response, apart from disputing the factual contentions stated in the second sentence.

116. Courts have granted the Commission similar injunctive relief prohibiting the misrepresentation of any tests studies, or research. *See, e.g., FTC v. QT, Inc.*, No. 1:03-cv-03578 (N.D. Ill. Nov. 13, 2006) (final judgment order), *available at* http://www.ftc.gov/os/caselist/0323011/061113qrayfinaljdgmntorder.pdf (for any drug, device, or other product purporting to provide health-related benefits); *FTC v. Nat'l Urological Group, Inc.*, 1:04-CV-3294-CAP (N.D. Ga. Dec. 16, 2008) (final judgment and permanent injunction), *available at* http://www.ftc.gov/os/caselist/0223165/090115nugjdgmthitech.pdf (for any health-related service or program, weight loss product, erectile dysfunction product, dietary supplement, food, drug, or device); *Direct Mktg. Concepts, Inc.*, No. 1:04-cv-11136-GAO (D. Mass. Aug. 13, 2009) (final order and judgment for permanent injunction), *available at* http://www.ftc.gov/os/caselist/0233138/090827directfo.pdf (for any food, drug, dietary supplement, cosmetic, or device). The Commission has also included such a provision in numerous settlements. *See, e.g.*, *Brown*, Docket No. C-4337, 2011 FTC LEXIS 248 (F.T.C. Oct. 13, 2011) (consent order) (for any product or service); *Oreck Corp.*, 151 F.T.C. 289 (2011) (consent order) (for any product); *The Dannon Co., Inc.*, 151 F.T.C. 62 (2011) (consent order) (for any yogurt, dairy drink, or food or drink containing a probiotic); *Nestle HealthCare Nutrition, Inc.*, 151 F.T.C. 1 (2011) (consent order) (for any drink product containing probiotics, or certain nutritionally complete drinks); *Kellogg Co.*, Docket No. C-4262, 2009 FTC LEXIS 154 (F.T.C. July 27, 2009) (consent order) (for any morning food or snack food); *Native Essence Herb Co.*, Docket No. 9328, 2009 FTC LEXIS 101 (F.T.C. May 7, 2009) (consent order) (for any product).

Response to Conclusion 116:

Respondents have no specific response.

117. Part III of the Order addresses health benefit claims for Covered Products. It provides that representations, other than representations covered by Part I, about the health benefits, performance, or efficacy of any Covered Product must be non-misleading and supported by "competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted in the relevant scientific fields, when considered in light of the entire body of relevant and reliable evidence, to substantiate that the representation is true."

Response to Conclusion 117:

Respondents have no specific response.

118. "Commission orders requiring respondents to have competent and reliable scientific evidence, as defined in this Order, that is based on the expertise of professionals in the area and that has been conducted and evaluated by persons qualified to do so, are typical and have been consistently upheld." *Daniel Chapter One*, 2009 FTC LEXIS 157, at *278-79 (initial decision) (citing *Telebrands Corp.*, 140 F.T.C. at 347; *aff'd*, 457 F.3d 354; *Kraft, Inc.*, 114 F.T.C. at 149, *aff'd*, 970 F.2d 311; *Thompson Med. Co.*, 104 F.T.C. at 844, *aff'd*, 791 F.2d at 192; *Removatron Int'l Corp.*, 111 F.T.C. at 318, *aff'd*, 884 F.2d at 1498).

Response to Conclusion 118:

Respondents have no specific response.

119. The seriousness and deliberateness of Respondents' violations, the duration of the deceptive advertising campaign, the difficultly that consumers have in judging the truth or falsity of the challenged claims, and the transferability of the claims justifies the appropriateness of the Order's fencing-in relief.

Response to Conclusion 119:

This Conclusion is incorrect and is contrary to the record in this case.

* * *

Respectfully Submitted,

/s/ Kris Diaz

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Counsel for Respondents

Dated: February 7, 2012

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

In the Matter of	)	
	)	
POM WONDERFUL LLC and	)	
ROLL GLOBAL LLC,	)	
as successor in interest to Roll	)	
International Corporation,	)	
	)	
companies, and	)	Docket No. 9344
	)	PUBLIC
STEWART A. RESNICK,	)	
LYNDA RAE RESNICK, and	)	
MATTHEW TUPPER, individually and	)	
as officers of the companies.	)	

CERTIFICATE OF SERVICE

I hereby certify that this is a true and correct copy of the PUBLIC version of Respondents' **REPLY TO COMPLAINT COUNSEL'S PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW**, and that on this 7th day of February, 2012, I caused the foregoing to be served by FTC E-File, hand delivery and e-mail on the following:

Donald S. Clark
The Office of the Secretary
Federal Trade Commission
600 Pennsylvania Avenue, NW
H-159
Washington, DC 20580

The Honorable D. Michael Chappell
Administrative Law Judge
Federal Trade Commission
600 Pennsylvania Avenue, NW
Rm. H-110
Washington, DC 20580

I hereby certify that this is a true and correct copy PUBLIC version of Respondents' **REPLY TO COMPLAINT COUNSEL'S PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW**, and that on this 7th day of February, 2012, I caused the foregoing to be served by e-mail on the following:

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Dated: February 7, 2012