ORIGINAL

UNITED STATES OF AMERICA
BEFORE THE 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
	)	
STEWART A. RESNICK,	)	PUBLIC
LYNDA RAE RESNICK, and	)	
MATTHEW TUPPER, individually and	)	
as officers of the companies.	)	

COMPLAINT COUNSEL'S REPLY TO RESPONDENTS' PROPOSED FINDINGS OF FACT

Mary K. Engle
Associate Director

Heather Hippsley
Assistant Director

Serena Viswanathan
Tawana E. Davis
Devin W. Domond
Janet M. Evans
Mary L. Johnson
Elizabeth K. Nach
Michael F. Ostheimer
Elise D. Whang
Andrew D. Wone

Federal Trade Commission
Bureau of Consumer Protection
Division of Advertising Practices
600 Pennsylvania Ave., N.W.
NJ-3212
Washington, D.C. 20580
Telephone: (202) 326-3090
Facsimile: (202) 326-3259

Counsel Supporting the Complaint

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ATTACHMENT A

VIOLATIONS OF REQUIREMENTS IN ORDER ON POST-TRIAL BRIEFS

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RESPONDENTS' PROPOSED FINDINGS OF FACT

I. CASE BACKGROUND

A. Summary of Complaint and Answer

1. The FTC's Complaint

1. The Federal Trade Commission ("FTC") issued the Complaint in this matter on September 24, 2010 against POM, Roll Global, Stewart A. Resnisck, Lynda Rae Resnick and Matthew Tupper (collectively "Respondents"). (CX1426_0002).

Response to Finding No. 1:
Complaint Counsel does not disagree.

2. The Complaint challenges POM's advertising of their POM Wonderful 100% Pomegranate Juice ("POM Juice"), POMx Pills, containing pomegranate extract, and POMx Liquid, a liquid form of the POMx Pills. (CX142_0003).

Response to Finding No. 2:
Complaint Counsel does not disagree.

3. The FTC alleges that Respondents have disseminated or have caused to be disseminated deceptive and misleading advertising which violates Sections 5 and 12 of the Federal Trade Commission Act ("FTCA"). (CX1426_0020).

Response to Finding No. 3:
Complaint Counsel does not disagree.

4. The FTC has taken the position, as stated by David Vladeck, Director of the FTC's Bureau of Consumer Protection, that "Any consumer who sees POM Wonderful products as a silver bullet against disease has been misled." (PX0449_0001; Press Release, *FTC Complaint Charges Deceptive Advertising by POM Wonderful*, Federal Trade Commission, Sept. 9, 2010, *at* http://www.ftc.gov/opa/2010/09/pom.shtm).

Response to Finding No. 4:
The proposed finding is unsupported because the evidence cited is not in the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel also notes that this statement was made to the press, and it is the Complaint that sets out the FTC's allegations in this matter.

5. More specifically, Complaint Counsel alleges that POM's advertisements at issue have represented that, expressly or by implication, 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, is clinically proven to prevent or treat: 1) heart disease, including by (a) decreasing arterial plaque, (b) lowering blood pressure, and/or (c) improving blood flow; 2) prostate cancer, including by prolonging prostate-specific antigen doubling time; and 3) erectile dysfunction. (CX1426_0017-0019).

Response to Finding No. 5:
The proposed finding is incomplete. Complaint Counsel has summarized its allegations at Complaint Counsel's Findings of Fact ("CCFF") ¶ 3.

2. The Respondents' Answer

6. Respondents filed their Answer on October 18, 2010. (PX0364).

Response to Finding No. 6:
Complaint Counsel agrees.

7. In their Answer, Respondents assert that the Complaint fails to state a claim upon which relief can be granted under Section 5 of the FTC Act, 15 U.S.C. §45. (PX0364-0007).

Response to Finding No. 7:
Complaint Counsel agrees that Respondents made this assertion in their Answer, but Complaint Counsel disagrees with this conclusion.

8. Respondents assert that the FTC lacks authority to impose all or part of the relief sought under the FTC Act, the Administrative Procedure Act, and the First and Fifth Amendments of the U.S. Constitution. (PX0364-0007).

Response to Finding No. 8:
Complaint Counsel agrees that Respondents made this assertion in their Answer, but Complaint Counsel disagrees with this conclusion.

9. Respondents further assert that the Complaint and the FTC's contemplated relief improperly seek to restrict consumers' access to valuable information about the potential health benefits of Respondents' products and therefore are contrary to public interest. (PX0364-0007).

Response to Finding No. 9:
Complaint Counsel agrees that Respondents made this assertion in their Answer, but Complaint Counsel disagrees with this conclusion.

10. Respondents also assert by that taking this enforcement action the FTC has, without adequate justification, changed its position with respect to the dissemination of such information and is seeking to impose new and unwarranted standards for the advertising

of food products without adequate notice to the public, in particular to consumers and the business community. (PX0364-0007).

Response to Finding No. 10:
Complaint Counsel agrees that Respondents made this assertion in their Answer, but Complaint Counsel disagrees with this conclusion.

11. Respondents admit that POM disseminated the advertising and promotional materials attached to the Complaint as Exhibits A through N. (PX0364-0003).

Response to Finding No. 11:
Complaint Counsel agrees.

12. However, Respondents deny any inference, characterization, suggestion or legal argument concerning those materials caused by selective quotation or comment added by the Complaint Counsel in the Complaint or attached exhibits. (PX0364-0003).

Response to Finding No. 12:
Complaint Counsel agrees that Respondents made this denial in their Answer, but Complaint Counsel disagrees with this conclusion.

13. Respondents deny the dissemination dates alleged in the Complaint. (PX0364-0003).

Response to Finding No. 13:
Complaint Counsel does not disagree that Respondents made this denial in their Answer, but notes that Respondents denied the dissemination dates because "Respondents [were] without information sufficient to confirm the dates any particular material was posted or removed from POM's website or otherwise disseminated . . . ." (PX0364-0007, Answer ¶¶ 9-10). Respondents offered no evidence at trial to refute or call into question the dissemination dates Complaint Counsel has cited, which are supported by, among other evidence, declarations by VMS Integrated Media Intelligence Solutions and Naomi Eskin. (CX0474; CX0371).

14. Respondents deny that their advertisements conveyed the messages alleged by Complaint Counsel and assert all messages conveyed by any of the advertisements were supported and/or that Respondents had a reasonable basis for any claims made. (PX0364-0003-0006).

Response to Finding No. 14:
Complaint Counsel agrees that Respondents made this denial in their Answer, but

Complaint Counsel disagrees with this conclusion.

15. Respondents deny the allegations that they, in any way, engaged in deceptive acts or practices. (PX0364-0003-0006).

Response to Finding No. 15:
Complaint Counsel agrees that Respondents made this denial in their Answer, but

Complaint Counsel disagrees with this conclusion.

16. Respondents affirmatively maintain that they possessed and relied upon substantial scientific research indicating the health benefits of their products and substantiating their advertising and promotional materials. (PX0364-0003-0006).

Response to Finding No. 16:
Complaint Counsel agrees that Respondents made this assertion in their Answer, but

Complaint Counsel disagrees with this conclusion.

B. Procedural Background

17. An unusually large body of scientific evidence was presented at trial and is part of this record.

Response to Finding No. 17:
The proposed finding is not supported by any reference to the record, in violation of the

Court's Order on Post-Trial Briefs. Complaint Counsel has no specific response.

18. Between December 3, 2010 and April 28, 2011, twenty-six percipient witness and fourteen expert witness depositions were taken.

Response to Finding No. 18:
Complaint Counsel has no specific response.

19. The final pre-hearing conference was held on May 19, 2011, with trial commencing on May 24, 2011.

Response to Finding No. 19:
Complaint Counsel agrees.

20. Complaint Counsel concede this case is different from previous cases brought before the Commission and they are not claiming Respondents are selling "snake oil." (Tr., 69).

Response to Finding No. 20:
Complaint Counsel has no specific response.

21. 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. (*See*, JX2 Attachment A).

Response to Finding No. 21:
Complaint Counsel has no specific response, except to note that approximately 1,875 exhibits were admitted into evidence, though a segment of these exhibits were admitted on a conditional basis. (JX0002, Attachments A and B).

22. Respondents submitted into evidence more than ninety scientific studies and reports sponsored by Respondents. (See PX Exhibit Nos. 2-12, 14-23, 38-41, 49-51, 53-66, 68-71, 73-77, 81-130, 136-148, 174-175).

Response to Finding No. 22:
Complaint Counsel has no specific response.

23. A total of twenty-four live witnesses testified at trial, including fourteen experts.

Response to Finding No. 23:
Complaint Counsel agrees.

24. The testimonial portion of the trial concluded on November 4, 2011 after nineteen days of trial.

Response to Finding No. 24:
Complaint Counsel agrees.

25. The hearing record was closed on November 18, 2011, pursuant to Commission Rule 3.44(c), by Order dated November 18, 2011.

Response to Finding No. 25:
Complaint Counsel agrees.

26. On January 11, 2012, the parties filed concurrent post-trial briefs, proposed findings of fact, and findings of law.

Response to Finding No. 26:
Complaint Counsel agrees.

C. Evidence Before This Court

These findings of fact are based on the exhibits properly admitted into evidence, the transcripts of testimony at trial, and the briefs submitted by the parties. References to the record are abbreviated as follows:

CX – Complaint Counsel's Exhibit

PX – Respondents' Exhibit

RX – Respondents' Exhibit

JX1- Joint Stipulations of Law and Facts dated May 24, 2011

JX2 – Joint Stipulations on Admissibility of Exhibits dated May 24, 2011

JX2 Attachment A – Joint Exhibits Admitted Without Objection dated May 24, 2011

JX2 Attachment B – Conditionally Admitted Exhibits Subject to Objection dated May 24, 2011

JX3- Joint Stipulations dated November 14, 2011

Tr. – Transcript of Testimony before the ALJ

Dep. – Transcript of FTC Deposition

Tropicana Dep. – Transcript of Deposition taken in *POM Wonderful v. Tropicana*

Coke Dep. – Transcript of Deposition taken in *POM Wonderful v. Minute Maid*

Welch's Dep. – Transcript of Deposition taken in *POM Wonderful v. Welch Foods*

Ocean Spray Dep. – Transcript of Deposition taken in *POM Wonderful v. Ocean Spray*

Tropicana Tr. –Transcript of *POM Wonderful v. Tropicana*

II. SUMMARY OF KEY FINDINGS

A. Key Findings Regarding the Advertisements

27. Complaint Counsel is not alleging that any advertisements of POM convey the message that the challenged products "cure" any disease or condition. Complaint Counsel did not provide any expert testimony, or extrinsic evidence that consumers cannot and do not distinguish between a health message that a product is healthy for you, or of assistance in maintaining the health of a particular area of the body (erectile, heart, prostrate) and a

message that the product has an effect, like a drug in preventing or treating a particular condition of the body. Yet, Complaint Counsel asks this court to adopt this significant premise fundamental to its claims.

Response to Finding No. 27:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel has no specific response other than to refer to its Responses to Findings in Section XVII and Respondents' Appendix of Advertisements.

28. Complaint Counsel did not provide any expert opinion or competent extrinsic evidence on what messages the ads actually conveyed, including whether the ads conveyed "clinically proven" claims.

Response to Finding No. 28:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel has no specific response other than to refer to its Responses to Findings in Section XVII and Respondents' Appendix of Advertisements.

29. Complaint Counsel did not provide any expert opinion or extrinsic evidence on whether and to what extent consumers interpreted the ads to convey that the Challenged Products prevent or reduce your risk against disease, like broccoli or blueberries prevent or reduce your risk against disease, or whether the ads conveyed "prevention" in more absolute and targeted sense, like a drug or drug treatment, even an over-the-counter treatment such as Tough Action Tenactin, that says on its bottle that it can "prevent" and "cure" athelete's foot.

Response to Finding No. 29:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel has no specific response other than to refer to its Responses to Findings in Section XVII and Respondents' Appendix of Advertisements.

30. Complaint Counsel did not provide any extrinsic evidence or expert opinion on whether and to what extent a consumer looks at the ads referring to a scientific study whose participant suffered from a condition or disease, and where the advertisement explicitly

refers to the condition or the disease, and concludes that the consumption of the product will treat or prevent that disease or condition.

Response to Finding No. 30:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel has no specific response other than to refer to its Responses to Findings in Section XVII and Respondents' Appendix of Advertisements.

31. Complaint Counsel did not present any extrinsic evidence or expert testimony that consumers do not distinguish between claims that the product "prevents" a condition and claims that the product "treats" a condition.

Response to Finding No. 31:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel has no specific response other than to refer to its Responses to Findings in Section XVII and Respondents' Appendix of Advertisements.

32. Even if the Commission could conclude that the "treat" and "prevent" claims were implied by the advertisements, POM's survey expert responded to these assertions with a well-conducted survey of his own, which Complaint Counsel failed to rebut.

Response to Finding No. 32:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Moreover, the proposed finding is unsupported by the record as a whole. Respondents' survey expert did not conduct an ad meaning copy test. (Reibstein, Tr. 2494 ("The purpose of this study was not to test any particular ads. The purpose of this study was to look at what their motivations were for buying POM."); Mazis, Tr. 2671, 2690-95; CX1297 (Mazis, Report at 0010-11)).

33. Professor David Reibstein, POM's survey expert, concluded from his survey that less than 1.9% of POM's consumers purchase the 100% juice product because they believe it will alleviate a disease condition. (PX0223-0020).

Response to Finding No. 33:

Complaint Counsel does not disagree as to what Dr. Reibstein concluded but disagrees with the implication that the Reibstein survey validly measures either the materiality of the challenged claims or the motivations of POM Juice purchasers. (*See* CCFF ¶¶ 657-61; CX1297 (Mazis, Report at 0008-10)). Furthermore, Complaint Counsel notes that the Reibstein survey has no relevance to either the materiality of the challenged POMx claims or the purchase motivations of POMx purchasers. (CCFF ¶ 654).

34. Complaint Counsel do not address Professor Reibstein's survey directly and instead refer to POM's internal surveys, consumer logs and creative briefs to identify an "intent" sufficient to respond to Professor Reibstein's conclusions, but these references are insufficient to rebut Professor Reibstein's conclusions.

Response to Finding No. 34:
The proposed finding is not supported by any reference to the record in violation of the Court's Order on Post-Trial Briefs and mischaracterizes the evidence in that Complaint Counsel did address Dr. Reibstein's survey directly. (*See* CCFF ¶¶ 651-61).

35. Complaint Counsel failed to offer in this case evidence regarding the advertisements or the issue of materiality that they presented in previous cases before the Commission.

Response to Finding No. 35:
The proposed finding is not supported by any reference to the record in violation of the Court's Order on Post-Trial Briefs and mischaracterizes the evidence. CCFF Section V provides a detailed analysis of the challenged advertisements, and CCFF Section VI provides ample evidence of the materiality of the challenged claims.

36. Complaint Counsel expert, Professor Michael Mazis, failed to prepare any survey or present any opinion, on the messages conveyed in POM's advertisements or on the subject of materiality.

Response to Finding No. 36:
The proposed finding is not supported by any reference to the record in violation of the Court's Order on Post-Trial Briefs and mischaracterizes the evidence. Dr. Mazis was called as a rebuttal witness to respond to Dr. Reibstein, including the Reibstein survey

and Dr. Reibstein's assertion in his report that the A&U Study is not "reliable or relevant." (CX1297 (Mazis, Report at 0001-02, 12-13); PX0223 (Reibstein, Report at 0003)). As such, he was not asked to affirmatively opine on the claims conveyed or whether those claims would be material. (Mazis, Tr. 2651-2751; CX1297 (Mazis, Report at 0001-15); PX0359 (Mazis, Dep. at 1-243)). Dr. Mazis also expressed his opinion that the A&U study demonstrated that the challenged heart disease and prostate cancer claims are material. (Mazis, Tr. 2688-89, 2760; CX1297 (Mazis, Report at 0012-13)).

37. Complaint Counsel expert, Professor David Stewart, also failed to present any opinion on the messages conveyed in POM's advertisements or on the subject of materiality.

Response to Finding No. 37:
The proposed finding is not supported by any reference to the record in violation of the Court's Order on Post-Trial Briefs and mischaracterizes the evidence. Dr. Stewart was called as a rebuttal witness to respond to Dr. Butters (CX1295 (Stewart, Report at 0004)) and he was not asked for his affirmative opinions on the claims conveyed or whether those claims would be material. (Stewart, Tr. 3158-3242; CX1295 (Stewart, Report at 0001-19); PX0357 (Stewart, Dep. at 1-195)). Dr. Stewart did express views disagreeing with Dr. Butters about the messages conveyed in the challenged ads. (CX1295 (Stewart, Report at 0005-18); Stewart, Tr. 3169-3222).

38. Professor Mazis, however, did testify that at least 3 exposures of any given ad was necessary before that ad could impact purchasing behavior. (Stewart, Tr. 3228-29; Mazis, Tr. 2752).

Response to Finding No. 38:
The proposed finding mischaracterizes Dr. Mazis's testimony, is incomplete, and is irrelevant. Dr. Mazis's cited testimony regards the impact of ad exposures on "beliefs" and not on "purchase behavior." (Mazis, Tr. 2752). He did not testify that three exposures were necessary to impact beliefs, but instead stated "sometimes one exposure

can influence people, influence people's beliefs, but . . . if you have repetition, that tends to influence people a lot more." (Mazis, Tr. 2752). Dr. Mazis also stated, "the impact of advertising on beliefs about a product is not an appropriate measure of materiality or ad claim communication." (CX1297 (Mazis, Report at 0009)).

39. Yet, Mazis, in stark contrast to his testimony given in previous cases before the Commission, never gave any opinion about the number of exposures of any ad on consumers in this matter.

Response to Finding No. 39:
The proposed finding is not supported by any reference to the record in violation of the Court's Order on Post-Trial Briefs, mischaracterizes Dr. Mazis's testimony in previous cases, and is irrelevant. *See* Response to Finding 38.

40. Accordingly, the FTC failed to meet its burden of proof on this fundamental issue.

Response to Finding No. 40:
The proposed finding is not supported by any reference to the record in violation of the Court's Order on Post-Trial Briefs and is a legal conclusion. *See* Response to Finding 38.

B. The Advertisements Do Not Convey the Messages That The FTC Claims and Respondents Have Competent and Reliable Science to Support the Actual Claims Made

41. Complaint Counsel has now, late in trial and afterwards, narrowed the universe of advertisements to approximately 70 ads, from hundreds and hundreds of ads. (PX0263-0002-0013; PX0267-0002-0030).

Response to Finding No. 41:
The proposed finding is incorrect. Complaint Counsel is challenging 43 individual advertisements or promotional materials as examples of Respondents' claims that violate the FTC Act. (*See* CCFF Section V and Appendix A).

42. Complaint Counsel focuses on POM's ads with the most aggressive health benefit claims that ran years ago, were discontinued and have not been disseminated within the last 4 to 7 years. Respondents assert that these ads were accurate and substantiated. Because Complaint Counsel has not presented evidence that it is probable Respondents will disseminate these ads again, these "outlier" ads cannot form the basis for the injunctive relief sought by the commission. (*See infra* XVII(E)).

Response to Finding No. 42:
Complaint Counsel agrees that POM's ads make aggressive health benefit claims, but disagrees that such claims ceased four to seven years ago. The 43 challenged advertisements and promotional materials span from 2003 through 2010. *See* Responses to Findings in the cross-referenced section. In addition, the proposed finding makes a legal conclusion.

43. POM's advertisements do not convey or imply the message that their products are "clinically proven" to prevent, treat or reduce the risk of disease as claimed by Complaint Counsel. (CX01426_0017-0020; Appendix of Advertisements, attached hereto as Appendix B).

Response to Finding No. 43:
Complaint Counsel disagrees. Complaint Counsel is challenging 38 of 43 ads as making establishment claims. (*See* CCFF Section V and Appendix A). *See also* Responses to Findings in Section XVII and the Appendix of Advertisements.

44. Complaint Counsel failed to present significant extrinsic evidence or expert opinion to support their interpretation of the claims allegedly made by POM's advertising. (Appendix of Advertisments).

Response to Finding No. 44:
The proposed finding is a legal conclusion, which is unsupported by the record as a whole. (*See* CCFF Sections V-VI, and Appendix A).

45. Even assuming that Complaint Counsel is entitled to a presumption of materiality, Respondents' survey expert Professor Reibstein, through his testimony and survey evidence, successfully rebutted any such presumption. (*See infra* XVIII(A)).

Response to Finding No. 45:
The proposed finding is unsupported by the record. (*See* CCFF Section VI).

46. Respondents have a rational basis, and competent and reliable scientific evidence to support the claims that were expressly and implicitly made. (*See* supra XII-IV; XVII; Appendix of Advertisments).

Response to Finding No. 46:
The proposed finding is a legal conclusion, which is unsupported by the record as a whole. (*See* CCFF Section VII).

C. Key Findings Regarding the Science Supporting the Health Benefits of the Challenged Products

47. Complaint Counsel presented no opposing scientific studies or evidence conducted by others or FTC experts showing that Respondents' claims were affirmatively false, i.e., that the challenged products do not, in fact, have the health benefits explicitly or implicitly conveyed in the advertisements.

Response to Finding No. 45:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel has no specific response.

48. Complaint Counsel did not present any expert opinion that the challenged products do not have the health benefits explicitly or implicitly conveyed in the advertisements.

Response to Finding No. 48:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs, and is unsupported by the record as a whole. (*See* CCFF Section VII).

49. At a minimum, Complaint Counsel failed to show, by a preponderance of the evidence, that the health benefit claims made in POM's advertisements were, in fact, false.

Response to Finding No. 49:
The proposed finding is a legal conclusion, which is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs.

50. Both Respondents' and Complaint Counsel's experts opined that an absence of a "positive" result in a scientific study does not support, or prove, the negative or opposing conclusion. (Sacks, Tr. 1608-09; CX1352 (Heber, Dep. at 218); PX0361 (Sacks, Dep. at 223-24, 230, 238, 243); Goldstein, Tr. 2598-99; Heber, Tr. 1981).

Response to Finding No. 50:
The proposed finding is incomplete and mischaracterizes the cited evidence. When asked about the results of individual studies, Dr. Sacks testified that a lack of statistical significance or positive result does not *prove* a negative. (*See, e.g.,* Sacks, Tr. 1608-09 (regarding Ornish CIMT study)). In this case, however, Respondents' RCTs repeatedly revealed no improvement in carotid intima-media thickness (CIMT), blood pressure, and

biomarkers of inflammation and oxidation, or improvements in erectile function. Moreover, the Carducci Dose Study failed to show statistical significance as a dose response study on the effects of POMx Pills on PSADT in men with prostate cancer. (CCFF ¶¶ 825, 829, 870-71, 882-84, 903-04, 918-19, 933, 942, 946-49, 951, 956, 960, 1013-25). Such evidence does not prove that the efficacy claims were affirmatively false, but it does substantially undermine the Respondents' weak affirmative evidence on efficacy. Further, this evidence supports the conclusion that the establishment claims were false.

51. The totality of the evidence includes all studies, positive and negative studies, large and small studies, unpublished and published studies and basic science, (test tube and animal), as well as human clinical trials. (Heber, Tr. 1948-50; 2056; 2086, 2149, 2166, 2182; PX0353 (Heber, Dep. at 178); CX1352 (Heber, Dep. at 243)). Ornish, Tr. 2327-31, 2354-55; Miller, Tr. 2194; PX0206-0007, 0015; PX0004, PX0005, CX0611, PX0014, PX0020, PX0021, PX0023, PX0038, PX0127, PX0139, PX0002, PX0007, PX0008, PX0009, PX0010, PX0015, CX0543, PX0017, PX0022, CX0053, PX0055, PX0056, PX0057, PX0058, PX0059).

Response to Finding No. 51:
Complaint Counsel has no specific response.

52. RCTs are not required to make any claim of health benefits for a safe whole food or whole food product, such as the Challenged Products. (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).

Response to Finding No. 52:
The proposed finding mischaracterizes the cited evidence. The POM Products are not whole foods or whole food products. RCTs are required for the specific disease benefit claims at issue. (*See* CCFF ¶¶ 124-26, 130-32, 134; CCFF Section VII).

D. Matthew Tupper Is Not Personally Liable and No Order Should Issue Against Him

53. Matthew Tupper was the former President of POM Wonderful, but he retired from that position at the end of 2010. (Tupper, Tr. 2972-73).

Response to Finding No. 53:
The proposed finding is unsupported by the cited evidence. When he testified on October 12, 2011, Mr. Tupper confirmed that he was the President of POM. (Tupper, Tr. 2972). He also testified that he would "most probably" leave POM by the end of the year, but there is no evidence in the record to confirm that he has retired, or that he did so in 2010. (Tupper, Tr. 2973).

54. Mr. Tupper will not be working for Roll Global or any other company owned by the Resnicks after his retirement from POM Wonderful. His involvement with POM Wonderful or any other Resnick related entity is over. (Tupper, Tr. 2974).

Response to Finding No. 54:
Complaint Counsel has no specific response.

55. Mr. Tupper has never had an ownership interest or equity shares in POM Wonderful (and never has) and has no expectation of such interest. (CX1353 (Tupper, Dep. at 14); Tupper, Tr. 2973).

Response to Finding No. 55:
Complaint Counsel objects to the deposition testimony cited in the proposed finding, with respect to whether Mr. Tupper has equity shares in POM, because it is non-designated testimony. Complaint Counsel has no specific response regarding whether Mr. Tupper has an ownership interest in POM.

56. Although Mr. Tupper managed the day-to-day operations on behalf of the Resnicks and was involved in several aspects of POM Wonderful's operations, excluding the science program and the advertisements none were under his exclusive or even majority 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 103-04); Tupper, Tr. 2974).

Response to Finding No. 56:
The proposed finding is unsupported by the cited evidence. Mr. Tupper has been involved in all aspects of POM's business, including POM's medical research and marketing of the POM Products. (*See* CCFF ¶ 53). Indeed, Respondents admit that "Mr. Tupper, as an officer of [POM], together with others, formulates, directs, or controls the policies, acts, or practices of [POM]." (*See* CCFF ¶ 48). His responsibilities have

included supervising, among others, POM's Vice President of Marketing and marketing staff, Vice President of Clinical Development, and Vice President of Scientific and Regulatory Affairs, as well as preparing detailed medical research summaries, reviewing advertising copy, and acting as a liaison between marketing staff and researchers conducting studies sponsored by POM. (*See* Tupper, Tr. 2974; CCFF ¶¶ 49-86).

57. In fact, Mr. Tupper had no more authority at POM than was delegated to him by Mr. Resnick. (S. Resnick, Tr. 1870).

Response to Finding No. 57:
Complaint Counsel has no specific response.

III. THE RESPONDENTS

A. The Respondents

1. POM Wonderful LLC

58. POM Wonderful ("POM Wonderful" or "POM") is a limited liability company organized under the laws of the State of Delaware. (CX1426_0002); (CX1367 (S. Resnick, Welch's Dep. at 8); CX1437; PX0364-0001).

Response to Finding No. 58:
Complaint Counsel agrees. (*See* CCFF ¶ 88).

59. POM Wonderful's principal office or place of business is at 11444 West Olympic Boulevard, Los Angeles, California 90064. (CX1426_0002; PX0364-0001).

Response to Finding No. 59:
Complaint Counsel agrees. (*See* CCFF ¶ 88).

60. POM Wonderful is wholly owned by the Stewart and Lynda Resnick Revocable Trust, dated December 27, 1988 ("1988 Resnick Trust"). (CX1426_0002; PX0364-0001; CX1384_0008).

Response to Finding No. 60:
Complaint Counsel agrees. (*See* CCFF ¶¶ 9-10).

61. Respondent POM Wonderful is a member-managed company, and the 1988 Resnick Trust is the sole member. (CX1426_0002; PX0364-0001).

Response to Finding No. 61:
Complaint Counsel agrees. (*See* CCFF ¶ 90).

62. In 2002, POM first launched POM Wonderful 100% Pomegranate Juice, the first premium, all-natural pomegranate juice made from pomegranates grown from POM's orchards. (L. Resnick, Tr.146).

Response to Finding No. 62:
Complaint Counsel does not disagree that POM launched POM Juice in 2002. (*See* CCFF ¶ 136). Complaint Counsel has no specific response regarding the remainder of the proposed finding.

63. POM Wonderful is currently in the business of selling fresh pomegranates and pomegranate-related products, including 100% pomegranate juice ("POM juice") and pomegranate extract products known as POMx pills and POMx liquid ("POMx"). (S. Resnick, Tr.1630-31); CX1364 (Tupper, Coke Dep. at 20); CX1374 (Tupper, Ocean Spray Dep. at 26); CX1363 (S. Resnick, Coke Dep. at 45-46).

Response to Finding No. 63:
Complaint Counsel agrees. (*See also* CCFF ¶¶ 122-23).

2. Respondent Roll Global LLC

64. Roll International Corporation is a separate corporation organized under the laws of the State of Delaware. (CX1426_0002; PX0364-0001).

Response to Finding No. 64:
Complaint Counsel does not disagree. (*See* CCFF ¶ 92).

65. Roll International was reorganized at the end of 2010 and is currently known as Roll Global ("Roll"). (S. Resnick, Tr.1629).

Response to Finding No. 65:
Complaint Counsel agrees. (*See* CCFF ¶ 93).

66. Roll is wholly owned by the 1988 Resnick Trust. (CX1426_002-003; PX0364-0001).

Response to Finding No. 66:
Complaint Counsel agrees. (*See* CCFF ¶¶ 9-10, 93).

67. Roll is a privately held corporation. (S. Resnick, Tr. 1630).

Response to Finding No. 67:
The proposed finding is unsupported by the cited evidence.

68. POM Wonderful, FIJI Water, Suterra, Paramount Farms, Paramount Citrus, Teleflora, Neptune Shipping, Paramount Farming, and Justin Winery are among the separate

operating business under Roll's umbrella. (CX1364 (Tupper, Coke Dep. at 16-17); CX1374 (Tupper, Ocean Spray Dep. at 36); Perdigao, Tr. 593-94).

Response to Finding No. 68:
Complaint Counsel agrees. (*See also* CCFF ¶¶ 12, 108).

69. Stewart and Lynda Resnick are the sole owners of Roll and its affiliated companies, including POM Wonderful. (S. Resnick, Tr. 1629; CX1360 (S. Resnick, Dep. at 15); PX1376 (S. Resnick, Ocean Spray Dep. at 13)).

Response to Finding No. 69:
Complaint Counsel agrees. (*See* CCFF ¶¶ 9-10, 110).

70. Roll's affiliated companies pay Roll for certain provided services. (CX1376 (S. Resnick, Ocean Spray Dep. at 24-25); L. Resnick, Trial Tr. 89; CX1359 (L. Resnick, Dep. at 26); Perdigao Tr. 616-17; CX1384_0011, 0014).

Response to Finding No. 70:
Complaint Counsel does not disagree. (CCFF ¶¶ 115-16).

71. For example, Firestation acts as Roll's in-house advertising agency. Firestation bills POM and other Roll entities separately, and each client pays for all advertising and marketing expenses incurred. (CX1376 (S. Resnick, Ocean Spray Dep. at 24-25); L. Resnick, Tr. 89; CX1359 (L. Resnick, Dep. at 26); Perdigao Tr.616-17; CX1384_0011, 0014).

Response to Finding No. 71:
Complaint Counsel does not disagree that Fire Station acts as Roll's in-house advertising agency or that Fire Station bills POM and other Roll entities separately. However, the proposed finding's assertion that "each client pays for all advertising and marketing expenses incurred" is unsupported by the record as a whole. Roll has admitted that not all expenses, such as advertising and marketing services, provided to POM were reimbursed. (CCFF ¶ 115).

3. Respondents Stewart and Lynda Resnick

72. Stewart Resnick is the Chairman and President of Roll. (S. Resnick, Tr. 1629; CX1363 (S. Resnick, Coke Dep. at 54-55)).

Response to Finding No. 72:
Complaint Counsel agrees. (*See* CCFF ¶ 13).

73. Stewart Resnick is the Chairman of POM Wonderful. (CX1426_0003; PX0364-0002).

Response to Finding No. 73:
Complaint Counsel agrees. (*See* CCFF ¶ 13).

74. Stewart A. Resnick has the ultimate authority at POM Wonderful. (S. Resnick, Tr. 1869); CX1372 (S. Resnick, Tropicana Dep. at 25-26); (S. Resnick, Tr.1631; CX1360 (S. Resnick, Dep. at 20-21).

Response to Finding No. 74:
Complaint Counsel has no specific response.

75. Notwithstanding his co-ownership of POM Wonderful, Respondent Stewart Resnick has very little involvement in the marketing of POM Wonderful's pomegranate products. (S. Resnick, Tr.1869; CX1360 (S. Resnick, Dep. at 49); CX1363 (S. Resnick, Coke Dep. at 95); CX1376 (S. Resnick, Ocean Spray Dep. at 140-42)).

Response to Finding No. 75:
The proposed finding is unsupported by the record as a whole. Of his various businesses, Mr. Resnick spends the second greatest amount of his time on the POM business and, among other activities, sets the overall budgets for POM, including the marketing and advertising budget, and has been intimately involved in the development of POM's scientific research program. (*See* CCFF ¶¶ 24-27, 30-33). Mr. Resnick also has authority over "any decisions made with respect to what do[es] [POM] talk about, [and] how do[es] [POM] talk about it," including "authority for advertising the benefits of POM." (Tupper, Tr. 2975).

76. Stewart Resnick is not involved in the day-to-day decisions related to the advertising of POM Wonderful's products. (S. Resnick, Tr. 1869-70).

Response to Finding No. 76:
Complaint Counsel has no specific response.

77. 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).

Response to Finding No. 77:

Complaint Counsel has no specific response, except to note that Mr. Resnick testified that he has delegated the authority to decide which ads should run to Mr. Tupper. (S. Resnick, Tr. 1870).

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

Response to Finding No. 78:
Complaint Counsel has no specific response.

79. Lynda Resnick is involved in POM's marketing, branding, public relations, and product development. (CX1363 (S. Resnick, Coke Dep. at 41); (CX1364 (Tupper, Coke Dep. at 27); (CX1347 (Glovsky, Dep. at 36)).

Response to Finding No. 79:
Complaint Counsel agrees.

80. Both Lynda and Stewart Resnick have the ultimate authority in developing POM's marketing strategies. (Tupper, Tr. 2974-75; CX1362 (L. Resnick, Coke Dep. at 47, 78)).

Response to Finding No. 80:
Complaint Counsel has no specific response.

81. Lynda Resnick's involvement with POM Wonderful has decreased since 2007. (L. Resnick, Tr. 86; CX1359 (L. Resnick, Dep. at 22); CX1375 (L. Resnick, Tropicana Dep. at 20).

Response to Finding No. 81:
Complaint Counsel has no specific response.

82. Lynda Resnick has the final approval authority in deciding POM's marketing and advertising content and concepts. (CX1368 (L. Resnick, Welch's Dep. at 9); L. Resnick, Tr. 93).

Response to Finding No. 82:
Complaint Counsel does not disagree.

83. POM Wonderful is owned solely by Stewart and Lynda Resnick. (S. Resnick, Tr. 1629; CX1359 (L. Resnick, Dep. at 26); Perdigao Tr. 616-17; CX1384_0011, 0014).

Response to Finding No. 83:
Complaint Counsel agrees. (*See* CCFF ¶¶ 9-10, 110).

4. Respondent Matthew Tupper

84. Mr. Tupper served as the Vice President of Strategy for Roll from 2001 to 2003. (CX1364 (Tupper, Coke Dep. at 24-25); CX1371 (Tupper, Tropicana Dep. at 9); CX1374 (Tupper, Ocean Spray Dep. at 32-33)).

Response to Finding No. 84:
Complaint Counsel agrees. (*See* CCFF ¶¶ 45-46).

85. Mr. Tupper was first employed by POM Wonderful in 2003 and originally held the title of Chief Operating Officer. (Tupper, Tr. 2972, CX1353 (Tupper, Dep. at 21); CX1364 (Tupper, Coke Dep. at 14)).

Response to Finding No. 85:
Complaint Counsel agrees. (*See* CCFF ¶ 46).

86. In 2005, Mr. Tupper's title changed to President of POM. (Tupper, Tr. 2972; CX1369 (Tupper, Welch Dep. at 10); CX1374 (Tupper, Ocean Spray Dep. at 13, 33); CX1353 (Tupper Dep. at 9); CX1364 (Tupper Coke Dep. at 14)).

Response to Finding No. 86:
Complaint Counsel agrees. (*See* CCFF ¶ 47).

87. Mr. Tupper was not engaged in the marketing piece of POM's science-marketing dialogue prior to 2007. (Tupper, Tr. 2976-77).

Response to Finding No. 87:
The proposed finding is unsupported by the record as a whole. As POM's president, Mr. Tupper attended most of the marketing meetings with Mrs. Resnick ("LRR Meetings"), which included discussions of POM's scientific research. (CCFF ¶¶ 46-47, 72, 188; CX1347 (Glovsky, Dep. at 149-50)).

88. Prior to 2007 Mr. Tupper had only limited involvement in the relationship between science and marketing. (Tupper, Tr. 2976-77).

Response to Finding No. 88:
Complaint Counsel has no specific response.

89. It was not until sometime in 2007 that Mr. Tupper first began to engage in connecting POM's science to its advertising. (Tupper, Tr. 2975-77).

Response to Finding No. 89:
Complaint Counsel has no specific response.

90. Mr. Tupper has never had any ownership interest in POM Wonderful and has no expectation of ever having such an interest. (CX1353 (Tupper, Dep. at 14); Tupper, Tr. 2973).

Response to Finding No. 90:
Complaint Counsel has no specific response.

91. Mr. Tupper reported directly to Stewart Resnick. (CX1364 (Tupper, Coke Dep. at 27-28, 107); CX1367 (S. Resnick Welch Dep. at 53).

Response to Finding No. 91:
Complaint Counsel has no specific response, except to note that the cited evidence also states that Mr. Tupper reports to Mrs. Resnick. (CX1367 (S. Resnick, Welch Dep. at 53)).

92. Mr. Tupper had a "dotted line" reporting to Lynda Resnick. (CX1375 (L. Resnick, Tropicana Dep. at 23-24)).

Response to Finding No. 92:
Complaint Counsel does not disagree. (*See also* CCFF ¶ 23).

93. On behalf of the Resnicks, Mr. Tupper managed the day-to-day operations of POM Wonderful, including the POM marketing team. (Tupper, Tr. 2974; CX1363 (S. Resnick Coke Dep., 42)).

Response to Finding No. 93:
Complaint Counsel does not disagree.

94. 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 his 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)).

Response to Finding No. 94:
The proposed finding is unsupported by the cited evidence because the cited deposition testimony does not fully address Mr. Tupper's involvement in, nor control over, "POM's operations, science, advertisements and general POM theme."

95. Mr. Tupper had no more authority at POM Wonderful than was delegated to him by Stewart Resnick. (S. Resnick, Tr. 1870).

Response to Finding No. 95:

Complaint Counsel has no specific response.

96. Mr. Tupper was responsible for administering POM marketing and scientific research budgets but did not have the authority to set those budgets. (Tupper, Tr. 912-913).

Response to Finding No. 96:
Complaint Counsel has no specific response.

97. In fact, Mr. Resnick set all budgets for POM Wonderful. (S. Resnick, Tr. 1631).

Response to Finding No. 97:
The proposed finding mischaracterizes the evidence. When asked if he "set the budgets for POM," Mr. Resnick testified that "[he] would say certainly the macro budget," not that he set all budgets. (S. Resnick, Tr. 1631; s*ee also* CCFF ¶ 26).

98. Mr. Tupper consulted Stewart Resnick or Lynda Resnick for any major restructuring or personnel decisions. (Tupper, Tr. 903; CX1364 (Tupper, Coke Dep. at 31)).

Response to Finding No. 98:
The proposed finding is unsupported by the cited evidence and is incomplete. Mr. Tupper did indeed testify that "for any major restructuring, [he] would consult with the [Resnicks]"; however, with respect to personnel decisions, Mr. Tupper has hired and fired POM employees on his own. (*See* CCFF ¶ 58). For example, he testified that he has made the decision to fire a marketing department head. (Tupper, Tr. 903). He has also testified that though "[he] may consult with others in making [his] decision, gather feedback, et cetera . . . unfortunately the decision [to fire POM employees] rest *[sic]* on [his] shoulders." (CX1364 (Tupper, TCCC Dep. at 106)).

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

Response to Finding No. 99:
Complaint Counsel has no specific response.

100. Mr. Tupper did not, independent of the Resnicks, develop the marketing direction or decide how the POM Products would be marketed. 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. 2974-2975).

Response to Finding No. 100:
Complaint Counsel has no specific response.

101. Mr. Tupper did not have the final approval authority in deciding POM's marketing and advertising content, concepts and media plans. (CX1368 (L. Resnick Welch's Dep. at 9); L. Resnick, Tr. 93; PX1347 (Glovsky, Dep. at 36); CX1357 (Kuyoomjian, Dep. at 84)).

Response to Finding No. 101:
Complaint Counsel has no specific response.

102. When there were disputes or issues to resolve regarding advertising decisions, the final authority was either Lynda or Stewart Resnick's, not Mr. Tupper's. (CX1365 (Perdigao, Coke Dep. at 36-37)).

Response to Finding No. 102:
Complaint Counsel has no specific response, except to note that the cited evidence limits

the proposed finding to the period after September 2007.

103. Since 2007, Mr. Tupper sought to ensure that POM's marketers correctly portrayed and interpreted the science in the advertisements and that POM's advertisements were vetted by the legal department. (Tupper, Tr. 2975-76).

Response to Finding No. 103:
Complaint Counsel has no specific response.

104. POM has funded many millions of dollars of scientific research by renowned scientists, resulting in over 70 peer-reviewed publications. (CX1360 (S. Resnick Dep. at 257); Liker, Tr. 1888).

Response to Finding No. 104:
Complaint Counsel has no specific response.

105. Mr. Tupper personally believes that all of the ads that POM has run were adequately supported by the body of science conducted on the Challenged Products. (Tupper, Tr. 3015).

Response to Finding No. 105:
Complaint Counsel has no specific response.

106. Mr. Tupper retired from POM Wonderful at the end of the 2011. Mr. Tupper knew he was leaving the company and informed Stewart and Lynda Resnick of his intentions in June 2011. (Tupper, Tr. 2973).

Response to Finding No. 106:
Complaint Counsel has no specific response, but notes that although Mr. Tupper testified that he would "most probably" leave POM by the end of 2011, there is no evidence in the record to confirm that he has indeed done so. (Tupper, Tr. 2973).

107. Mr. Tupper will not be working for Roll Global or any other company owned by the Resnicks after his retirement from POM Wonderful. (Tupper, Tr. 2974).

Response to Finding No. 107:
Complaint Counsel has no specific response.

IV. THE RESPONDENTS' AND COMPLAINT COUNSEL'S PRESENTATION OF EXPERT EVIDENCE AT TRIAL

A. Respondents Experts

108. Respondents' experts testified to an extraordinary body of science demonstrating that Respondents possess competent reliable scientific evidence to substantiate any reasonable construction of POM's advertisements.

Response to Finding No. 108:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel disagrees with the conclusions in this proposed finding.

109. In many cases, Respondents' experts testified that the body of science on pomegranates support health benefit claims that far exceed what POM actually conveyed in its advertising.

Response to Finding No. 109:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel disagrees with the conclusions in this proposed finding.

1. Dr. Denis Miller

110. Dr. Denis Miller is a board certified pediatrician and pediatric hematologist and oncologist licensed to practice medicine in the state of New Jersey. (PX0206 at 1; PX0354 (Miller, Dep. at 16)).

Response to Finding No. 110:

Complaint Counsel has no specific response.

111. 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. (PX0206 at 2; Miller, Tr. 2190).

Response to Finding No. 111:
Complaint Counsel has no specific response.

112. He directs one of the largest pediatric oncology/hematology programs in the world and holds an endowed chair. (PX0206 at 3).

Response to Finding No. 112:
Complaint Counsel has no specific response.

113. Dr. Miller has designed, managed, and directed many different research studies calculated to develop new anti-cancer agents (PX0206 at 2-3).

Response to Finding No. 113:
Complaint Counsel has no specific response.

114. Dr. Miller has authored or co-authored over 300 book chapters, peer-reviewed articles, and abstracts mostly on cancer and blood disorders. (PX0206 at 4; Miller, Tr. 2191).

Response to Finding No. 114:
Complaint Counsel has no specific response.

115. Complaint Counsel have retained Dr. Miller on several matters, and he testified for Complaint Counsel previously in *Daniel Chapter One*. (PX0206 at 5, 18).

Response to Finding No. 115:
Complaint Counsel agrees that Dr. Miller has consulted for FTC staff in other matters,

and that he testified for Complaint Counsel in *Daniel Chapter One*.

116. Dr. Miller testified at trial in this matter that, in his opinion and the consensus of the scientific opinion, Respondents do not need RCTs to substantiate their health claims because, among other weighted factors, the Challenged Products are harmless pure fruit products and Respondents never urged the Challenged Products as substitutes for proper medical treatment. (Miller, Tr. 2194).

Response to Finding No. 116:
Complaint Counsel agrees that Dr. Miller testified at trial in this matter that in his

opinion, Respondents do not need RCTs to substantiate their health claims because the

Challenged Products are harmless pure fruit products. However, the proposed finding's

assertion that he testified at trial that "Respondents never urged the Challenged Products as substitutes for proper medical treatment" is unsupported by the cited evidence and mischaracterizes his actual testimony at trial, in which he testified he did not evaluate any of the advertising claims made regarding the health benefits of POM products. (Miller, Tr. 2210).

117. Dr. Miller distinguished this case against Respondents from *Daniel Chapter One*, a case for which he served as a principal expert witness for the FTC. (Miller, Tr. 2193).

Response to Finding No. 117:
Complaint Counsel has no specific response.

118. He opined that, in *Daniel Chapter One*, RCTs were required to substantiate the Respondents' claims because the product was recommended in place of conventional medical treatment, and the mixture had potentially toxic side effects. Above all else, the nature of the product and its safety are the linchpins in determining the level of substantiation required to support one's claim. (Miller, Tr. 2193).

Response to Finding No. 118:
Complaint Counsel agrees that Dr. Miller testified in this matter about his testimony in *Daniel Chapter One*, but the proposed finding's assertion that "[a]bove all else, the nature of the product and its safety are the linchpins in determining the level of substantiation required to support one's claim" is not supported by the evidence cited.

2. Dr. David Heber

119. 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).

Response to Finding 119:
Complaint Counsel has no specific response.

120. Dr. Heber is a treating physician with patients, and has been a member of the faculty of UCLA Medical School for 33 years. He is currently a Professor of Medicine in Public Health. (Heber, Tr. 1937; CX1407 (Heber, Tropicana Tr. 76)).

Response to Finding 120:
Complaint Counsel has no specific response.

121. Dr. Heber 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).

Response to Finding 121:
Complaint Counsel has no specific response.

122. He has co-authored over 200 peer-reviewed publications in the field of nutrition and its relation to various diseases and written 25 chapters in other scientific texts. (Heber, Tr. 1939-40).

Response to Finding 122:
Complaint Counsel has no specific response.

123. He 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).

Response to Finding 123:
Complaint Counsel has no specific response.

124. Dr. Heber summarized Respondents' basic research and science in the areas of heart, prostate, erectile function, and the bioavailability, absorption, and safety of the Challenged Products. (Heber, Tr. 1936-103).

Response to Finding 124:
Complaint Counsel has no specific response.

125. Dr. Heber and Dr. Miller maintain that RCTs are not necessary to properly substantiate health claims for harmless, pure fruit products, like the Challenged Products. In fact, Dr. Heber opined that RCTs are both expensive and often unreliable in dealing with foods, as opposed to drugs. (Heber, Tr. 1949-50, 2166, 2179, 2182).

Response to Finding 125:
The proposed finding is unsupported by the cited evidence. The cited pages contain no testimony by Dr. Miller, and at the cited pages, Dr. Heber states that RCTs are expensive, but he does not say that they are "unreliable." (Heber, Tr. 1949-50, 2166, 2179, 2182).

126. Experts in the nutrition field consider competent and reliable science to support health claims for pomegranate juice based on the totality of evidence, which does not necessarily include RCTs. (Heber, Tr. 2182).

Response to Finding 126:
The proposed finding mischaracterizes the record evidence. (*See* CCFF ¶ 1102).

127. Dr. Heber testified as to the basic mechanisms of action underlying the health benefit properties of pomegranate juice. (Heber, Tr. 1957, 2112-13; CX1407 (Heber, Tropicana Tr. 228-31).

Response to Finding 127:
The proposed finding mischaracterizes the record as a whole, insofar as it implies that pomegranate juice has been shown by competent and reliable scientific evidence to provide specific health benefits. (*See* CCFF ¶ 1102).

128. He testified that pomegranate polyphenols have anti-oxidative and anti-inflammatory properties that have dramatic implications for multiple conditions affecting human health, including the prolongation of nitric oxide in the body, aging, cancer, mental function, and heart disease. (Heber, Tr. 1957, 2112-13; CX1407 (Heber, Tropicana Tr. 228-31).

Response to Finding 128:
The proposed finding is unsupported by the cited evidence. Dr. Heber testified that *plants* have anti-inflammatory activities with implications for various diseases (Heber, Tr. 1957), and admitted that antioxidant potency in laboratory tests does not necessarily translate into such activity in the body. (Heber, Tr. 2112-13). CX1407 ends at page 136. (*See also* CCFF ¶¶ 960-61 (Respondents' RCTs repeatedly showed no change in antioxidant and anti-inflammatory markers that were tested)).

129. Dr. Heber testified that POM juice and POMx are completely safe. (Heber, Tr. 2009).

Response to Finding 129:
The proposed finding mischaracterizes the evidence. Dr. Heber corrected himself two lines later and testified that "pomegranate juice and pomegranate extract are generally recognized as safe," referring to the Food and Drug Administration's GRAS definition. (Heber, Tr. 2009). *See also* Responses to Finding 201 (noting signals of potential safety problems in some of the study results) and Finding 1011 (detailed analysis by FDA of safety and toxicity profile for pomegranate extract).

130. He also opined that the antioxidant effect measured in the laboratory has not been different in POM juice and POMx. Dr. Heber firmly believes that pomegranate juice and POMx have the same impact on oxidative stress. (Heber, Tr. 2186-87).

Response to Finding 130:
This finding mischaracterizes the record as a whole. Dr. Heber admitted that he published a study showing that pomegranate juice had greater antioxidative activity than pomegranate extract. (Heber, Tr. 2187; CX1188_0001, 0006 (Heber study finding that pomegranate juice has more antioxidant activity than extract, which the article attributes to the juice's anthocyanin content)).

131. Dr. Heber also reviewed Respondents' body of cardiovascular research, including research done by Dr. Michael Aviram, Dr. Dean Ornish, and Dr. Michael Davidson. Dr. Heber concluded Respondents' science showed that the Challenged Products were likely to cause a significant improvement in cardiovascular health and help to reduce the risk of cardiovascular disease. (Heber, Tr. 2012).

Response to Finding 131:
The proposed finding is unsupported by the cited evidence. On the page cited, Dr. Heber testified only that there was "competent and reliable evidence that POM and POMx are likely to lessen the risk of cardiovascular disease." (Heber, Tr. 2012). Dr. Heber, however, does not hold himself out as an expert in cardiovascular disease (CCFF ¶ 728), was not asked to opine on whether the heart benefit claims challenged in the complaint were true or substantiated (CCFF ¶¶ 730-731), and did not consider all of the available clinical evidence when reaching his conclusions (CCFF ¶¶ 849, 874).

132. Dr. Heber reviewed Respondents' body of prostate health research, including animal research, studies done in vitro, and the clinical research done by Dr. Allan Pantuck and Dr. Michael Carducci. Based on this body of research, he concluded that it is likely POM juice and POMx lengthen PSA doubling time for men who have prostate cancer and those men may experience a deferred recurrence of the disease or death from prostate cancer. (Heber, Tr. 2012).

Response to Finding 132:
The first sentence of the proposed finding is not supported by the cited evidence. Complaint counsel has no specific response to the second sentence of the proposed finding, except to note that at his deposition, when asked about the prostate cancer evidence, Dr. Heber repeatedly stated only that the body of research provides support for

"*potential* health benefits for prostate cancer including prolongation of PSA doubling time." (CCFF ¶ 732).

133. He also opined, based on this body of research, 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).

Response to Finding 133:
Complaint counsel has no specific response, except to note that at his deposition, when asked about the prostate cancer evidence, Dr. Heber repeatedly stated only that the body of research provides support for "*potential* health benefits for prostate cancer including prolongation of PSA doubling time." (CCFF ¶ 732).

134. Dr. Heber also reviewed Respondents' studies on erectile function. Dr. Heber opined that the animal studies showed that pomegranate juice created a marked improvement in proper erectile function and would probably do so in humans due to the effect of pomegranate juice prolongation on the lifespan of nitric oxide in the body. (Heber, Tr. 1968-69; CX1407 (Heber, Tropicana Tr. 242)).

Response to Finding 134:
Complaint Counsel objects to the proposed finding on the grounds that Dr. Heber was not qualified as an expert in erectile dysfunction (ED) and he admitted that he is not an expert in erectile function treatment. (CCFF ¶ 728). Respondents offered him as an expert in "the relationship between nutrition and various diseases, including coronary heart disease and cancer, other diseases as well, but those are the things he's going to talk about." (Tr. 1940; *see* CCFF ¶ 729). Further, the proposed finding is unsupported by the cited evidence, which does not support the first sentence, or the assertion that Dr. Heber testified about a "marked improvement in erectile function" in animals, or the assertion that Dr. Heber said pomegranate juice would "probably" show an ED benefit in humans. In fact, at trial, Dr. Heber said only that there was a showing of increased blood flow to the penis in an animal model, but that "in humans, it's much harder to measure that." (Heber, Tr. 1969). There is no page 242 in CX1407.

135. Dr. Heber opined that Dr. Forest's erectile study on humans showed that consumption of POM juice created a marked improvement in erectile function among men who had experienced erectile dysfunction, and it had major clinical significance in showing a benefit from pomegranate juice despite barely missing statistical significance. (Heber, Tr. 1830-31, 1979).

Response to Finding 135:
The proposed finding is unsupported by the cited evidence. Trial transcript pages 1830-31 cite Respondents' attorney's opening statement, which is not evidence in the record, and trial transcript page 1979 does not discuss any specific conclusion of the Forest/Padma-Nathan RCT Study. (Tr. 1830-31; Heber, Tr. 1979). Moreover, Dr. Heber admitted that he is not an expert in erectile function treatment. (CCFF ¶ 728).

3. Dr. Dean Ornish

136. Dr. Dean Ornish is a medical doctor and Clinical Professor of Medicine at the University of California at San Francisco. (Ornish, Tr. 2314).

Response to Finding 136:
Complaint Counsel has no specific response.

137. For over 34 years, Dr. Ornish directed clinical research on the relationship between diet and lifestyle and coronary heart disease. He was the first to prove by a series of RCTs that heart disease could be reversed by simply making changes in diet and lifestyle. (Ornish, Tr. 2316-17).

Response to Finding 137:
The proposed response mischaracterizes the record insofar as it uses the word "simply." Dr. Ornish's research focuses on the proposition that *comprehensive, intensive* dietary and lifestyle changes can improve medical risk factor changes in people with disease, including coronary heart disease. (*See* CCFF ¶ 734).

138. Dr. Ornish has written six published books on the subject of the effect of diet and lifestyle on heart disease and other diseases. (Ornish, Tr. 2318).

Response to Finding 138:
Complaint Counsel does not disagree.

139. Dr. Ornish's research has been reported in many prestigious journals, and he has written numerous articles for distinguished peer-reviewed journals. (Ornish, Tr. 2318-19).

Response to Finding 139:

Complaint Counsel does not disagree.

140. Dr. Ornish testified at trial that heart health claims for pomegranate juice need not be substantiated by expensive RCTs, and the totality of Respondents' scientific evidence must be considered. (Ornish, Tr. 2320-31).

Response to Finding 140:
Complaint Counsel does not disagree, except to note that when called upon to conduct studies to evaluate whether or not pomegranate juice had heart disease benefits suggested by the Aviram studies, Dr. Ornish designed and conducted two randomized controlled trials costing thousands of dollars. (Ornish Tr. 2385; CCFF ¶ 820). Dr. Ornish testified that "I'm the one who actually encouraged the Resnicks to do these studies." (Ornish, Tr. 2386).

141. Dr. Ornish responded to the criticisms of his studies by Complaint Counsel's expert, Dr. Frank Sacks and opined that, in a nutritional context, in vitro and animal studies may be more effective in testing the efficacy of a nutrient. (Ornish, Tr. 2327-30, 2331-55).

Response to Finding 141:
The proposed finding is unsupported. The cited pages do not contain the word "animal" or the terms "in vitro" or "nutritional context." In the cited pages, among other things, Dr. Ornish stated that one should look at the totality of the evidence (Ornish, Tr. 2330); he described RCTS as "a powerful tool" for determining whether a "drug or a fruit or a device" is "helpful or not" (Ornish, Tr. 2327); he described the elements of RCTs (Ornish, Tr. 2327-30); and he described the RCTs that he conducted for the Resnicks on pomegranate juice, as well as Dr. Sacks' discussion of those studies. (Ornish, Tr. 2331-55).

142. He testified that Complaint Counsel's position that only RCTs are good science is overly simplistic and runs the danger of depriving the public of important nutritional information by discouraging research on natural products. (Ornish, Tr. 2325-28).

Response to Finding 142:

Complaint Counsel agrees that Dr. Ornish stated that "it's a very simple-minded approach to say that only randomized trials are good science and everything else is really not." (Ornish Tr. 2327-28). Complaint Counsel disagrees that this reflects the government's position.

143. Dr. Ornish testified that the totality of Respondents' scientific studies conducted on the cardiovascular system convinces him that pomegranate juice is effective in reducing the risk of cardiovascular problems, and even reversing, in come instaces, adverse conditions already present in the cardiovascular system (Ornish, Tr. 2354-55).

Response to Finding 143:
The proposed finding is irrelevant, insofar as it does not address the claims challenged in the Complaint. In addition, it mischaracterizes Dr. Ornish's testimony. At trial, he testified only as to the two studies that he had conducted. (Ornish, Tr. 2354-55).

4. Dr. Arthur Burnett

144. Dr. Arthur Burnett is a Professor of Urology serving on the faculty of the Department of Urology at the Johns Hopkins University School of Medicine/Johns Hopkins Hospital. (PX0149-0001; Burnett, Tr. 2241).

Response to Finding No. 144:
Complaint Counsel has no specific response.

145. 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. (PX0149-0001; Burnett, Tr. 2240 – 41).

Response to Finding No. 145:
Complaint Counsel has no specific response.

146. 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. (PX0149-0001; Burnett, Tr. 2241).

Response to Finding No. 146:
Complaint Counsel has no specific response.

147. Dr. Burnett has authored and published over 180 original peer-reviewed articles and 40 book chapters. (PX0149-0003).

Response to Finding No. 147:
Complaint Counsel has no specific response.

148. Dr. Burnett has treated between 10,000 and 15,000 patients for erectile dysfunction. (Burnett, Tr. 2244).

Response to Finding No. 148:
Complaint Counsel has no specific response, except to note that Dr. Burnett testified that he sees about 10 to 15 patients per week with erectile dysfunction and has been doing so for more than 20 years. (Burnett, Tr. 2244).

149. Dr. Burnett has conducted world renowned research on nitric oxide ("NO"). (PX0149-0003).

Response to Finding No. 149:
Complaint Counsel has no specific response.

150. Complaint Counsel's erectile health expert, Dr. Arnold Melman, recognizes "[t]hat Dr. Burnett of Johns Hopkins is a man highly respected in his field." (Melman, Tr. 1166).

Response to Finding No. 150:
Complaint Counsel has no specific response, except to note that the court recognized Dr. Melman as an expert in urology as it relates to the treatment, prevention, and reduction of risk of erectile dysfunction; and in clinical testing involving erectile dysfunction. (CCFF ¶ 720).

151. Dr. Burnett explained at trial that the basic scientific mechanisms by which pomegranate juice, through its high antioxidant content, aids and enhances the critical function of nitric oxide in improving vascular blood flow to the penis and promoting the vascular biological health of the penis. (PX0149-0004-07; PX0349 (Burnett, Dep. at 87-90, 103, 118, 137); Burnett, Tr. 2250-56, 2303).

Response to Finding No. 151:
Complaint Counsel has no specific response.

152. Dr. Burnett reviewed the work on the unique nitric oxide effect found in pomegranate juice done by Nobel Laureate Dr. Louis Ignarro and confirmed that nitric oxide was the principal source of proper erectile function. (PX484; PX0149-004-005; Burnett, Tr. 2249-50, 2253-56; 2276; PX0058).

Response to Finding No. 152:
Complaint Counsel has no specific response.

153. Dr. Burnett concluded that the Respondents' basic scientific and clinical evidence is sufficient to support the conclusion that it is likely that pomegranate juice has a beneficial effect on erectile function. (PX0149-0006-0007; PX0349 (Burnett, Dep. at 103, 118, 137); Burnett, Tr. 2255-56).

Response to Finding No. 153:
Complaint Counsel does not disagree that this was part of Dr. Burnett's testimony, but the proposed finding is incomplete because Respondents' and Complaint Counsel's experts testified that POM juice has not been shown to treat erectile dysfunction in humans (CCFF ¶¶ 1086-90), and that *in vitro* and animal studies cannot alone show efficacy in humans. (CCFF ¶¶ 763-64; PX0349 (Burnett, Dep. at 117-18)).

154. Dr. Burnett also opined that RCTs should not be required to substantiate such claims for harmless pure fruit products like pomegranates, before permitting this information to be given to the public. (PX0149-0006-0007; Burnett, Tr. 2272-74, 2303; PX0349 (Burnett, Dep. at 118, 137)).

Response to Finding No. 154:
The proposed finding is incomplete because it does not specify the claim being made, or that it is being made about POM Juice. In fact, Dr. Burnett stated that experts would require two to three RCTs to reach a conclusion about pomegranate juice's efficacy. (CCFF ¶ 783).

5. Dr. Irwin Goldstein

155. Dr. Goldstein is a 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. (PX0189-0001-0002; PX0352 (Goldstein, Dep. at 14)).

Response to Finding No. 155:
Complaint Counsel has no specific response.

156. Dr. Goldstein has been certified by the American Board of Urology since 1982. (PX0189-0001).

Response to Finding No. 156:
Complaint Counsel has no specific response.

157. He was a Professor of Urology and Professor of Gynecology at the Boston University School of Medicine from 1990-2005 and 2002-2005. (PX0189-0002-0003).

Response to Finding No. 157:
Complaint Counsel has no specific response.

158. Dr. Goldstein has published over 250 original peer-reviewed manuscripts in male and female sexual medicine. (PX0189-0002-0003).

Response to Finding No. 158:
Complaint Counsel has no specific response.

159. Dr. Goldstein was part of the original advisory board to Pfizer that engaged in an 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). (Goldstein, Tr. 2590-91).

Response to Finding No. 159:
Complaint Counsel has no specific response, except to note that the cited evidence does not identify the drug names or manufacturers of the brands Levitra or Cialis. (Goldstein, Tr. 2591).

160. Complaint Counsel's designated erectile-health expert, Dr. Melman, also recognizes Dr. Goldstein as "highly regarded" in the field. (Melman, Tr. 1166-67).

Response to Finding No. 160:
Complaint Counsel has no specific response, except to note that the court recognized Dr. Melman as an expert in urology as it relates to the treatment, prevention, and reduction of risk of erectile dysfunction; and in clinical testing involving erectile dysfunction. (CCFF ¶ 720).

161. Dr. Goldstein agreed that RCT studies were not required for substantiating claims that pomegranate juice can aid in erectile health. (Goldstein, Tr. 2601-02).

Response to Finding No. 161:
Complaint Counsel has no specific response.

162. He testified that in vitro and animal studies showed a likelihood that pomegranate juice improves erectile health. (Goldstein, Tr. 2601-02, 2605; PX0352 (Goldstein, Dep. at 37-42)).

Response to Finding No. 162:

Complaint Counsel has no specific response.

163. Dr. Goldstein opined that the consumption of pomegranate juice is a logical option for men who are not responsive to conventional drugs designed to treat erectile dysfunction and who are unwilling to consider invasive or mechanical therapies for treatment of their erectile dysfunction. (PX0189-0005; PX0352 (Goldstein, Dep. at 37-42); Goldstein, Tr. 2605, 2641).

Response to Finding No. 163:
Complaint Counsel has no specific response.

164. Dr. Goldstein concluded that reasonable and competent scientific evidence shows that pomegranate produced a definite benefit to proper and effective erectile function. (Goldstein, Tr. 2605).

Response to Finding No. 164:
The proposed finding mischaracterizes the evidence and is incomplete. Dr. Goldstein testified about the reduction of risk or amelioration of erectile dysfunction caused by endothelial dysfunction and did not describe any benefit to "proper and effective erectile function." (Goldstein, Tr. 2605). Dr. Goldstein further testified that he does not recommend POM Juice as a treatment for erectile dysfunction and that "'you have to study humans to make statements about humans.'" (CCFF ¶¶ 764, 1090).

6. Dr. Jean deKernion

165. Dr. Jean deKernion is the Chairman of the Department of Urology and Senior Associate Dean for Clinical Affairs at the UCLA School of Medicine. (PX0160-0001).

Response to Finding No. 165:
The proposed finding is unsupported by the cited evidence.

166. He served as dean of the Department of Urology at the UCLA School of Medicine for twenty-six years. (deKernion, Tr. 3039).

Response to Finding No. 166:
Complaint Counsel has no specific response.

167. Dr. deKernion is a practicing urologist certified by both the American Board of Surgery and the American Board of Urology. (deKernion, Tr. 3039-40).

Response to Finding No. 167:
Complaint Counsel has no specific response.

168. Dr. deKernion has been involved in basic and clinical research and has published 228 papers in peer-reviewed journals. (PX0161-0001).

Response to Finding No. 168:
Complaint Counsel has no specific response.

169. For six years, he was the associate editor of the prestigious Journal of Urology and acted as a reviewer for approximately twenty other peer-reviewed journals. (PX0161-0002).

Response to Finding No. 169:
Complaint Counsel has no specific response.

170. Dr. deKernion testified that in the case of fruit juice such as POM juice, that has low or no toxicity, RCTs are not required. (deKernion, Tr. 3060).

Response to Finding No. 170:
Complaint Counsel has no specific response except to note that Complaint Counsel's prostate expert, Dr. Eastham, opined that even safe products can have negative effects. Dr. Eastham testified that his opinion is "based upon experience that we had with Vitamin E and selenium. They are innocuous substances . . . . When the studies were done, they didn't work and they did cause problems, so . . . it's a leap of faith to make a claim that something is innocuous when it hasn't been very well-studied in the scientific realm." (Eastham Tr. 1329; *see also* CCFF ¶1106 (stating SELECT trial stopped early because of increased incidence of prostate cancer in men taking Vitamin E)).

171. Dr. deKernion testified that Respondents' *in vitro* and animal studies showed that pomegranate juice inhibited the growth of prostate cancer cells and actually killed them. (deKernion, Tr. 3044-45, 3120).

Response to Finding No. 171:
Complaint Counsel has no specific response except to note that Dr. deKernion also testified at his deposition that he "can't prove that it can kill the cell" in humans. (PX0351 (deKernion, Dep. at 110)).

172. Dr. deKernion stated that the PSA doubling-time studies of Dr. Pantuck and Dr. Carducci both showed a dramatic lengthening of PSA doubling time, which Dr. deKernion opined was a valid and effective endpoint for recurrence and death from prostate cancer after a radical prostatectomy. (deKernion, Tr. 3061).

Response to Finding No. 172:
The proposed finding is not supported by the cited evidence.

173. He opined that there is a high degree of probability that POM products inhibit the clinical development of prostate cancer cells even in men not diagnosed with prostate cancer. (deKernion, Tr. 3061, 3119, 3126).

Response to Finding No. 173:
Complaint Counsel has no specific response except to note that Dr. deKernion failed to opine that Respondents' claims that the POM Products treat, prevent, or reduce the risk of prostate cancer are substantiated.

174. Dr. deKernion also concluded there was a high degree of probability that POM products provide a special benefit to men with rising PSA after radical prostatectomy and that POM products lengthened PSA doubling time, thus, deferring death from prostate cancer. (deKernion, Tr. 3126).

Response to Finding No. 174:
Complaint Counsel has no specific response except to note that Dr. deKernion failed to opine that Respondents' claims that the POM Products treat, prevent, or reduce the risk of prostate cancer are substantiated.

7. Professor Ronald Butters

175. Professor Ronald Butters is an expert in the science of linguistics, which is the study of all forms of human language. (Butters, Tr. 2813, 2816).

Response to Finding No. 175:
Complaint Counsel has no specific response.

176. He is a Professor Emeritus at Duke University and has been on faculty at Duke for over forty years. (Butters, Tr. 2812).

Response to Finding No. 176
Complaint Counsel has no specific response.

177. He served as the Chairman of the Linguistics Department at Duke and Chairman of Duke University's English Department. (Butters, Tr. 2812).

Response to Finding No. 177
Complaint Counsel has no specific response.

178. He is a member of the advisory board of the New Oxford American Dictionary and has served as editor and co-editor of multiple prestigious scientific and academic publications. He participates in numerous professional associations and is the past president of the International Association of Forensic Linguistics. (Butters, Tr. 2812-13).

Response to Finding No. 178:
Complaint Counsel has no specific response other than to note that the cited evidence only shows that Dr. Butters's editorial responsibilities were as the editor for the American Dialect Society and a co-editor for the International Journal of Speech, Language, and Law. It also shows that he participates or participated in three professional associations. (Butters, Tr. 2812-13).

179. He has written many textbooks and books on the subjects of linguistics, semantics, and semiotics. (Butters, Tr. 2814-15).

Response to Finding No. 179:
The proposed finding mischaracterizes Dr. Butters's testimony and is incorrect. He did not claim to have written "many" textbooks and books on the subjects of linguistics, semantics, and semiotics. (Butters, Tr. 2814-15). In fact, he has written one "textbook" (a "Composition Guide" or stylesheet) and three other "books" or "monographs." (PX0159-0005).

180. Professor Butters viewed all of POM's advertisements listed in Complaint Counsel's complaint and all the advertisements admitted into evidence. (Butters, Tr. 2817).

Response to Finding No. 180:
Complaint Counsel does not disagree that Dr. Butters reviewed all of POM's advertisements listed in the Commission's complaint, but the cited testimony does not support the proposed finding's assertion that he reviewed all of the advertisements admitted into evidence. (Butters, Tr. 2817).

181. He considered the advertisements in their totality and took into account the nature of the Challenged Products. (Butters, Tr. 2817).

Response to Finding No. 181:

Complaint Counsel agrees that Dr. Butters claimed at trial to have considered the ads in their totality, but disagrees that he in fact did so. Professor Butters "deconstruct[ed] the POM Wonderful advertising, dismissing or discounting individual elements of the advertising to reach a conclusion about the communication of the advertising." (CX1295 (Stewart, Report at 0006)).

182. Professor Butters based his opinion on the language used in the advertisements and the implied message as would be interpreted by a reasonable person. (Butters, Tr. 2818).

Response to Finding No. 182:
The proposed finding is unsupported by the cited evidence. Dr. Butters did not claim to have analyzed the messages in the ads as would a "reasonable person." (Butters, Tr. 2818). Dr. Butters analyzed the challenged ads from the perspective of the ordinary adult user of the English language in America. (Butters, Tr. 2816-17 ("I didn't think in terms of – just of consumers"), 2831, 2833-34). He testified that he had no understanding of the term "reasonable consumer" as used in an FTC case and he never used the terms "reasonable person" or "reasonable consumer" in his report. ((PX0350 (Butters, Dep. at 38; PX0158 (Butters, Report at 0001-43)).

183. Professor Butters concluded that none of Respondents advertisements stated explicitly or implied that the Challenged Products actually prevented or cured any disease. (Butters, Tr. 2818-19).

Response to Finding No. 183:
Complaint Counsel does not disagree as to the nature of Dr. Butters's testimony but disagrees with his unsupported conclusion.

184. He also testified that none of POM's advertisements stated explicitly or implied that the Challenged products "treated" disease in the sense that the Challenged Products were a form of medical treatment or a substitute for conventional medical treatment. (Butters, Tr. 2819).

Response to Finding No. 184:

Complaint Counsel does not disagree as to the nature of Dr. Butters's testimony but disagrees with his unsupported conclusion.

185. He also explained that use of the term "may" would not cause a reasonable person to believe that the product will produce that result. (Butters, Tr. 2822).

Response to Finding No. 185:
Complaint Counsel does not disagree as to the nature of Dr. Butters's testimony but disagrees with his unsupported conclusion. (*See* CCFF ¶¶ 610-13; CX1295 (Stewart, Report at 0015) ("Searleman and Carter (1988) offer empirical evidence that the presence of qualifiers increases the credibility of claims relative to the absence of a similar claim without a qualifier. Indeed, these researchers found that the use of the hedge word 'may' rather than the stronger term 'will' created greater credence for the claim.")).

8. Professor David Reibstein

186. Professor David Reibstein is a tenured member of the faculty of Wharton School at the University of Pennsylvania, one of the nation's most distinguished schools of business and finance, and has been on faculty for thirty-one years. (Reibstein, Tr. 2481).

Response to Finding No. 186:
Complaint Counsel has no specific response.

187. Professor Reibstein has provided management education in the field of marketing to more than 300 companies. (Reibstein, Tr. 2485).

Response to Finding No. 187:
Complaint Counsel has no specific response.

188. He has designed, executed, and supervised hundreds of market research studies for over thirty years, including surveys concerning consumer behavior. (Reibstein, Tr. 2485-86).

Response to Finding No. 188:
Complaint Counsel has no specific response.

189. Professor Reibstein has written textbooks on the field of marketing, serves on the board of American Marketing Association, and is currently the Chairman-elect of that organization. (Reibstein, Tr. 2484; PX0356 (Reibstein, Dep. at 14)).

Response to Finding No. 189:
Complaint Counsel has no specific response.

190. Professor Reibstein offered expert testimony on the subject of materiality. Professor Reibstein also reviewed the Bovitz survey, upon which Complaint Counsel relies to suggest that POM's advertisements convey disease claims. (Reibstein, Tr. 2508).

Response to Finding No. 190:
The cited evidence does not support the proposed finding's assertion that Dr. Reibstein offered expert testimony on the subject of materiality. (Reibstein, Tr. 2508). Dr. Reibstein never explained how his study related to materiality. (Reibstein, Tr. 2480-2586; PX0223 (Reibstein, Report at 0001-0022); PX0356 (Reibstein, Dep. at 1-187)). At the time he designed his study, Dr. Reibstein was not familiar with the concept of materiality in an FTC case. (PX0356 (Reibstein, Dep. at 41-42)).

191. He concluded that the Bovitz survey did not address consumers' motivations for purchasing pomegranate juice. (Reibstein, Tr. 2509).

Response to Finding No. 191:
Complaint Counsel has no specific response except to note that the Bovitz Survey was designed and commissioned by POM to evaluate the effectiveness of the then-running "Super Hero" advertising campaign compared to POM's earlier "Dressed Bottle" campaign, including the main idea message communication and the communication of benefits. (*See* CCFF ¶ 579; PX0225-0012-14). It was not designed to evaluate consumers' purchase motivations. (PX0225-0001-47).

192. Among many other flaws, the Bovitz survey did not even ask any questions about purchasing motivations and was limited to billboard advertisements, which Complaint Counsel conceded are not at issue in this case. (Reibstein, Tr. 2509, 2574).

Response to Finding No. 192:
The proposed finding mischaracterizes the record. That the Bovitz Survey did not ask about purchasing motivations was not a flaw and the cited evidence does not support describing it as a flaw. (Reibstein, Tr. 2509, 2574). The Bovitz Survey was designed and commissioned by POM to evaluate the effectiveness of the then-running "Super Hero" advertising campaign compared to POM's earlier "Dressed Bottle" campaign,

including the main idea message communication and the communication of benefits. (*See* CCFF ¶ 579; PX0225-0012-14). The cited evidence also does not support the incorrect assertion that the Bovitz Survey has "many other flaws" (Reibstein, Tr. 2509, 2574). *See also* Responses to Findings 2752-2771. Finally, the results of the Bovitz Survey are not limited to billboard ads, but are applicable to non-billboard advertisements using identical headlines and imagery. (*See* CCFF ¶¶ 584-85, 596).

193. Professor Reibstein also reviewed the A&U Survey and the AccentHealth survey. The A&U survey was conducted to figure out why people purchase pomegranate juice. (Reibstein, Tr. 2517).

Response to Finding No. 193:
Complaint Counsel has no specific response.

194. In Professor Reibstein's expert opinion, the A&U survey was invalid and not reliable for multiple reasons. (Reibstein, Tr. 2518-21).

Response to Finding No. 194:
Complaint Counsel does not disagree as to the nature of Dr. Reibstein's testimony but disagrees with his conclusion and also notes that Dr. Reibstein acknowledged that he would not completely disregard the A&U responses to "helps protect against prostate cancer" as a reason that consumers consume POM Juice. (*See* CCFF ¶ 647).

195. Professor Reibstein also concluded that the AccentHealth survey, which surveyed persons in urologists' offices as they were leaving and showed them a print ad, was severely flawed and unreliable. (Reibstein, Tr. 2522).

Response to Finding No. 195:
Complaint Counsel has no specific response.

196. Professor Reibstein prepared a survey for Respondents to understand the underlying motivations that consumers had for purchasing pomegranate juice and what those motivations might have been. (PX0356 (Reibstein, Dep. at 11, 39); Reibstein, Tr. 2487).

Response to Finding No. 196:
Complaint Counsel does not disagree except to note that the Reibstein survey was prepared to measure purchase motivation rather than the materiality of the challenged

claims for POM Juice and that even as to purchase motivation it is seriously flawed and inadequate. (CCFF ¶¶ 657-61; CX1297 (Mazis, Report at 0008-10); Reibstein, Tr. 2494). Furthermore, Complaint Counsel notes that the Reibstein survey has no relevance to either the materiality of the challenged POMx claims or the purchase motivations of POMx purchasers. (CCFF ¶ 654).

197. In particular, Professor Reibstein's survey looked at the influential power of POM's advertisements on consumer purchasing behavior and how those advertisements influenced consumer motivation in those that purchased pomegranate juice. (PX0356 (Reibstein, Dep. at 52).

Response to Finding No. 197:
The proposed finding is unsupported by the cited evidence and is unsupported by the record. Dr. Reibstein's survey did not adequately measure the impact of advertising. (Mazis, Tr. 2671, 2690-95; CX1297 (Mazis, Report at 0009-11). Dr. Reibstein did not show survey respondents any of POM's advertisements. (Reibstein, Tr. 2494 ("The purpose of this study was not to test any particular ads. The purpose of this study was to look at what their motivations were for buying POM.")).

198. Professor Reibstein stated in his report and testified at trial that his survey overwhelmingly shows that less than 1% of POM buyers purchase POM juice to prevent, cure, or treat any disease. (Reibstein, Tr. 2493).

Response to Finding No. 198:
Complaint Counsel does not disagree regarding what Dr. Reibstein stated, but disagrees with the implication that the Reibstein survey adequately measured purchase motivation or validly measured the materiality of the challenged POM Juice claims. (CCFF ¶¶ 657-61; CX1297 (Mazis, Report at 0008-10)).

199. Less than 1% of those surveyed even mentioned any disease in stating why they buy POM. (Reibstein, Tr. 2525).

Response to Finding No. 199:

Complaint Counsel disagrees with the implication of the finding that the Reibstein survey adequately measured purchase motivation or validly measured the materiality of the challenged POM Juice claims. *See* Response to Finding 198.

B. Complaint Counsel's Experts

200. Unlike Respondents' experts, each of Complaint Counsel's experts was significantly impeached. (Stampfer, Tr. 813-14, 823-826, 830, 840; Melman, Tr. 1134, 153-55, 1158; PX0360 (Melman, Dep. at 59, 130-31); Eastham, Tr. 1339-40; PX0178-0001, 0006, 0009; Sacks, Tr. 1541-46; 1554, 1561, 1608-09; PX0361 (Sacks, Dep. at 142-43).

Response to Finding No. 200:
Complaint Counsel does not disagree that its experts were cross-examined by Respondents' Counsel, but disagrees that the proposed finding and the cited evidence shows that they were "significantly impeached." For example, the first two transcript citations (Stampfer, Tr. 813-14 and 823-826) show that Dr. Stampfer did not testify inconsistently with his deposition testimony. As another example, Dr. Eastham did not testify inconsistently with an article he authored; *see* Response to Finding 230. Moreover, Complaint Counsel disagrees that Respondents' experts were not impeached at trial.

201. Complaint Counsel provided no expert testimony denying the safety of the Challenged Products.

Response to Finding No. 201:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Moreover, the proposed finding is incorrect. Dr. Sacks testified that, for scientific purposes, the burden is on the proponent to show safety. (Sacks, Tr. 1539). He noted that there are signals of potential safety problems in some of the study results, including transient increases in blood glucose, triglycerides, lipoprotein A, and gamma GT, as well as the weight gain seen in Dr. Davidson's CIMT study. (Sacks, Tr. 1525; *see also* PX0361 (Sacks, Dep. at 73-74 (stating that there had not been

enough RCTs on the juice or the pills to satisfactorily evaluate safety and that there were safety signals in some of the small studies that need to be evaluated in larger studies)). Dr. Stampfer, too, testified that there was evidence in the materials he reviewed of an increase in triglyceride levels, "which could be expected with higher carbohydrate load;" he stated that juices with a high sugar content, such as pomegranate juice, are associated with higher risk of diabetes and weight gain. (PX0362 (Stampfer, Dep. at 195-96); s*ee also* CCFF ¶ 1021 (accelerated prostate cancer in the Carducci study)). Thus, pomegranate juice and the pomegranate extracts have not been shown to be safe. (Sacks, Tr. 1525).

202. Complaint Counsel provided no expert testimony regarding the bioavailability or absorbency of the Challenged Products.

Response to Finding No. 202:

The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Moreover, the proposed finding is irrelevant. As Dr. Heber advised the court in a federal court FTC case challenging the efficacy of a weight loss supplement, "while it is possible to show a number of statistically significant [but] physiologically minor effects of various agents . . . there is a separate burden of proof to demonstrate that these items are efficacious in weight loss therapy. . . . [M]erely showing that something has a potential metabolic effect does not relieve the parties of demonstrating a significant weight loss effect in a properly designed study with adequate numbers of subject and appropriate controls, including placebo controls." (PX0353A02-0008).

203. Complaint Counsel provided no expert testimony denying equivalency between POM juice and POMx.

Response to Finding No. 203:

The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Moreover, the proposed finding mischaracterizes the record as to the differences between POMx and POM Juice. (CCFF ¶¶ 125-26, 964-65). Respondents knew that because of the differences, POMx required separate substantiation. (CCFF ¶¶ 130-31 (Mrs. Resnick stating that pomegranate extract necessitated a new round of science to determine safety and efficacy)).

204. Complaint Counsel provided no expert opinion on what messages the advertisements conveyed or on materiality.

Response to Finding No. 204:

The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Dr. Mazis determined that POM's A&U Study demonstrated that the challenged heart disease and prostate cancer claims are material. (Mazis, Tr. 2688-89, 2760; CX1297 (Mazis, Report at 0012-13). Respondents' marketing expert, Dr. Reibstein, himself admits that the challenged claims regarding the treatment or prevention of heart disease, prostate cancer, and erectile dysfunction would likely be important to consumers. (CCFF ¶ 638). Dr. Stewart did express views disagreeing with Dr. Butters about the messages conveyed in the challenged ads. (CX1295 (Stewart, Report at 0005-18); Stewart, Tr. 3169-3222).

205. In addition, Professor Mazis, in stark contrast to how he has been utilized by Complaint Counsel in previous cases, provided (1) no factual analysis of the ads; and (2) provided no competing survey either on the ads or on the subject of materiality.

Response to Finding No. 205:

The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Moreover it is irrelevant. The proposed finding mischaracterizes Complaint Counsel's use of Dr. Mazis as a rebuttal witness to respond to Dr. Reibstein. (CX1297 (Mazis, Report at 0001-02)).

1. Professor Meir Stampfer

206. Professor Stampfer is not a cardiologist or urologist. (Stampfer, Tr. 868).

Response to Finding 206:
Complaint Counsel does not disagree, except to refer to Dr. Stampfer's substantial expertise. (CCFF ¶¶ 694-701).

207. Professor Stampfer testified to an improper substantiation standard as a matter of law. He stated that there was "some evidence" supporting Respondents' claims, but the evidence is insufficient substantiation unless those claims are proven "beyond a reasonable doubt." (Stampfer, Tr. 797-98).

Response to Finding 207:
The proposed finding mischaracterizes the record. Dr. Stampfer made clear that he "didn't mean that in a legal sense." (Stampfer, Tr. 797-978).

208. Professor Stampfer does not hold himself to this same high standard. Professor Stampfer conceded at trial that he has publicly made statements that food and beverage products lower the risk of certain diseases, in the absence of RCT studies and even where the product is not completely safe. (Stampfer, Tr. 801-02, 805, 810).

Response to Finding 208:
The proposed finding is irrelevant and mischaracterizes the record. Just as medical professionals must make treatment decisions in the face of imperfect information, public health professionals must make recommendations about types of foods the population should eat based on imperfect information. (Stampfer, Tr. 876-77). Dr. Stampfer concedes that in making public health statements about alcohol, he may have used the wrong terminology and suggested a causal relationship instead of an association. However, his assessment on alcohol is based on the results of many dozens of observational studies looking at the relationship between alcohol and either cardiovascular disease or all-cause mortality, involving *over a million persons and lasting decades*; further, his assessment is consistent with the U.S. Dietary Guidelines. (Stampfer, Tr. 801-02, 877-78).

209. He also admitted to making a number of public health recommendations in the absence of RCT studies. (Stampfer, Tr. 813-14).

Response to Finding 209:
The proposed finding is irrelevant. Just as medical professionals must make treatment decisions in the face of imperfect information, public health professionals must make recommendations about what types of foods to eat based on imperfect information. (Stampfer, Tr. 876-77).

210. 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).

Response to Finding 210:
Complaint Counsel does not disagree.

211. 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).

Response to Finding 211:
The proposed finding mischaracterizes the record. Dr. Stampfer stated that he favors giving information to the public, but that the risk of harm does not play a role in evaluating the existence of a causal link. (Stampfer, Tr. 827-29).

212. 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).

Response to Finding 212:
Complaint Counsel does not disagree except to note that Dr. Stampfer made clear that the level of evidence required depended on the claim being made: "If the claim implies that a causal link has been established, then you have to have evidence to back it up." (Stampfer, Tr. 830-31).

213. Professor Stampfer provided no opinion about the specific chemical structure of pomegranate antioxidants. (PX0362 (Stampfer, Dep. at 199)).

Response to Finding 213:

The proposed finding is irrelevant.

214. Professor Stampfer provided no opinion about how pomegranate antioxidants are metabolized in the human body (i.e. mechanisms of action). (PX0362 (Stampfer, Dep. 200).

Response to Finding 214:
The proposed finding is irrelevant. *See* Response to Finding 202.

215. Professor Stampfer provided no opinion about the antioxidant effect of pomegranate juice relative to POMx. (PX0362 (Stampfer, Dep. at 200, 203)).

Response to Finding 215:
The proposed finding mischaracterizes the evidence. When asked if he had an opinion on difference between pomegranate juice and POMx in terms of antioxidant effect on human health, Dr. Stampfer stated that "if you're talking about the effect on human health, in my opinion, no benefit for either has been established." (PX0352 (Stampfer, Dep. at 200).

216. Professor Stampfer provided no opinion about the extent to which the antioxidant effect of pomegranate juice on human health is attributable to anthocyanins as opposed to other forms of antioxidants. (PX0362 (Stampfer, Dep. at 203).

Response to Finding 216:
The proposed finding mischaracterizes the record. On the cited page, Dr. Stampfer responded that he didn't have an opinion on anthocyanin effects on issues *other than* human health. (PX0362 (Stampfer, Dep. at 203).

217. Professor Stampfer provided no opinion about the safety of pomegranate juice, apart from its being a sugary drink. (PX0362 (Stampfer, Dep. at 195-96)).

Response to Finding 217:
The proposed finding is incomplete. Dr. Stampfer testified that "I didn't see anything suggesting harm besides the usual harm that comes with fruit juice, sugary beverages. So there was some evidence in some of the material that was provided of increase in triglyceride levels which you expect with higher carbohydrate load. So in general, juices with high sugar content they are associated with higher risk of diabetes and weight gain but that is not specific to pomegranate juice." (PX0362 (Stampfer, Dep. at 195-96)).

218. Professor Stampfer provided no opinion about whether there are additional safety concerns for POMx relative to pomegranate juice. (PX0362 (Stampfer, Dep. at 201)).

Response to Finding 218:
The proposed finding is unsupported by the cited evidence. (PX0362 (Stampfer, Dep. at 201 (discussing POMx and pomegranates, not juice)).

219. Professor Stampfer was not asked to and did not create a rebuttal to the Heber report. (PX0362 (Stampfer, Dep. at 187-88)).

Response to Finding 219:
The proposed finding is irrelevant.

2. Dr. Arnold Melman

220. Dr. Arnold Melman testified as Complaint Counsel's expert in urology and erectile health. (Melman, Tr. 1081).

Response to Finding No. 220:
The proposed finding is incorrect. The court recognized Dr. Melman as an expert in urology as it relates to the treatment, prevention, and reduction of risk of erectile dysfunction; and in clinical testing involving erectile dysfunction. (CCFF ¶ 720).

221. Dr. Melman testified that he didn't know the meaning of "RCT" studies. (Melman, Tr. 1134).

Response to Finding No. 221:
The proposed finding is incomplete because Dr. Melman stated that he did not know the "'term RCT study[,]'" and preferred the phrase "randomized, double-blind, placebo-based trial." (Melman, Tr. 1134-35). Dr. Melman was accepted by the court as an expert in clinical testing involving erectile dysfunction and testified extensively about what constitutes a well-designed RCT in humans. (CCFF ¶¶ 720, 773-75, 777, 779, 781-83, 1055).

222. Dr. Melman conflated orgasm with erectile function and testified that reaching orgasm is absolutely required to show improvement in erectile function even when erection is achieved. (Melman, Tr. 1141-47).

Response to Finding No. 222:

The proposed finding mischaracterizes Dr. Melman's testimony. Dr. Melman testified that treatment of erectile dysfunction means that a man can complete intercourse with sexual satisfaction and that according to the NIH definition, sexual satisfaction for men can include orgasm. (Melman, Tr. 1142-43).

223. Dr. Melman conceded that in requiring RCTs, he was applying the FDA's standard for drugs. He also held the absurd position that pomegranate juice and water are drugs. (PX0360 (Melman, Dep. at 17-19); Melman, Tr. 1140-41, 1165).

Response to Finding No. 223:
The proposed finding mischaracterizes the evidence. Dr. Melman used the word "drug," to refer to "any product with an active ingredient," including the polyphenol agents in pomegranate juice (Melman, Tr. 1141, 1196), and his analysis of the applicable standard was based what experts in the erectile dysfunction field would require when evaluating whether eight ounces of pomegranate juice daily treats, prevents, or reduces the risk of erectile dysfunction in humans. (CCFF ¶¶ 1055-56, 1102; Melman, Tr. 1196).

224. Dr. Melman, like Professor Stampfer, holds his own conduct to a lower standard than he would apply to Respondents. Dr. Melman hopes to market a gene transfer therapy for erectile dysfunction, and, in an interview, Dr. Melman made overblown public statements that this therapy produced spontaneous normal erections in men suffering from erectile dysfunction, the therapy was "modifying the aging process", and it was the "fountain of youth". (Melman, Tr. 1148, 1153-55).

Response to Finding No. 224:
The proposed finding is incomplete and mischaracterizes the evidence. Dr. Melman testified that the gene transfer therapy product was not on the market, has not been sold, and would require FDA approval before being made available to consumers. (Melman, Tr. 1151).

225. Dr. Melman made these statements based solely on animal research despite knowing that people have died and become very sick from gene transfer therapy and without the support of the elaborate clinical studies he testified were absolutely necessary. (Melman, Tr. 1155, 1158; PX0360 (Melman, Dep. at 59, 130-31)).

Response to Finding No. 225:

The proposed finding is incomplete. Dr. Melman testified that the gene transfer therapy product was not on the market, has not been sold, and would require FDA approval before being made available to consumers. (Melman, Tr. 1151).

226. Dr. Melman also attempted to criticize the Forest/Padma-Nathan RCT for using the GAQ questionnaire, a widely used and commonly accepted questionnaire, that Dr. Melman knew nothing about prior to this case and had made no effort to familiarize himself with. (Melman, Tr. 1180-82; Goldstein, Tr. 2602, 2603; Burnett, Tr. 2304; PX0349 (Burnett, Dep. at 127); CX1337 (Forest, Dep. at 79)).

Response to Finding No. 226:
The proposed finding mischaracterizes the evidence. Dr. Melman testified that he researched the GAQ and determined that it was not a validated measure. (Melman, Tr. 1181). Furthermore, the evidence shows that experts in the erectile dysfunction field would not accept results from a non-validated measure, like the GAQ, to alone show that a product treats, prevents, or reduces the risk of erectile dysfunction in men. (CCFF ¶¶ 1056-57, 1060-61).

227. Not knowing that the quote was from the opinion of the United States Supreme Court, Dr. Melman, on cross-examination, stated that he completely disagreed with the statement "medical professionals and researchers do not limit the data they consider to statistically significant evidence." (Melman, Tr. 1178-80).

Response to Finding No. 227:
The proposed finding is partially irrelevant. It is irrelevant whether Dr. Melman knew any quote was from a U.S. Supreme Court opinion.

3. Dr. James Eastham

228. Dr. Eastham testified that RCTs are required for health claims and that disease prevention studies should involve ten to thirty thousand men, which are "incredibly expensive" and in the range of $600 million. (Eastham, Tr. 1322-28).

Response to Finding No. 228:
The proposed finding is incomplete in that Dr. Eastham also testified that: 1) the size of the study depends upon "the statistics of the study and what claims in terms of benefits that are projected;" and 2) "cost shouldn't necessarily change the bar of scientific effort .

. . just because something is expensive and difficult to do doesn't mean that that relieves someone from the burden of proof." (Eastham Tr. 1328-29).

229. Despite his insistence that RCTs are necessary to support claims made about a harmless product, such as fruit juice, Dr. Eastham nonetheless has performed many prostatectomies, which carry the risk of very serious side effects, even in the absence of RCTs. (Eastham, Tr. 1329-32).

Response to Finding No. 229:
The proposed finding is irrelevant. This case has to do with commercial advertising for the purpose of selling Respondents' products directly to the public; not the surgical practice of physicians following the standard of care for treatment of prostate cancer.

230. Dr. Eastham also insisted that no one accepts PSA doubling time as a surrogate for progression or death from prostate cancer. However, Dr. Eastham was impeached by his own article which characterizes PSA doubling time "as an important factor in the evaluation of men with newly diagnosed prostate cancer or prostate cancer that recurs after treatment", and that it "can be used as a surrogate marker for prostate cancer specific death." Other parts of that article cited studies showing that "only PSADT was a significant predictor of either systematic progression or local recurrence [of disease] and that "PSADT was the strongest predictor of eventual clinical recurrence." Dr. Eastham concluded in his article that "PSADT is an important prognostic marker in men with biochemical failure after local therapy for prostate cancer, and it predicts the probably response to salvage radiotherapy, progression to metastatic disease and prostate cancer specific death". (Eastham, Tr. 1339-40; PX0178-0001, 0006, 0009).

Response to Finding No. 230:
The proposed finding mischaracterizes Dr. Eastham's testimony in that he stated that "no one accepts *modulation of PSA doubling time* as a surrogate for clinical progression or death from prostate cancer." Moreover, Complaint Counsel does not disagree that Dr. Eastham's article states as such. However, the article does not impeach his testimony because it does not discuss *modulation of PSA doubling time* as a surrogate.

231. Dr. Eastham contended in defense of the article, that PSADT was a predictive surrogate only at the moment of treatment, and subsequent changes in PSADT were not predictive of disease recurrence or death. However, Dr. Eastham was unable to explain when it stopped being predictive. (Eastham, Tr. 1344).

Response to Finding No. 231:

The proposed finding mischaracterizes Dr. Eastham's testimony. Dr. Eastham testified that PSA doubling time at baseline (at the moment of biochemical recurrence prior to treatment) is a predictor of death and that changes in PSADT after recurrence have not been well-studied to determine when PSADT stops being an accurate predictor of survival. (*See* Eastham, Tr. 1343-45).

4. Dr. Frank Sacks

232. Dr. Sacks insisted that RCTs, which can cost hundreds of millions of dollars, are required to substantiate health claims even where a product is safe and provides a benefit to the public. (Sacks, Tr. 1535-37).

Response to Finding 232:
The proposed finding mischaracterizes the evidence. Dr. Sacks stated that safety and benefits must both be shown through RCTs. (Sacks, Tr. 1534-35). He also made clear that the cost of RCTs can vary substantially. (*See* Sacks, Tr. 1534-35). The Davidson CIMT Study cost less than $3 million. (CCFF ¶ 878). The Ornish CIMT study cost less than $500,000. (CCFF ¶ 823).

233. However, Dr. Sacks agreed that we must weigh the risk that the product will do harm against the risk of keeping potentially beneficial information from the public. (Sacks, Tr. 1559).

Response to Finding 233:
The proposed finding is irrelevant. The testimony at issue related to the basis for making public health recommendations. *See* Response to Finding 209.

234. He conceded that his requirement of two RCTs is the FDA standard for drugs, and he also admitted that in evaluating a natural food, RCTs are simply not necessary in all cases. (Sacks, Tr. 1541-46).

Response to Finding 234:
Complaint Counsel has no specific response to this proposed finding's statement about the FDA standard for drugs. With regard to the remainder of the finding, Dr. Sacks made an exception for whole foods in categories already tested in the DASH diet, for the

purposes of showing that a diet high in fruits, vegetables, whole grains and fish, and low in meat, sodium and sugars is beneficial for blood pressure. (*See* Sacks Tr. 1541-46).

See also Responses to Findings 1218-24.

235. When discussing the DASH Diet recommendation, Dr. Sacks stated that fruits as a category, including pomegranates, should be held to a lower standard of evidence than that of a drug and RCTs are not necessary. (Sacks, Tr. at 1545-46, 1554; PX0361 (Sacks, Dep. at 142-43)).

Response to Finding 235:
See Responses to Findings 1218-1224.

236. Dr. Sacks also acknowledges that RCTs are not feasible because of logistical, financial, and ethical considerations. (Sacks, Tr. 1561).

Response to Finding 236:
The proposed finding is incomplete and mischaracterizes the evidence. Dr. Sacks previously stated that a "major trial with hard clinical outcomes" on sodium reduction might not be feasible. He also testified that blinding participants as to sodium intake is difficult given the distinct taste of sodium. (Sacks, Tr. 1560-61).

237. Dr. Sacks also agreed that lack of statistical significance for a positive result is not proof of a negative or proof that pomegranate does not work. (Sacks, Tr. 1608-09).

Response to Finding 237:
See Response to Finding 50.

5. Professor David Stewart

238. Complaint Counsel offered Professor David Stewart as a rebuttal witness to Professor Ronald Butters, even though Professor Stewart is not an expert in linguistics, the subject of Dr. Butters' testimony. (Stewart, Tr. 3168-69).

Response to Finding No. 238:
Complaint Counsel has no specific response.

239. Professor Stewart conceded that he was not offering any opinion on how consumers would interpret POM's advertisements but was only criticizing Professor Butters' methodology. He stated that he did not even know if Complaint Counsel had any evidence on the meaning of the advertisements. (PX0357 (Stewart, Dep. at 52)).

Response to Finding No. 239:

This proposed finding's assertion that Dr. Stewart "stated that he did not even know if Complaint Counsel had any evidence on the meaning of the advertisements" mischaracterizes Dr. Stewart's testimony. Dr. Stewart agreed that he did not know if the FTC had any evidence that shows "how consumers perceive the ads *at the level of a net impression*." (PX0357 (Stewart, Dep. at 52) (emphasis added)). At trial, Dr. Stewart was asked whether he knew of "any evidence on how consumers perceive the ads," and he said not "beyond what I've talked about today." (Stewart, Tr. 3226). Dr. Stewart had testified during his direct testimony about creative strategies and the Bovitz Survey, which are evidence as to how consumers perceive POM's challenged ads. (Stewart, Tr. 3185-98, 3202-22).

240. Professor Stewart conceded that he was not an expert in the legal standards by which advertisements are judged. (PX0357 (Stewart, Dep. at 67)).

Response to Finding No. 240:
Complaint Counsel has no specific response.

241. He also stated that headlines like "Amaze your Cardiologist" and "Floss Your Arteries" would not be taken literally by consumers. (Stewart, Tr. 3230)

Response to Finding No. 241:
The proposed finding is incomplete. On redirect, Dr. Stewart testified that "[j]ust because they're not taken literally doesn't mean that [those headlines] aren't making some serious claims," and that they could very well communicate significant cardiovascular health benefits. (Stewart, Tr. 3240).

242. 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).

Response to Finding No. 242:
The proposed finding's assertion that Dr. Stewart testified that "there was not any other evidence of any such effect" is unsupported by the cited evidence. (Stewart, Tr. 3235).

243. Professor Stewart testified that his reliance on the creative briefs would be affected if they were typically modified, rejected, or ignored after they were written. (Stewart, Tr. 3196).

Response to Finding No. 243:
Complaint Counsel has no specific response, other than that the cited testimony appears at Stewart, Tr. 3234-35.

244. Professor Stewart testified as to the OTX and Bovitz Surveys. Professor Stewart conceded that at least "three good exposures" to an advertisement were necessary before a consumer would take away the advertisement's message and that it could require "many more exposures" to get "three good exposures." (Stewart, Tr. 3228-29).

Response to Finding No. 244:
The proposed finding mischaracterizes Dr. Stewart's testimony and is irrelevant. He did not testify regarding the OTX Study and the cited evidence does not support the assertion that he did. (Stewart, Tr. 3158-3242; PX0357 (Stewart, Dep. at 1-195)). Dr. Stewart did not testify that at least "three good exposures" to an advertisement were necessary before a "consumer would "take away the advertisement's message." (Stewart, Tr. 3228-29). Rather, asked whether it takes three good exposures to an ad for the message of the ad to be effective on the consumer, he stated "there is a general rule of thumb that suggests that three exposures [to an ad] is an optimal number of exposures." (Stewart, Tr. 3228). The number of ad exposures is irrelevant.

245. A federal court has previously rejected Professor Stewart's expert opinions. (Stewart, Tr. 3255).

Response to Finding No. 245:
The proposed finding is incomplete. The court initially rejected his declaration, but he subsequently testified in the matter. (Stewart, Tr. 3225).

246. Professor Stewart conceded that neither he nor Professor Butters were opining on Respondents' intent. (Stewart, Tr. 3233; PX0357 (Stewart, Dep. at 120, 130)).

Response to Finding No. 246:

The proposed finding mischaracterizes Dr. Stewart's testimony. In the cited evidence he testified that he did not know the Respondents' "actual," "real," or "specific" intent." (Stewart, Tr. 3233; PX0357 (Stewart, Dep. at 130)). Dr. Stewart testified that POM's creative briefs were evidence of intent. (*See, e.g.*, Stewart, Tr. 3193-96).

6. Professor Michael Mazis

247. Complaint Counsel offered Professor Michael Mazis as a rebuttal expert to Professor Reibstein. (CX1297_0002).

Response to Finding No. 247:
Complaint Counsel has no specific response.

248. In stark contrast to previous work Professor Mazis has done for Complaint Counsel in other litigation, he did not (a) conduct any facial analysis of POM's ads or offer any expert opinion on them; (b) conduct any surveys on the ads, or (c) provide any expert opinion on the exposure of the ads to consumers, despite testifying that such exposures were critical to having an effect on consumers.

Response to Finding No. 248:
The proposed finding is not supported by any reference to the record in violation of the Court's Order on Post-Trial Briefs. Furthermore, the proposed finding mischaracterizes Dr. Mazis's testimony in this and other matters and is irrelevant. *See* Response to Finding 38.

249. Despite his testimony that the appropriate measure of materiality is the potential impact of the challenged claim on the purchase behavior to show materiality, Professor Mazis also conceded that, to his knowledge, there was no evidence that POM's advertisements did cause anyone to buy the Challenged Products because it prevented, cured or treated any disease or even that "POM ads were material to the purchase decision." (Mazis, Tr. 90, 95, 96, 2700).

Response to Finding No. 249:
The proposed finding is unsupported by the cited evidence. In addition, Complaint Counsel notes that Dr. Mazis testified that the A&U study shows that consumers would find a claim that drinking POM juice treats, prevents or reduces the risk of heart disease

to be material and that they would find a claim that drinking POM juice treats, prevents or reduces the risk of prostate cancer to be material. (Mazis, Tr. 2688-89, 2760).

250. Like Professor Stewart, Professor Mazis testified that for an advertisement to affect the purchasing behavior of a consumer, a consumer would need more than one exposure. (Mazis, Tr. at 2752; Stewart, Tr. 3228-29).

Response to Finding No. 250:
The proposed finding mischaracterizes the testimony of Drs. Stewart and Mazis, is incomplete, and is irrelevant. *See* Responses to Findings 38 and 244.

V. THE DEVELOPMENT OF POM WONDERFUL'S SCIENCE PROGRAM

A. Initiation of the Program

251. Respondents' interest in pomegranates first began in 1986 when Stewart and Lynda Resnick acquired approximately 100 acres of pomegranate trees as part of a larger agricultural purchase. (CX1363 (S. Resnick, Coke Dep. at 26-27); S. Resnick, Tr. 1852-53).

Response to Finding No. 251:
Complaint Counsel does not disagree, except to note that the cited testimony does not identify a specific purchase date beyond "the mid '80s" or "the late '80s." (*See also* CCFF ¶ 147 ("[i]n 1987, Stewart and Lynda Resnick acquired farmland containing over 100 acres of mature pomegranate trees")).

252. Rather than use the acreage for citrus, Stewart and Lynda Resnick decided to keep the acres of pomegranates and began increasing their pomegranate acreage in the early 1990s based upon the initial sales of fresh pomegranates. (CX1367 (S. Resnick, Welch Dep. at 15)).

Response to Finding No. 252:
Complaint Counsel has no specific response.

253. Currently, Respondents Stewart and Lynda Resnick own approximately 18,000 acres of pomegranate orchards and are the largest growers of pomegranates in the United States. (CX1374 (Tupper, Ocean Spray Dep. at 29-30)).

Response to Finding No. 253:
Complaint Counsel has no specific response.

254. Years before launching their pomegranate products, Respondents set out to establish the health benefits of the fruit. Dr. Leslie Dornfeld, who was a close personal friend of the Resnicks and Professor of Internal Medicine at UCLA, explained the rich ancient history of the pomegranate's health giving properties and the health benefits associated with higher intake of polyphenolic antioxidants. (L. Resnick, Tr. 150; CX1363 (S. Resnick, Coke Dep. at 61-63); CX0105_0003; CX1362 (L. Resnick, Coke Dep. at 71-72); S. Resnick, Tr. 1855-56); CX1359 (L. Resnick, Dep. at 82)).

Response to Finding No. 254:
Complaint Counsel has no specific response.

255. Intrigued by the folklore surrounding the pomegranate's health giving properties, Respondents set out to decipher if there was any scientific truth to the history. (CX1360 (S. Resnick, Dep. at 84-85); PX1372 (S. Resnick, Tropicana Dep. at 32); CX1362 (L. Resnick, Coke Dep. at 71-72)).

Response to Finding No. 255:
Complaint Counsel has no specific response.

256. In addition to their intrigue with the fruit's history, the Resnicks motivation to fund the exploration of the health benefits of pomegranates also originated from a family history of cardiovascular problems, Stewart Resnick's own battle with multiple cancers, and a strong belief in the connection between good nutrition and health. (S. Resnick, Tr. 1853-55; CX1376 (S. Resnick, Ocean Spray Dep. at 30-31); (CX1360 (S. Resnick, Dep. at 84)).

Response to Finding No. 256:
Complaint Counsel has no specific response.

257. In 1998, Respondents and Dr. Leslie Dornfeld collaborated with Dr. Michael Aviram, the Head of the Technion Lipid Research Laboratory at the Rambam Medical Center in Haifa, Israel, known for his groundbreaking work exploring the antioxidant properties of red wine, to understand the antioxidant power and potential cardiovascular benefits of pomegranate 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).

Response to Finding No. 257:
Complaint Counsel has no specific response.

258. Dr. Aviram's initial research paper showed that pomegranate possessed remarkable anti-oxidative and anti-atherosclerotic properties. (CX1358 (Aviram, Dep. at 7); PX0004).

Response to Finding No. 258:

Complaint Counsel does not disagree that the proposed finding reflects Dr. Aviram's own testimony about his study, with the exception of the added word "remarkable," but disagrees with the conclusion drawn.

259. Based on this paper, Dr. Michael Aviram believed and represented to Stewart Resnick that the antioxidant properties found in the pomegranate were the most powerful he had ever researched. (CX1363 (S. Resnick, Coke Dep. at 66)).

Response to Finding No. 259:
The proposed finding is unsupported by the cited evidence. The cited deposition testimony does not establish what Dr. Aviram believed, but only what Mr. Resnick "[thought] he would say." In addition, the cited deposition testimony does not identify a specific paper by Dr. Aviram. Mr. Resnick testified that Dr. Aviram had "published some papers in different journals" and agreed that the finding was that the pomegranate had a great content of antioxidant qualities, not necessarily that it had "the most powerful" antioxidant properties. (*See* CX1363 (S. Resnick, Coke Dep. at 66)).

260. Despite the impressive findings and enthusiasm from Dr. Aviram, Respondents did not go public with these findings at that time. Respondents instead embarked on further research to see if there was any truth to these initial findings and the folklore surrounding the fruit's medicinal properties. (Ornish, Tr. 2325); (CX1360 (S. Resnick, Dep. at 84-85); PX1372 (S. Resnick, Tropicana Dep. at 32); (CX1376 (S. Resnick, Ocean Spray Dep. at 31-32)).

Response to Finding No. 260:
Complaint Counsel has no specific response.

261. Dr. Dornfeld initially oversaw the development of POM's research program until he was no longer able to do so for health-related reasons. (Liker, Tr. 1877).

Response to Finding No. 261:
Complaint Counsel does not disagree.

262. Dr. Dornfeld recruited Dr. Harley Liker to be his successor as POM's Medical Director. (S. Resnick, Tr. 1858).

Response to Finding No. 262:
Complaint Counsel has no specific response.

263. Dr. Liker is a practicing medical doctor and board certified medical internist with an extensive background in biomedical research and has authored published papers published in peer-reviewed journals. (Liker, Tr. 1873-75).

Response to Finding No. 263:
Complaint Counsel agrees that Dr. Liker is a practicing medical doctor and board certified medical internist, but notes that he has no licensed medical subspecialties. (Liker, Tr. 1910). Complaint Counsel further agrees that Dr. Liker has a background in biomedical research, but notes that to the extent Respondents characterize it as "extensive," Dr. Liker has coauthored just eleven peer-reviewed journal articles, four of which were POM studies. (Liker, Tr. 1929). He failed to disclose his affiliation with POM in these four articles even though his role as a coauthor was because of his work for POM, not as a UCLA researcher. (Liker, Tr. 1929-32).

264. Harley Liker has been a member of the faculty at UCLA School of Medicine since 1995 and was promoted to Associate Clinical Professor of Medicine in 2010. (Liker Tr. 1873; CX1350 (Liker Dep. at 15)).

Response to Finding No. 264:
Complaint Counsel does not disagree.

265. In 2001, Dr. Liker began working as POM's Medical Director. (Liker, Tr. 1876-77; CX1350 (Liker, Dep. at 27-28)).

Response to Finding No. 265:
Complaint Counsel does not disagree, except to note that according to the cited testimony, Dr. Liker began working with POM in 2001, but did not become its official medical director until 2002. (*See also* CCFF ¶ 161).

266. Part of his duties as POM's Medical Director is to assist Respondents' in the development of their research program by ensuring that Respondents use the best researchers and the science is conducted in a rigorous manner. (Liker, Tr. 1878-80; CX1350 (Liker, Dep. at 32-33)).

Response to Finding No. 266:
Complaint Counsel has no specific response.

267. After identifying the area of scientific interest, Dr. Liker determines the leading experts in that scientific field and reaches out to them to conduct the Respondents research. (Liker, Tr. 1878-80).

Response to Finding No. 267:
The proposed finding is incomplete, as it does not indicate, as reflected in the cited evidence, that Dr. Liker has worked with Mr. Tupper, Mr. Resnick, and POM's scientific director in performing these tasks. (*See* Liker, Tr. 1880).

268. In over span of a decade, Respondents sponsored over a hundred studies at forty-four different institutions. (Liker, Tr. 1887-88).

Response to Finding No. 268:
Complaint Counsel has no specific response, except to note that of the studies POM had conducted as of 2010, approximately 40 percent were performed at UCLA or by Dr. Aviram at the Technion Faculty of Medicine. (*See* CX1241; CX1360 (S. Resnick, Dep. at 113-17)).

269. More than seventy of the studies sponsored by the Respondents have been published in top peer-reviewed scientific journals. Seventeen of these published studies are human clinical trials. (Liker, Tr. 1888; PX0014; CX0908; PX0060; PX0061; PX0004; CX0611; PX0020; PX0021; PX0023; PX0073; PX0074; PX0075; PX0005; PX0127; PX0136; PX0139; PX0146; Trombold JR, Barnes JN, Critchley L, and Coyle EF, *Ellagitannin Consumption Improves Strength Recovery 2-3 d after Eccentric Exercise*, Med. Sci. Sports Exerc., Vol. 42, No. 3, pp. 493-498, 2010).

Response to Finding No. 269:
Complaint Counsel has no specific response, except to note that the tally of published studies is Dr. Liker's estimate, and the cited testimony does not characterize the peer-reviewed journals as "top" peer-reviewed journals. (*See* Liker, Tr. 1888).

B. POM's Continued Investment In Its Research Program

1. Purpose

270. Despite Respondents' belief that they have sufficient scientific substantiation for any health claims made in POM Wonderful's advertising, Respondents continue to sponsor medical research to uncover the full spectrum of benefits of their pomegranate products. (S. Resnick, Tr. 1752, 1861-63).

Response to Finding No. 270:
Complaint Counsel has no specific response.

271. The goal of the research program is to uncover the truth behind the health benefits of the pomegranate--not to make health benefit claims. (CX1363 (S. Resnick, Coke Dep. at 59); S. Resnick, Tr. 1752-53; CX1374 (Tupper, Ocean Spray Dep. at 87); Tupper, Tr. 3001; CX1360 (S. Resnick, Dep. at 145-46)).

Response to Finding No. 271:
The proposed finding is unsupported by the record as a whole. In notes on 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." (CCFF ¶ 159). More recently, POM's Medical Research Portfolio Review from 2009 contains numerous references to "[a]dditional, targeted research for Marketing / PR / Medical Outreach purposes, and "aggressively communicat[ing]" or "aggressively publiciz[ing] results." (CX1029). Indeed, Mrs. Resnick described POM's "unique selling proposition," which she defines as "what [it is] about your product or service that sets you apart from the competition," as "health in a bottle." (CCFF ¶¶ 281, 289). 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 [POM's] product than pomegranate juice in general . . . ." (CCFF ¶ 283). For example, POM communicates to consumers "its belief that pomegranate juice is beneficial in treating some causes of impotence, for the purpose of promoting sales of its product." (CCFF ¶ 284). In addition, Mr. Tupper testified that POM typically does not include links on its website to published studies on non-POM products. (CX1374 (Tupper, OS Dep. at 89)).

272. Stewart Resnick was more interested in understanding whether a benefit would be shown and how the product worked rather than whether or not the findings reached statistical

significance. (S. Resnick, Tr. 1859; Liker, Tr. 1881-84; CX1336 (Davidson, Dep. at 142)).

Response to Finding No. 272:
Complaint Counsel agrees Mr. Resnick testified as such, but notes that the citation to CX1336, Dr. Davidson's deposition, does not support the proposed finding. In addition, the scientific method requires statistical analyses to determine a benefit. (CCFF ¶ 778).

273. Respondent Stewart Resnick told the scientists that his primary interest in conducting the research is to establish the truth. (CX1358 (Aviram, Dep. at 74)).

Response to Finding No. 273:
The proposed finding mischaracterizes the cited evidence. Dr. Aviram testified that he heard Mr. Resnick express this, not necessarily that Mr. Resnick told other scientists this.

274. Respondents even chose to sponsor studies even when they were told by scientists that the study, for any number of reasons related to the study, will likely not show a health benefit from consuming pomegranate. (S. Resnick, Tr.1859).

Response to Finding No. 274:
The proposed finding is unsupported by the cited evidence.

275. They did so to uncover the truth; to see what might happen. (CX1363 (S. Resnick, Coke Dep. at 59); S. Resnick, Tr. 1752-53; CX1374 (Tupper, Ocean Spray Dep. at 87); Tupper, Tr. 3001; CX1360 (S. Resnick, Dep. at 145-46)).

Response to Finding No. 275:
Complaint Counsel does not disagree Respondents testified as such, but the "truth" in scientific research requires following the scientific method. (CCFF ¶¶ 762-83).

276. Respondents, for example, chose to use study designs, including the Davidson BART study, even when researchers suggested and communicated to Respondents that the study would likely not yield positive results. (CX1336 (Davidson Dep. at 142)).

Response to Finding No. 276:
The proposed finding is unsupported by the cited deposition testimony.

277. Respondents chose study designs after being told that that those designs would not yield positive results because Respondents' motivation was to uncover the truth and to see if real benefits exist—not to just use the studies in marketing. CX1363 (S. Resnick, Coke Dep. at 59); S. Resnick, Tr. 1752-53; CX1336 (Davidson Dep. at 142); CX1374 (Tupper, Ocean Spray Dep. at 87); Tupper, Tr. 3001; CX1360 (S. Resnick, Dep. at 145-46)).

Response to Finding No. 277:
See Responses to Findings 271 and 275.

278. Respondents have invested over $35 million dollars in their research program and continue to spend money to invest in further research. (S. Resnick, Tr. 1864; CX1363 (S. Resnick, Coke Dep. at 74; Tupper, Tr. 1015).

Response to Finding No. 278:
Complaint Counsel has no specific response.

279. Respondents believe that their scientific inquiries have gone far beyond the depth of research typically sponsored or conducted by other food and supplement companies. (CX1353 (Tupper, Dep. at 212-13; Tupper, Tr. 1014).

Response to Finding No. 279:
Complaint Counsel has no specific response.

280. Respondents have sponsored over a hundred studies at forty-four different institutions that have explored the effect of POM products on many different areas of health, including, the cardiovascular system, immunity, athletic performance, erectile health, prostate cancer, skin care, cognitive function, dental health, and urinary tract health. (CX1353 (Tupper, Dep. at 47-49); Tupper, Tr. 2979-81); Liker, Tr. 1887-88).

Response to Finding No. 280:
Complaint Counsel has no specific response, except to note that of the studies POM had conducted as of 2010, approximately 40 percent were performed at UCLA or by Dr. Aviram at the Technion Faculty of Medicine. (*See* CX1241; CX1360 (S. Resnick, Dep. at 113-17)).

281. Respondents' research efforts branch in various directions in order to examine the role that oxidation and inflammation play in many seemingly unrelated diseases and conditions. Over time, additional characteristics of the Challenged Products and its derivatives have come to light expanding both the scope of the company's research portfolio and the rationale that supports it. (CX1353 (Tupper, Dep. at 47-49); Tupper, Tr. 2979-81; Heber Tr. 1957, 2112-13, 2185).

Response to Finding No. 281:
Complaint Counsel has no specific response.

2. Depth of the Research Program

282. Anti-inflammation and anti-oxidative tendencies have beneficial implications for many different areas of human health, such as aging, cancer, heart disease, diabetes, and dementia. (Tupper, Tr. 2999; deKernion, Tr. 3046; Heber Tr. 1957, 2112-13, 2185).

Response to Finding No. 282:
Complaint Counsel agrees that the witnesses testified as such, but notes that these tendencies were evaluated in Respondents' human RCTs and failed to show any benefit. (CCFF ¶¶ 960-61, 1103-05).

283. Pomegranate polyphenols' anti-inflammatory and anti-oxidative properties are the connecting characteristics establishing the interrelationship between all of POM's science whether or not the results were positive or negative, published or unpublished. (Tupper, Tr. 3000-02).

Response to Finding No. 283:
See Response to Finding 282. (*See also* S. Resnick, Tr. 1711-12 ("in order to get sometimes good results, initially, you scatter gun, and there's a lot of areas that we thought that we would get results in and we didn't")).

284. POM has sponsored published research that has shown positive results, including, immunity, cognitive function, dental health, and urinary tract health. Yet, POM has chosen to not publicly discuss or make advertising claims in many of these areas until the science is sufficiently developed. (Tupper, Tr. 2979-81).

Response to Finding No. 284:
The proposed finding is unsupported by the record as a whole. For example, Mrs. Resnick testified in October 2010 that she would not feel comfortable and confident telling consumers in an ad today that POM Juice can help prevent Alzheimer's because she "[didn't] think [POM's] research is really exhaustive enough." (CX1375 (L. Resnick, Dep. at 102)). Yet, from at least 2003 through 2008, Respondents promoted the purported benefits of POM Juice for Alzheimer's in their print advertising and public relations efforts. (*See, e.g.*, CCFF ¶¶ 326, 341, 349, 542, 570). Furthermore, POM routinely advertises its research spending with claims that its products are "supported" or "backed" by tens of millions of dollars in medical and scientific research at the world's leading universities. (CCFF ¶ 309). However, regardless of whether studies are published or not published, have good results or bad results, or are incomplete, all are

nonetheless counted in the research-spending tallies POM touts in its advertisements. (*See* CCFF ¶¶ 320-24).

285. Respondents' do not advertise every newly discovered health benefit property without much deliberation and thought. (Tupper, Tr. 2979-81; S. Resnick, Tr. 1860).

Response to Finding No. 285:

The proposed finding is unsupported by the record as a whole. Respondents have at times pushed to advertise the purported health benefits of the POM Products even before research results were available. For example, on July 1, 2006, Mrs. Resnick emailed POM staff that "[t]here are stories [about the Pantuck Phase II Prostate Cancer Study on POM Juice] all over the internet this morning; sadly they don't mention [POM]. This is probably a lost opportunity." (CX0060_0001). Lamenting that "[b]y the time [POM had] juice in the market place it [would] be so late to promote the facts," Mrs. Resnick ordered, "GET THE STUDY COMPLETED WITH RATS AND POMX ASAP[.] I assume the human study with POMX [is] in the works, if it isn't I want a time table . . . when it will be and the end date. GET POMX LIQUID AND PILLS DONE. Please advise when you will have packaging and product available . . . start working on advertising immediately." (CX0060_0001). Nine days later POM announced in a press release, "POMx, a Highly Concentrated Form of Healthy Pomegranate Antioxidants, Becomes Available to Consumers for the First Time," and cited the Pantuck Phase II Prostate Cancer Study. (CX0065_0002; *see also* CCFF ¶¶ 556-62). Commenting on the press release, Ms. Posell wrote, "[w]e need news, and this press release had it!! I use the prostate cancer study [on POM Juice] to substantiate our statements about POMx." (CCFF ¶ 559). However, Ms. Glovsky testified that she believed the press release was "premature" because no POMx product was available for purchase yet. (CCFF ¶ 561).

286. Respondents hold themselves to a higher standard than their competitors when it comes to having enough information to make an advertising statement about the benefits of pomegranates. (S. Resnick, Tr. 1866).

Response to Finding No. 286:
Complaint Counsel has no specific response, except to note that the proposed finding reflects Mr. Resnick's opinion.

287. Respondents' competitors have advertised many more areas in which pomegranate juice provides a benefit. (S. Resnick, Tr. 1865-66).

Response to Finding No. 287:
Complaint Counsel has no specific response, except to note that the proposed finding reflects Mr. Resnick's opinion.

288. One of Respondents' competitors put out an advertisement with seventeen different benefits from pomegranate juice. (S. Resnick, Tr. 1866).

Response to Finding No. 288:
The proposed finding is unsupported by the cited testimony or by the record as a whole. This testimony was based on an exhibit that was not specifically identified at trial and is not in evidence, in violation of the Court's Order on Post-Trial Briefs.

289. Respondents advertise only about three of those seventeen benefits—heart, prostate, and erectile dysfunction. (S. Resnick, Tr. 1866).

Response to Finding No. 289:
Complaint Counsel has no specific response, except to note that the "seventeen benefits" were never identified for the record, and are unsupported by the record as a whole. *See* Response to Finding 288.

290. Respondents believe that those seventeen benefits exist but do not advertise all the other fourteen benefits because Respondents don't feel that it meets their degree of adequate scientific information. (S. Resnick, Tr. 1866).

Response to Finding No. 290:
Complaint Counsel has no specific response, except to note that the "seventeen benefits" were never identified for the record, and are unsupported by the record as a whole. *See* Response to Finding 288.

291. Stewart Resnick's stated policy on the relationship between scientific studies and POM's advertising requires that the advertisements accurately represent the scientific conclusions. (Tupper, Tr. 2979).

Response to Finding No. 291:
Complaint Counsel agrees that Mr. Tupper testified as such, but notes that Mr. Resnick testified that he does not write ads nor determine the studies that are advertised. (*See* S. Resnick, Tr. 1708-10).

292. POM includes in its advertising references to its science only if it is published clinical research involving human subjects. (PX1353 (Tupper, Dep. at 134)).

Response to Finding No. 292:
The proposed finding is unsupported by the record as a whole. POM routinely advertises its spending on scientific research with claims that its products are "supported" or "backed" by tens of millions of dollars in medical and scientific research at the world's leading universities. (CCFF ¶ 309). However, regardless of whether studies are published or not published, have good results or bad results, or are incomplete, all are nonetheless counted in the research-spending tallies POM touts in its advertisements. (*See* CCFF ¶¶ 320-24).

293. Respondents continue to conduct research in areas where they have already seen ongoing positive results. (Tupper, Tr. 984-85, 994; PX0023; PX0014; PX0060; PX0061).

Response to Finding No. 293:
Complaint Counsel disagrees to the extent that the proposed finding is intended to support the conclusion that the cited "ongoing positive results" were sufficient to substantiate Respondents' challenged advertising claims.

294. For example, POM currently has ongoing research in the areas of cardiovascular health and prostate health despite having previously sponsored human clinical research yielding positive results. (Tupper, Tr. 984-85, 994; PX0023; PX0014; PX0060; PX0061).

Response to Finding No. 294:
Complaint Counsel does not disagree that POM is conducting ongoing cardiovascular and prostate research, except to the extent that the proposed finding is intended to support

the conclusion that Respondents' human clinical research yielded positive results sufficient to substantiate Respondents' challenged advertising claims. As detailed in CCFF Section VII, Respondents' studies often suffered from design flaws or were preliminary in nature, and the studies that were well-designed and well-conducted, such as those by Davidson, did not produce positive results.

295. Respondents also have continued to conduct both basic research and animal studies in areas where the research has shown ongoing positive results in humans. (PX0009, PX0002, PX0125, PX0017, PX0010).

Response to Finding No. 295:
See Response to Finding 294.

3. Current Focus of the Research Program

296. Respondents are currently seeking botanical drug approval for POMx from the FDA under two different health indications. (Tupper, Tr. 3006-08).

Response to Finding No. 296:
Complaint Counsel has no specific response.

297. Respondents are seeking botanical drug approval not because they believe they ever advertised the POM products as drugs but in order to distinguish their products in the marketplace. (Tupper, Tr. 3006-08).

Response to Finding No. 297:
Complaint Counsel does not disagree Mr. Tupper testified as such, but notes that Respondents also are seeking drug approval because the IRBs of five research institutions believed the prostate cancer studies were intended to market POMx as a drug. (CCFF ¶¶ 686-93).

298. POM is not seeking botanical drug approval for POM Wonderful 100% juice from the FDA because the FDA has no provision or process to obtain drug approval for a juice. (Tupper, Tr. 3006).

Response to Finding No. 298:
Complaint Counsel does not disagree, except to note that Mr. Tupper testified as such and the correct citation is Tupper, Tr. 3007, and that Mr. Tupper acknowledged there is an

FDA process to seek FDA approval for a health claim regarding reduction of risk for a juice. (*See* CCFF ¶ 683).

299. 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).

Response to Finding No. 299:
Complaint Counsel has no specific response, except to note that the correct citation is Tupper, Tr. 3009-11.

300. One of these summaries entitled "Medical 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. David Kessler, and Dr. David Heber, and Mr. Resnick. (Tupper, Tr. 942, 939, 3008-09; CX1353 (Tupper, Dep. at 248-49); Dreher, Tr. 556).

Response to Finding No. 300:
Complaint Counsel has no specific response.

301. 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).

Response to Finding No. 301:
The proposed finding is unsupported by the cited evidence.

302. 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).

Response to Finding No. 302:
Complaint Counsel has no specific response.

303. 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).

Response to Finding No. 303:
Complaint Counsel has no specific response, except to note that the correct citation is Tupper, Tr. 3012-14.

304. 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)

Response to Finding No. 304:
The proposed finding mischaracterizes the cited testimony. The cited testimony pertains to prostate cancer prevention, not to all research in POM's Medical Research Portfolio Review. (Dreher, Tr. 564).

305. For example, POM assessed in the Medical Research Portfolio Review that the required action would be two studies with 1000 plus patients. (CX1029_0004).

Response to Finding No. 305:
Complaint Counsel does not disagree, except to note that this "required action" appears on the Medical Research Portfolio Review's "Prostate Cancer" page, in the "Botanical Drug (Pills only)[,] Prevent/Treat Prostate Cancer" section. (CX1029_0004).

306. This observation was made due to the fact that the FDA does not recognize PSA as a valid end point. (Dreher, Tr. 564).

Response to Finding No. 306:
The proposed finding mischaracterizes the cited testimony. In the cited testimony, Dr. Dreher did not connect this point with that in Finding 305, above.

307. 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 the candid assessment to establish the viability of obtaining FDA drug approval. (Tupper, Tr. 3014).

Response to Finding No. 307:
Complaint Counsel has no specific response.

308. Respondents do not believe this should be the legal standard their science should be held to in order to meet the FTC's substantiation requirements. Instead, Respondents contemplate that one day they could potentially seek FDA drug approval. (CX1265, CX1266, CX1268, CX1269, CX1270, CX1271, CX1272; Tupper, Tr. 3014).

Response to Finding No. 308:
The first sentence of the proposed finding is a legal conclusion, which is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. The second sentence of the proposed finding is incomplete, as Respondents have already filed

INDs, which are applications submitted to the FDA in the development cycle of a drug.

(*See* CCFF ¶¶ 693, 1033-34, 1099).

309. Respondents' standard in reviewing its science is, at times, even more severe than what is required for FDA drug approval. (PX0206 at 8-9).

Response to Finding No. 309:
The proposed finding is unsupported by the cited evidence. Dr. Miller's report does not address how Respondents review their own research.

310. For example, in some instances the FDA has not required one or more RCTs to approve a drug for use in clinical practice. (PX0206 at 8-9).

Response to Finding No. 310:
The proposed finding mischaracterizes the evidence. In fact, Dr. Miller testified that these were "randomized controlled trials," they just used the standard of care treatment as a control arm rather than a placebo control. (PX0354 (Miller, Dep. at 40)).

311. The FDA has also approved anticancer agents based on open-label randomized controlled trials without a placebo arm. (PX0206 at 8-9).

Response to Finding No. 311:
The proposed finding mischaracterizes the evidence. In fact, Dr. Miller testified that these were "randomized controlled trials," they just used the standard of care treatment as a control arm rather than a placebo control. (PX0354 (Miller, Dep. at 40)).

VI. POM'S METHODOLOGY IN SPONSORING STUDIES

A. Respondents' Diligent Effort to Ascertain the Truth

312. Respondents did not design its research solely to market the results but ultimately to understand how the consumption of pomegranate works in the human body. (CX1360 (S. Resnick, Dep. at 145-46); (Tupper, Tr. 3001).

Response to Finding No. 312:
Complaint Counsel disagrees to the extent that the proposed finding is intended to support the conclusion that the main purpose of Respondents' research was "ultimately to understand how the consumption of pomegranate works in the human body." As noted in

Response to Finding 271, since the company's early years, the first "direction" identified for POM's research program was "use in marketing." (*See* CCFF ¶ 159).

313. The goal of the research program is to uncover the truth behind the health benefits of the pomegranate and not to just market the results. (CX1363 (S. Resnick, Coke Dep. at 59); S. Resnick, Tr. 1752-53; CX1374 (Tupper, Ocean Spray Dep. at 87); Tupper, Tr. 3001; CX1360 (S. Resnick, Dep. at 145-46)).

Response to Finding No. 313:
See Response to Finding 312.

314. Respondents' diligent search for the truth about the medicinal and healing properties of pomegranates is evidenced by their insistence on the sponsorship of the very best research. (Liker, Tr. 1878-80, 1887-89; CX1350 (Liker, Dep. at 32-33); S. Resnick, Tr.1857, 1860-61).

Response to Finding No. 314:
Complaint Counsel has no specific response.

315. Respondents have sponsored studies designed with the highest level of scientific integrity, conducted by the best scientists at the best institutions in the world. (Liker, Tr. 1878-80, 1887-89; CX1350 (Liker, Dep. at 32-33); S. Resnick, Tr. 1857, 1860-61).

Response to Finding No. 315:
Complaint Counsel has no specific response.

316. To eliminate the potential for bias, POM Wonderful does not conduct its own medical research. CX1364 (Tupper, Coke Dep. at 55-56); CX1374 (Tupper, Ocean Spray Dep. at 14); CX1353 (Tupper, Dep. at 46); CX1363 (S. Resnick, Coke Dep. at 58-59)).

Response to Finding No. 316:
The proposed finding is unsupported by the record as a whole. Although POM does not directly conduct its own medical research, Respondents, and their consultants, have been heavily involved in the design and execution of studies. (*See* CCFF ¶¶ 30-32). As Respondents state in Findings 360 and 361, "[they] have made it clear that economics necessarily play a part in defining the parameters of the studies they sponsor" and "[f]or example, Respondent Stewart Resnick chose not to add more participants to Dr. Forest's erectile [dysfunction] study in order to power the study to reach statistical significance because doing so would cause Respondents to spend funds in excess of the study's

original budget." (*See* Respondents' Proposed Findings ¶¶ 360-61). In addition, Karen Edwards, a Roll employee, provided the study beverages and assisted the researchers in writing the journal article for the Forest Erectile Dysfunction Study, on which Dr. Liker was listed as a coauthor. (CCFF ¶ 106; CX0908).

317. Scientists conducting POM's research have not held any interest in Respondents' companies. (CX1364 (Tupper, Coke Dep. at 55-56); CX1374 (Tupper, Ocean Spray Dep. at 14); CX1353 (Tupper, Dep. at 46); CX1363 (S. Resnick, Coke Dep. at 58-59)).

Response to Finding No. 317:
The proposed finding is unsupported by the cited evidence. Mr. Resnick testified that no research was done by any entity in which *he* had an interest. (CX1363 (S. Resnick, TCCC Dep. at 58-59)).

318. Respondents, instead, chose to sponsor studies even when they were told by scientists that the study, for any number of reasons related to the study, will likely not show a health benefit from consuming pomegranate. (S. Resnick, Tr. 1859).

Response to Finding No. 318:
Complaint Counsel has no specific response.

319. Respondents, for example, chose to use study designs, including the Davidson BART study, even where researchers suggested and communicated to Respondents that the study would likely not yield positive results. (CX1336 (Davidson, Dep. at 142)).

Response to Finding No. 319:
The proposed finding is unsupported by the cited evidence.

320. Respondents chose study designs after being told that that those designs would not yield positive results because Respondents had faith those designs would show if a benefit existed. (CX1363 (S. Resnick, Coke Dep. at 59); S. Resnick, Tr. 1752-53; CX1336 (Davidson Dep. at 142); CX1374 (Tupper, Ocean Spray Dep. at 87); Tupper, Tr. 3001; CX1360 (S. Resnick, Dep. at 145-46)).

Response to Finding No. 320:
The proposed finding is unsupported by the cited evidence.

321. Respondents did not select studies merely because they thought it would obtain positive results or statistically significant results. (S. Resnick, Tr. 1859; Liker, Tr. 1881; CX1336 (Davidson, Dep. at 142)).

Response to Finding No. 321:

Complaint Counsel has no specific response. *See also* Responses to Findings 272 and 275.

322. For example, Dr. Liker and Dr. Forest advised Mr. Resnick that Dr. Forest's erectile function study was not sufficiently powered to yield statistically significant findings. (Liker, Tr. 1886-87).

Response to Finding No. 322:
Complaint Counsel does not disagree that the Forest/Padma-Nathan RCT Study was not sufficiently powered to yield statistically significant results, but the proposed finding is incorrect because Dr. Liker testified about a suggestion made by Dr. Padma-Nathan, not Mr. Forest. (Liker, Tr. 1886).

323. Mr. Resnick, because of cost, chose not to add more participants to Dr. Forest's study because he felt that the study as originally designed would sufficiently show whether or not there was a benefit to erectile function. (Liker, Tr. 1886-87; S. Resnick, Tr. 1716-18).

Response to Finding No. 323:
Complaint Counsel does not disagree that this was in part Mr. Resnick's testimony, but the proposed finding is incomplete because the Forest/Padma-Nathan RCT Study was a pilot study that was not sufficiently powered to achieve statistical significance. (CCFF ¶¶ 1064, 1071; CX1338 (Padma-Nathan, Dep. at 108-09)).

B. Respondents' Consultant Advisors

324. Respondents' approach in developing its research program was to listen to the advice of its scientific advisors and choose the studies that were more likely to show the real effects. (S. Resnick, Tr. 1859; Liker, Tr. 1881; CX1336 (Davidson, Dep. at 142)).

Response to Finding No. 324:
The proposed finding is unsupported by the cited evidence.

325. 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).

Response to Finding No. 325:

Complaint Counsel has no specific response, except to note that Respondents have nonetheless disregarded the advice of scientists in connection with the conduct of POM's research program. For example, despite Dr. Liker's and Dr. Padma-Nathan's advice to the contrary, Mr. Resnick chose not to add more participants to the Forest/Padma-Nathan RCT Study because doing so would cause Respondents to spend funds in excess of the study's original budget of $100,000 to $300,000. (Liker, Tr. 1886; CCFF ¶ 1063). *See also* Response to Finding 361.

326. Three groups of scientists advise Respondent Stewart Resnick about the findings and potential directions of POM's future research sponsorship—Respondents' internal scientific advisors, POM Research Summits, and POM's scientific advisory boards. (Liker, Tr. 1889-91).

Response to Finding No. 326:
Complaint Counsel agrees Dr. Liker testified as such, and notes he also testified that none of these scientists ever advised Respondents not to conduct human RCTs and none provided any advice on the types of claims Respondents could make to the public based on their research. (Liker, Tr. 1928-29).

327. Respondent Stewart Resnick had regular consultations with his scientific advisors, including Dr. Liker, Dr. David Heber, and Dr. Gillespie. (Liker, Tr. 1889-91; CX1374 (Tupper, Ocean Spray Dep. at 122); S. Resnick, Tr.1859).

Response to Finding No. 327:
Complaint Counsel has no specific response, except to note that Mr. Tupper would typically participate in these meetings. (*See* Liker, Tr. 1889; CX1349 (Gillespie, Dep. at 36)). *See also* Response to Finding 326.

328. Dr. Heber, Dr. Liker, and Dr. Gillespie helped oversee the progress and results of POM's research, and Dr. Liker and Dr. Gillespie, POM's head of science, informed Mr. Resnick of the status of the ongoing research. (Liker, Tr. 1889-91; CX1360 (S. Resnick Dep. at 32); CX1349 (Gillespie Dep. at 32-34, 36-37).

Response to Finding No. 328:
Complaint Counsel has no specific response.

C. POM Research Summits

329. Respondents hold periodic meetings, known as research summits, and invited distinguished scientists from institutions throughout the country to discuss the progress of the science and what additional studies should be undertaken. (Liker, Tr. 1890-92; Tupper, Tr. 1026-27; S. Resnick, Tr. 1858-59, 1872; CX1360 (S. Resnick, Dep. at 157-58)).

Response to Finding No. 329:
Complaint Counsel does not disagree. *See also* Response to Finding 326.

330. POM's research summits play a direct and integral part in both administering and developing POM's research program. (Liker, Tr. 1890-92; Tupper, Tr. 1026-27; S. Resnick, Tr. 1858-59, 1872; CX1360 (S. Resnick, Dep. at 157-58)).

Response to Finding No. 330:
Complaint Counsel has no specific response. *See also* Response to Finding 326.

331. At POM's research summits, the scientists conducting POM's research discuss the findings of their research and the potential areas of research that Respondents might consider. (Liker, Tr. 1890-91).

Response to Finding No. 331:
Complaint Counsel does not disagree. *See also* Response to Finding 326.

332. At the research summits, scientists are given an opportunity to present the findings of their research and to engage in a dialogue with Respondents guiding them as to the appropriate direction of future research. (Liker, Tr. 1890-92; Tupper, Tr. 1026-27; S. Resnick, Tr. 1858-59, 1872; CX1360 (S. Resnick, Dep. at 157-58)).

Response to Finding No. 332:
Complaint Counsel does not disagree. *See also* Response to Finding 326.

333. Participants and attendees of POM's research summits have included many esteemed and award winning scientists. (Liker, Tr. 1890-92; Tupper, Tr. 1026-27; S. Resnick, Tr. 1858-59, 1872; CX1360 (S. Resnick, Dep. at 157-58)).

Response to Finding No. 333:
Complaint Counsel has no specific response. *See also* Response to Finding 326.

334. Participants and attendees of POM's research summits have included Nobel Laureate Dr. Louis Ignarro, Dr. David Heber, Dr. Michael Carducci, and other scientists actively participating in POM's ongoing research. (Liker, Tr. 1890-92; Tupper, Tr. 1026-27; S. Resnick, Tr. 1858-59, 1872; CX1360 (S. Resnick, Dep. at 157-58)).

Response to Finding No. 334:
Complaint Counsel does not disagree. *See also* Response to Finding 326.

D. Respondents' Scientific Advisory Board

335. Respondent Stewart Resnick is also advised by members of POM's scientific advisory groups. (Liker, Tr. 1889-93).

Response to Finding No. 335:
Complaint Counsel does not disagree. *See also* Response to Finding 326.

336. Members of POM's scientific advisory boards are individuals who do not conduct the research for Respondents but who are experts in certain disease or health areas. (Liker, Tr. 1889-93).

Response to Finding No. 336:
The proposed finding is unsupported by the cited evidence. Dr. Liker testified that "*[o]ftentimes* the people that [POM] would ask to come to a scientific advisory board would be people that weren't actually working on research with us." (Liker, Tr. 1892 (emphasis added)). He also testified that, among others, Dr. Carducci from Johns Hopkins had been in the advisory group on prostate cancer. (Liker, Tr. 1892). Dr. Carducci has conducted POM-sponsored research looking at POMx use in men who have already been treated for prostate cancer ("Carducci Dose Study"). (*See* CCFF ¶¶ 1013-25).

337. Members of the advisory boards discuss the studies that are ongoing as well as those that have been completed. (S. Resnick, Tr. 1859).

Response to Finding No. 337:
Complaint Counsel does not disagree.

338. Members of the advisory board also discuss what additional studies should be done and make recommendations. (Liker, Tr. 1892-93).

Response to Finding No. 338:
Complaint Counsel does not disagree. *See also* Response to Finding 326.

339. POM's scientific advisory boards are divided by group, and there is a cardiovascular advisory group and a prostate advisory group. (Liker, Tr. 1892-93).

Response to Finding No. 339:

Complaint Counsel does not disagree, except to note that one of the groups is a prostate *cancer* advisory group. (Liker, Tr. 1892). *See also* Response to Finding 326.

340. Dr. Phillip Kantoff, Dr. David Kessler, and Dr. Carducci advise Respondents in the area of prostate cancer. (Liker, Tr. 1892-93).

Response to Finding No. 340:
Complaint Counsel does not disagree. *See also* Response to Finding 326.

341. Dr. Kantoff is employed at the Dana-Farber Cancer Institute at Harvard Medical School and runs the genitourinary oncology program. (Liker, Tr. 1892; Kantoff, Tr. 3257).

Response to Finding No. 341:
Complaint Counsel agrees.

342. Dr. David Kessler is the former head of the FDA. (S. Resnick, Tr. 1859, 1872).

Response to Finding No. 342:
Complaint Counsel agrees.

343. Dr. P.K. Shah, Dr. Gregg Fonarow, and Dr. Ben Ansell advise Respondents in the area of cardiovascular health. (Liker, Tr. 1892-93).

Response to Finding No. 343:
Complaint Counsel does not disagree.

344. Dr. Shah from Cedars-Sinai Medical Center is a world renowned cardiologist. (Liker, Tr. 1893).

Response to Finding No. 344:
Complaint Counsel has no specific response.

345. Dr. Fonarow runs the Congestive Heart Failure Program at UCLA. (CX1352 (Heber, Dep. at 236)).

Response to Finding No. 345:
Complaint Counsel has no specific response.

E. The Economic and Scientific Considerations of RCTs

1. The Limited Scientific Effectiveness of RCTs for Nutrients

346. Requiring Respondents to conduct two large RCTs to support the advertising claims is unreasonable because RCTs have limited effectiveness in testing the properties of a nutrient. (Sacks, Tr. 823; Ornish Tr.2327-29; PX0192-0022).

Response to Finding No. 346:

The proposed finding is unsupported by the cited evidence. At the pages cited, Dr. Sacks agreed that there can be feasibility issues (such as cost and difficulties in recruitment) when conducting RCTs for nutritional research, but he did *not* testify that RCTs have "limited effectiveness" in this area. (Sacks, Tr. 823). Similarly, Dr. Ornish stated that RCTs have their own set of limitations, citing an example where the control group was contaminated. However, rather than saying that RCTs are of limited effectiveness, Dr. Ornish called them a "powerful tool." (Ornish, Tr. 2327-29). The cited page of Dr. Heber's report, PX0192-022, did not address this issue at all.

347. RCTs are not as effective as in vitro and animal research in helping Respondents reach their goal of uncovering the truth as to the benefits of associated with pomegranates. (PX0192-0022; Sacks, Tr. 823; Ornish Tr.2327-29; (PX0361 (Sacks, Dep. at 89-91); Stampfer, Tr. 840).

Response to Finding No. 347:

The proposed finding is unsupported by the cited evidence. The cited testimony of Drs. Sacks and Stampfer discusses the purposes and value of *in vitro* and animal research, but it does not support the proposition that *in vitro* and animal research is superior to RCTs for the purpose of showing a health benefit in humans. The cited portions of Dr. Heber's report and Dr. Ornish's testimony do not discuss *in vitro* or animal research.

348. Professor Meir Stampfer testified and Respondents' expert Dr. Dean Ornish agreed that in a nutritional research context, there are specific and unique limitations in conducting RCTs. (Sacks, Tr. 823; Ornish Tr.2327-29).

Response to Finding No. 348:

The proposed finding is unsupported by the cited evidence. Dr. Sacks (whose testimony is cited, Sacks Tr. 823) agreed that there are feasibility limitations in conducting RCTs, but he did not state that they are specific or unique to nutrition research. Dr. Ornish noted that it is difficult to come up with a placebo treatment when conducting an RCT for a food or fruit, but with that exception, the difficulties with RCT conduct that he

discussed did not appear to be specific to nutrient research. (*See* Ornish, Tr. 2327-29). Further, in his own RCT studies for Respondents, Dr. Ornish used a placebo juice. (*See* CCFF ¶¶ 826, 855).

349. For example, unlike a drug, which can be identified and readily traced in the body, single nutrients enter the body and merge with others forming a milieu that does not lend itself to conclusive results in RCTs. (PX0192-0022; Sacks, Tr. 823; Ornish Tr. 2327-29).

Response to Finding No. 349:
The proposed finding is unsupported by the cited evidence.

350. Also, there is difficulty in designing a placebo that is sufficiently similar to the intervention. (Ornish Tr. 2328-29; PX0352 (Goldstein, Dep. at 84-85); PX0189-0003).

Response to Finding No. 350:
Complaint Counsel does not disagree that Dr. Ornish and Dr. Goldstein stated that it can be difficult to come up with a placebo treatment when conducting an RCT on a food product (Ornish, Tr. 2328; PX0352 (Goldstein, Dep. at 84-85)) but notes that this theoretical issue did not appear to pose a problem for Respondents, given that Dr. Ornish and Dr. Heber both conducted RCTs for Respondents, using placebo juices or placebo pills. (*See* CCFF ¶¶ 826, 855 (placebo juice); CCFF ¶ 930 (placebo capsules)). Complaint Counsel further notes that PX0189-0003 does not address this issue.

351. Further, Complaint Counsel's experts have testified in this case that, in some instances, animal and in vitro models are better suited to test a food or food derivative. (PX0361 (Sacks, Dep. at 89-91); Stampfer, Tr. 840).

Response to Finding No. 351:
The proposed finding is unsupported by the cited evidence insofar as it is intended to suggest that *in vitro* and animal research are sufficient to support efficacy claims for foods or food derivatives. Dr. Sacks stated at trial that *in vitro* and animal research provides useful information. (Sacks, Tr. 840). At his deposition, he stated that research starts with *in vitro* studies, to "isolate particular mechanisms," and that "animal studies are very useful. They isolate mechanisms. They're absolutely essential for safety

testing. So they have to proceed." (PX0361 (Sacks, Dep. at 89-90)). But Dr. Sacks also made clear that, if the findings in *in vitro* or animal studies are encouraging, the next step is to conduct a study in humans, and that when you study a product in a human "you'll get [the sum] total of all biological mechanisms that the food or nutrient activates or suppresses." (PX0361 (Sacks, Dep. at 90-91)).

352. For example, Dr. Frank Sacks and Professor Meir Stampfer conceded that animal studies may be more useful in safety testing than RCTs because it is easier to isolate mechanisms in highly controlled settings. (PX0361 (Sacks, Dep. at 89); Stampfer, Tr. 840).

Response to Finding No. 352:
See Response to Finding 351.

353. Complaint Counsel's experts have also testified that *in vitro* research, can more effectively than an RCT, isolate particular mechanisms or biological effects in highly controlled settings. (PX0361 (Sacks, Dep. at 90-91); Stampfer, Tr. 840).

Response to Finding No. 353:
See Response to Finding 351.

2. The High Cost of Conducting RCTs

354. Economics are a recognized factor to consider under *Pfizer et al*. *In re Pfizer, Inc.,* 81 F.T.C. 23, 30 (1972).

Response to Finding No. 354:
The proposed finding is a legal conclusion, which is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs.

355. It is the opinion of Dr. Denis Miller that the cost of the science is a factor to be considered in determining whether proper substantiation exists. (PX0206 at 7-8).

Response to Finding No. 355:
Complaint Counsel has no specific response.

356. It is an economically unreasonable requirement to hold Respondents to the same requirements that some drugs do not even meet. (PX0206 at 8-9).

Response to Finding No. 356:
The proposed finding is unsupported by the cited evidence.

357. The FDA, for example, has approved several anticancer agents without RCTs containing a placebo arm. (PX0206 at 8-9).

Response to Finding No. 357:
The proposed finding mischaracterizes the evidence. In fact, Dr. Miller testified that these were "randomized controlled trials," they just used the standard of care treatment as a control arm rather than a placebo control. (PX0354 (Miller, Dep. at 40)).

358. The FDA has also approved drugs for release under an accelerated program that have not been subject to RCTs. http://www.fda.gov/ForConsumers/ByAudience/ForPatientAdvocates/SpeedingAccesstoImportantNewTherapies/ucm128291.htm.

Response to Finding No. 358:
The cited hyperlink is not in the record, in violation of the Court's Order on Post-Trial Briefs.

359. Also, even in connection with drugs subjected to RCTs, many have been found to be dangerous or ineffective. (PX0377-001; PX0381).

Response to Finding No. 359:
The proposed finding is unsupported by the cited evidence. The cited documents only address two, not "many" drugs. Moreover, the characterization of these drugs as "dangerous or ineffective" is not supported by the cited documents. Complaint Counsel objects to PX0381 because the document was not produced during discovery in this matter. Complaint Counsel was therefore unable to question any witness as to the relevance of this exhibit to the issue of whether Respondents had sufficient substantiation for their claims, and to consider this exhibit now would be unduly prejudicial.

360. Respondents have made it clear that economics necessarily play a part in defining the parameters of the studies they sponsor. (Liker, Tr.1886-87; S. Resnick, Tr. 1716).

Response to Finding No. 360:
Complaint Counsel does not disagree.

361. For example, Respondent Stewart Resnick chose not to add more participants to Dr. Forest's erectile study in order to power the study to reach statistical significance because

doing so would cause Respondents to spend funds in excess of the study's original budget. (S. Resnick, Tr. 1716; Liker, Tr. 1886-87; CX0908).

Response to Finding No. 361:
Complaint Counsel has no specific response, except to note that Mr. Forest is not a doctor. (CX1337_0212).

362. Respondents also have adjusted protocols to keep the studies within budget. (CX1350 (Liker, Dep. at 37-38, 188-89)).

Response to Finding No. 362:
Complaint Counsel does not disagree.

363. Respondents also stated that they have not sponsored a 30-year RCT on prostate cancer and the consumption of pomegranate juice because it would be incredibly expensive. (S. Resnick, Tr. 1863-64).

Response to Finding No. 363:
Complaint Counsel does not disagree.

364. However, Respondents deny that any sacrifices to the studies' scientific integrity, soundness or reliability were made. Instead POM characterizes its economic decision as normal decisions necessary to moderate costs. (S. Resnick, Tr.1716-18; CX1360 (S. Resnick, Dep. at 228-29)).

Response to Finding No. 364:
The first sentence of the proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. The second sentence of the proposed finding is unsupported by the cited evidence.

365. Respondents' sponsorship of its scientific studies to obtain the information about the potential health benefits of their product has already cost Respondents $35 million. (S. Resnick, Tr. 1864; CX1363 (S. Resnick, Coke Dep. at 74; Tupper, Tr. 1015).

Response to Finding No. 365:
Complaint Counsel does not disagree that Mr. Resnick and Mr. Tupper testified as such, but notes that the cited dollar figure has not been corroborated by other evidence in the record.

366. RCTs are often very large, expensive studies costing hundreds of millions of dollars. (Heber, Tr. 1949).

Response to Finding No. 366:
Complaint Counsel does not disagree that Dr. Heber testified as such, but notes that RCTs may range substantially in cost. (Sacks, Tr. 1537). For example, the Davidson CIMT and BART/FMD studies, both well-designed, together cost less than $3 million. (CCFF ¶¶ 878, 903, 916).

367. Complaint Counsel's expert, Professor Meir Stampfer, characterized RCTs as a "huge expense" and stated that even the very simple ones are "very expensive". (Stampfer, Tr. 824-25).

Response to Finding No. 367:
Complaint Counsel has no specific response.

368. A single participant in an RCT can cost up to $10,000 per participant. (Liker, Tr. 1886-87).

Response to Finding No. 368:
Complaint Counsel has no specific response.

369. RCTs can cost anywhere from 6 million to 600 million dollars each. (Sacks, Tr.1537-38).

Response to Finding No. 369:
Complaint Counsel does not disagree to the extent that the cited range of $6 million to $600 million is a rough estimate. Complaint Counsel notes that well-designed RCTs may cost less than $6 million. For example, the Davidson CIMT and BART/FMD studies, both well-designed, together cost less than $3 million. (CCFF ¶¶ 878, 903, 916).

370. Dr. James Eastham testified that prevention studies should include ten to thirty thousand men, and that such studies are "incredibly expensive" and in the range of $600 million. (Eastham, Tr. 1322-28).

Response to Finding No. 370:
Complaint Counsel does not disagree, except to note that Dr. Eastham also testified that "cost shouldn't necessarily change the bar of the scientific effort." (Eastham, Tr. 1328-29).

371. Dr. Sacks testified in his deposition that it would be extremely costly to design a RCT study on cardiovascular disease because it would take years or decades to evaluate the effectiveness of an intervention. (PX0361 (Sacks, Dep. at 113)).

Response to Finding No. 371:
The proposed finding mischaracterizes the cited evidence. Though he agreed that RCTs on cardiovascular disease are expensive, Dr. Sacks questioned whether such studies would necessarily take many years to conduct. He noted that "[t]here are studies that can get a favorable result in a year and a half or [two] years." (PX0361 (Sacks, Dep. at 113); *see also* CCFF ¶ 784 (noting that, per Dr. Sacks' expert report, a study must be of sufficient duration)).

372. The well-known Women's Health Study cost $600 million and produced inconclusive results. (Heber, Tr. 1938; Ornish, Tr. 2329; CX1352 (Heber, Dep. 224)).

Response to Finding No. 372:
The proposed finding mischaracterizes the evidence to the extent that it is intended to support the conclusion that RCTs cost $600 million. RCTs may range substantially in cost. (Sacks, Tr. 1537). For example, the Davidson CIMT and BART/FMD studies, both well-designed, together cost less than $3 million. (CCFF ¶¶ 878, 903, 916). Complaint Counsel also notes that at trial, Drs. Ornish and Heber referred to the study cited in the proposed finding as the "Women's Health Initiative" study.

373. In the case of getting FDA approval of some drugs, companies have spent billions of dollars on research to get a new drug approved. (Ornish Tr. at 2324-25).

Response to Finding No. 373:
Complaint Counsel has no specific response, except to note that the proposed finding is based on Dr. Ornish's testimony alone and has not been corroborated by other evidence in the record.

374. Due to the "huge expense" of conducting an RCT, Professor Stampfer conceded that even governments and major institutions lack interest in conducting them. (Stampfer, Tr. 825).

Response to Finding No. 374:

The proposed finding mischaracterizes the cited testimony. Dr. Stampfer acknowledged that, because of the expense, even governments and major institutions *tend* to lack interest in funding randomized trials.

375. Further, unlike a drug, wherein the manufacturer receives patent protection and market exclusivity in return for cost intensive research, producers of natural food products, like Respondents, receive no comparable compensation for their investment. (Stampfer, Tr. 826-27).

Response to Finding No. 375:
The proposed finding mischaracterizes the cited testimony. Dr. Stampfer agreed that in dealing with nutrition, as opposed to pharmaceutical products, there usually is no intellectual property protection for these products, but his testimony did not specifically reference "patent protection and market exclusivity in return for cost intensive research."

376. And even if intellectual properties rights were available for POM juice, unlike some drugs which can drive a huge profit, Respondents sells its POM juice for only $4.00 to $5.00 on average. (Tupper, Tr. 982).

Response to Finding No. 376:
The proposed finding mischaracterizes the cited testimony. Mr. Tupper testified that POM Juice "sells for four or five dollars a bottle or a dollar a pill," but did not discuss intellectual property rights nor whether drugs can "drive a huge profit." (*See* Tupper, Tr. 982).

377. Notwithstanding this, POM has sponsored some RCT research. (PX0023; PX0014; PX0062; PX0064; CX0908).

Response to Finding No. 377:
Complaint Counsel does not disagree.

VII. RESPONDENTS' REASONED RELIANCE ON SCIENTISTS

378. Respondent Stewart Resnick relies heavily on the advice of scientists and scientific advisors in connection with the conduct of POM's research program. (S. Resnick, Tr. 1662, 1859; Liker, Tr. 1881; CX1336 (Davidson, Dep. at 142)).

Response to Finding No. 378:

The proposed finding is unsupported by the record as a whole. Although Mr. Resnick sought out advice from experts, he frequently ignored their counsel, as shown by their own proposed findings. (*See* Respondents' Findings of Fact 272, 274, 299, 301-302, 306, 318-323, 361-364, 591, 594, 595, 607, 1402-1405; *see also* CCFF ¶¶ 999-1000; 1015-18; 1033-34; 1044-54; 1096-1101).

379. Yet, importantly, though relying upon scientist in crafting their research program, Mr. Resnick and Respondents did so in a reasoned manner that underscored their responsibilities in disseminating truthful information regarding the health benefits of pomegranates. (CX1360 (S. Resnick, Dep. at 200-01, 1693); (Liker, Tr. 1903-04); PX0023; S. Resnick, Tr. 1693).

Response to Finding No. 379:
The proposed finding is unsupported by the cited evidence and record as a whole. The cited evidence has nothing to do with dissemination of advertising. In fact, Mr. Resnick testified that he had no interest in disseminating truthful information about the Davidson study in advertising. (*See* S. Resnick, Tr. 1707-10). Respondents' persistence in using the Challenged Claims after receiving warnings that the claims were deceptive also demonstrates their lack of regard for disseminating truthful information. (*See* CCFF ¶¶ 662-93, 817-21, 837-42, 867-68, 892-902, 950-73, 1044-45, 1119-30).

380. Respondents' approach in developing its research program was to listen to the advice of its scientific advisors and choose the studies that were more likely to show the real effects from the consumption of pomegranate juice, rather than to select studies likely to show a positive benefit. (S. Resnick, Tr. 1662, 1859; Liker, Tr. 1881; CX1336 (Davidson Dep. at 142)).

Response to Finding No. 380:
See Response to Finding 378.

381. Mr. Resnick told Dr. Michael Aviram that his primary interest in sponsoring research was to establish the truth. (CX1358 (Aviram, Dep. at 74)).

Response to Finding No. 381:
Complaint Counsel does not disagree Dr. Aviram testified as such, but notes that Dr. Aviram's testimony was in the context of explaining an email regarding publishing Dr.

Davidson's CIMT Study results. Dr. Aviram had told Dr. Dreher that "I think we should convince Stewart [Resnick] to agree to publish the Davidson research results . . ." and Dr. Dreher responded that "Stewart . . . has concerns that the contradictory results of this research between 12 vs 18 months might confound our previous CVD research." (CCFF ¶ 896).

382. Dr. Ornish also recalled meeting Stewart Resnick in the late 90's. Mr. Resnick indicated to Dr. Ornish that he had some early studies showing that pomegranate juice may be more beneficial than anybody realized, but rather than going public and marketing, he said that he wanted to fund research to see if it was true or not. (Ornish, Tr. 2325).

Response to Finding No. 382:
Complaint Counsel does not disagree Dr. Ornish testified as such.

383. Mr. Resnick depends on his experts and has no reason to believe they have told him anything but the truth. (S. Resnick, Tr. 1662).

Response to Finding No. 383:
Complaint Counsel does not disagree that Mr. Resnick sought the advice of experts in research, but notes he frequently ignored their counsel. *See* Response to Finding 378. In addition, Mr. Resnick did not get involved in advertising and what science was presented in the advertising. (S. Resnick, Tr. 1708-10).

384. Respondents held periodic meetings, known as research summits, and invited distinguished scientists from institutions throughout the country to discuss the progress of the science and what additional studies should be undertaken. (Liker, Tr. 1890-92; Tupper, Tr. 1026-27; S. Resnick, Tr. 1858-59, 1872; CX1360 (S. Resnick, Dep. at 157-58)).

Response to Finding No. 384:
Complaint Counsel does not disagree.

385. Respondent Stewart Resnick held meetings on specific health areas such as cardiovascular and prostate health, with noted experts in those fields to discuss what studies should be done, as well as to evaluate the results of the completed studies. (Liker, Tr. 1889-93).

Response to Finding No. 385:
Complaint Counsel does not disagree.

386. Respondents rely significantly upon scientists regarding the design of protocols, the meaning of the results of its sponsored studies, and the direction the research program should take. (Liker, Tr. 1894; (S. Resnick, Tr. 1732-33; CX1360 (S. Resnick, Dep. at 225-26); CX1376 (S. Resnick, Ocean Spray Dep. at 237-38; (CX1350 (Liker, Dep. at 186-87)).

Response to Finding No. 386:
Complaint Counsel does not disagree that Mr. Resnick sought the advice of experts but notes he frequently ignored their counsel. *See* Response to Finding 378.

387. Respondents' use of scientists to assist in structuring studies was absolutely appropriate if not critical to obtaining well-designed studies of significant scientific integrity. (Liker, Tr. 1894; (S. Resnick, Tr. 1732-33; CX1360 (S. Resnick, Dep. at 225-26); CX1376 (S. Resnick, Ocean Spray Dep. at 237-38; (CX1350 (Liker, Dep. at 186-87)).

Response to Finding No. 387:
Complaint Counsel has no specific response.

388. For example, the GAQ instrument was chosen and used as the primary measure in the Forest Padma-Nathan erectile study at Dr. Padma-Nathan's suggestion. (CX1350 (Liker, Dep. at 186-87)).

Response to Finding No. 388:
The proposed finding is based on hearsay that lacks satisfactory indicia of reliability pursuant to 16 C.F.R. § 3.43(b). The finding is not a statement by Dr. Padma-Nathan during a deposition, investigational hearing, prior testimony in Commission or other proceedings, or an expert report, and is instead testimony by Dr. Liker as to what he recalls Dr. Padma-Nathan said. Respondents chose not to call Dr. Padma-Nathan, who was on their Final Proposed Witness List and, therefore, reliance on this out of court statement is unfair. Furthermore, Dr. Padma-Nathan agreed the IIEF is usually the primary measure because it is more detailed than the GAQ and that the IIEF was added as a secondary measure because he "probably felt that the GAQ was insufficient . . . ." (CX1338 (Padma-Nathan Dep. at 92, 96)).

389. Mr. Resnick followed Dr. Michael Davidson's suggestion that a subgroup analysis and re-reading of the results take place to alleviate their confusion as to the results of his CIMT Study. (Liker, Tr. 1896-97).

Response to Finding No. 389:
The proposed finding mischaracterizes the testimony. Dr. Liker does not testify that Dr. Davidson suggested that re-reading be conducted. Rather, Dr. Liker testified that "we asked Dr. Davidson to . . . find an independent group to actually go back and . . . reread those images[.]" (Liker, Tr. 1894; CCFF ¶¶ 892-93). Although, Dr. Liker testified that Dr. Davidson suggested to try a subgroup analysis; however, Dr. Davidson also stated that "caution is warranted" with regard to the subgroup findings and "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. (Liker, Tr. 1897; CCFF ¶ 891).

390. Further, many different medical doctors assured Respondent Stewart Resnick that a placebo was not necessary and PSA doubling time was an acceptable endpoint in prostate cancer studies. (S. Resnick, Tr. 1732-33; CX1360 (S. Resnick, Dep. at 225-26); CX1376 (S. Resnick, Ocean Spray Dep. at 237-38)).

Response to Finding No. 390:
Complaint Counsel has no specific response except to note that 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 and that the lack of a placebo control group was a significant weakness in their prostate cancer studies. (*See* CCFF ¶¶ 995-96, 1014-16, 1044-54). Moreover, Dr. Liker testified that none of the scientists ever advised Respondents not to conduct RCTs. (Liker, Tr. at 1928-29).

A. Reliance Upon the Peer-Review Process

391. Respondents also relied, in part, on the peer-review process and the publication in peer-reviewed journals as an indication that the sponsored science was both good 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.").

Response to Finding No. 391:
Complaint Counsel has no specific response except to note that peer-review does not change the fact that Respondents' research fails to substantiate the Challenged Claims. (*See* CCFF Section VII). In addition, the Ornish MP study was published despite being rejected in the peer review process. (*See* CCFF ¶¶ 840-42). *See also* Response to Finding 392.

392. For example, when Respondents could not figure out the different results at twelve and eighteen months in the Davidson CIMT study, Respondents decided to turn the findings over to the peer-review process to decide whether or not the results were worthy of publication. (Liker, Tr. 1899-1900).

Response to Finding No. 392:
Complaint counsel does not disagree that Liker stated as such but disagrees with the conclusion. Respondents waited two and a half years before Mr. Resnick agreed to let the Davidson CIMT study be submitted for publication. (*See* CCFF ¶¶ 894-99). In addition, Respondents did NOT submit several well-done human RCTs for publication, including the Ornish cardiac arm of the MP study (CCFF ¶ 825) and the Ornish CIMT study (CCFF ¶¶ 857, 862-68), the Heber San Diego antioxidant level study (CCFF ¶¶ 633-38), the Davidson BART study (CCFF ¶¶ 913-14), and the Heber/Hill Diabetes Studies (CCFF ¶¶ 948-49), all of which showed negative results relating to heart disease.

393. More than seventy of the studies sponsored by the Respondents have been published in peer-reviewed journals. (Liker, Tr. 1888) .

Response to Finding No. 393:
See Responses to Findings 391 and 392.

394. At the very least, the publication in Respondents' research studies in peer-review journal is some evidence that the scientists vetting the research considered the studies important enough to publish. (Liker, Tr. 1899-1900; CX1352 (Heber Dep. at 199-200; *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.").

Response to Finding No. 394:

See Responses to Findings 391 and 392.

B. Reliance Upon Doctors' Statements

395. Respondents reasonably relied, in part, upon statements by scientists that the findings in the research were dramatic and impressive. (CX1363 (S. Resnick, Coke Dep. at 57-58, 66, 77-78); S. Resnick, Tr. 1662, 1734, 1736; CX1372 (S. Resnick, Tropicana Dep. at 44); PX0484; CX0004_0012; (CX1376 (S. Resnick, Ocean Spray Dep. at 31-32, 289)).

Response to Finding No. 395:
The proposed finding is unsupported by any reliable evidence. The cited evidence is self-serving statements by Mr. Resnick. Respondents had many of its researchers on its final witness list and chose not to have them testify about any such statements to respondents.

1. Statements about Cardiovascular Research

396. After reviewing the findings of his initial antioxidant research, Dr. Michael Aviram represented to Stewart Resnick that the antioxidant properties found in the pomegranate were the most powerful he had ever researched. (CX1363 (S. Resnick, Coke Dep. at 57, 66)).

Response to Finding No. 396:
The proposed finding is unsupported by the cited evidence. The cited deposition testimony does not establish what Dr. Aviram believed, but only what Mr. Resnick "[thought] he would say." In addition, the cited deposition testimony does not identify a specific paper by Dr. Aviram. Mr. Resnick testified that Dr. Aviram had "published some papers in different journals" and agreed that "the finding was that the pomegranate had a great content of antioxidant qualities," not necessarily that it had "the most powerful" antioxidant properties. (CX1363 (S. Resnick, Coke Dep. at 66)).

397. Dr. Davidson conveyed to Respondents and Dr. Liker that he was extremely enthusiastic about the results of his CIMT study and wanted the study published. (Liker, Tr. 1896; CX1350 (Liker, Dep. at 151)).

Response to Finding No. 397:
Complaint Counsel does not disagree Dr. Liker testified as such, but notes that, Respondents themselves concluded that the Davidson CIMT Study showed "no change"

in the overall population and that the CIMT results in the "hi-risk" category was only a 2-5% decrease. (CCFF ¶¶ 891, 902). Respondents were aware of the inadequacies of the heart disease research. Respondents' documents show that they knew they did not have enough science to make a treat, prevent, or reduce the risk of heart disease claims. (CCFF ¶¶ 966-73). POM's summary assessment noted that is 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; CCFF ¶¶ 966-73).

398. In an August 2008 email, Dr. Michael Aviram sent to Respondents Stewart and Lynda Resnick and Matt Tupper the statement "The use of Anti-oxidants, and Anti-inflammatory agents (POM WONDERFUL), could be of major importance in the protection against the other 70% cardiovascular events." (PX0476).

Response to Finding No. 398:
Complaint Counsel has no specific response.

399. When asked by Respondent Lynda Resnick what the findings of his recent publication were, Dr. Aviram stated in a January 2008 email that pomegranate juice and POMx were "very potent protectors against cardiovascular diseases." (PX0479-0001).

Response to Finding No. 399:
Complaint Counsel does not disagree the email states as such, but Complaint Counsel disagrees with the conclusion drawn. 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 matter as POM Juice. (CCFF ¶ 965). 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[.])" (CCFF ¶¶ 395, 792).

400. Dr. Ornish, in an email to Respondent Stewart Resnick and cc'ing Respondent Matt Tupper, announced the acceptance of his myocardial perfusion study. He stated, "As you know, this study showed, for the first time, that the progression of coronary heart disease may be reversed by drinking pomegranate juice as evidenced by improved blood flow to the heart measured by thallium scans." (PX0485-0001).

Response to Finding No. 400:
Complaint Counsel does not disagree the email states as such.

401. Dr. Aviram provided Respondents with a written statement that his research was the first to show that POMx polyphenols had similar cardio protective effects to those of pomegranate juice polyphenols in the reduction of atherosclerotic risks and promoting cardiovascular health. (PX0500-0003).

Response to Finding No. 401:
Complaint Counsel does not disagree that Dr. Aviram provided statements such as this as an expert endorser for Respondents' marketing and advertising materials of POM Products. (CCFF ¶¶ 791-92).

402. Dr. Aviram provided his opinion to Respondents that POMx "indeed promotes cardiovascular health." (PX0500-0003).

Response to Finding No. 402:
See Response to Finding 401.

403. Dr. Dean Ornish characterized the health benefits of pomegranate juice as "extraordinary." (PX0511).

Response to Finding No. 403:
Complaint Counsel does not disagree that Dr. Ornish provided this statement to be used in an article for Women's World magazine about his Ornish MP Study. (PX0511). Dr. Ornish provided similar statements for Respondents' press materials for POM Products. (CCFF ¶¶ 549-55).

404. Many of the doctors and cardiovascular researchers who were deposed in this case made statements supporting their research having shown a benefit from consuming pomegranate juice. (CX1350 (Liker, Dep. at 222); CX1358 (Aviram, Dep. at 6).

Response to Finding No. 404:
Complaint Counsel disagrees with the conclusion drawn. The cited evidence does not establish that "many doctors and cardiovascular researchers who were deposed in this case" agreed with the proposed finding. Moreover, Dr. Liker and Dr. Aviram were not experts in this matter and did not review or offer opinions on the Respondents' research

on POM Products and their effects on heart-related endpoints. (*See* CCFF ¶¶ 950-65, 1102).

405. For example, Dr. Michael Aviram stated that he is a great believer in pomegranate juice as an anti-atherosclerotic, and he believes that doctors and the public should be informed about those benefits. (CX1358 (Aviram, Dep. 48-49).

Response to Finding No. 405:
The proposed finding is incomplete. Complaint Counsel does not disagree Dr. Aviram testified as such, but notes that the cited evidence also shows that Dr. Aviram testified that, with regard to POMx, "unlike PJ, we know very little on it form a mechanistic point of view" and that he is not confident that POMx will work in the same matter as POM Juice. (CX1358 (Aviram, Dep. at 48); CCFF ¶ 965). Complaint Counsel disagrees with the conclusion drawn about the anti-atherosclerotic benefits of the POM products; Respondents were aware of the inadequacies of the heart disease research and their documents show that they knew they did not have enough science to make a treat, prevent, or reduce the risk of heart disease claims. (CCFF ¶¶ 966-73).

406. Based upon Dr. Aviram's research, Dr. Liker stated in his deposition that he believes that drinking POM Wonderful juice lowers other risk factors for heart disease. (CX1350 (Liker, Dep. at 221-22)).

Response to Finding No. 406:
Complaint Counsel does not disagree Dr. Liker testified as such with regard to a "POM Wonderful production shoot, March 23, 2004," (CX1350 (Liker, Dep. at 220). Complaint Counsel disagrees with the conclusion drawn about the heart disease benefits from the POM Products. Respondents were aware of the inadequacies of the heart disease research, and their documents show that they knew they did not have enough science to make a treat, prevent, or reduce the risk of heart disease claims, including claims about lowering blood pressure. (CCFF ¶¶ 966-73). POM's summary assessment 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; CCFF ¶¶ 966-973).

407. Based upon Dr. Aviram's research, Dr. Liker stated in deposition that he believes that "One glass a day has been shown to drastically reduce heart artery plaque" is an accurate statement. (CX1350 (Liker, Dep. at 221-22)).

Response to Finding No. 407:
See Response to Finding 406.

408. In deposition, Dr. Michael Aviram stated that after a year of studying the consumption of pomegranate juice, he concluded that pomegranate juice had greater antioxidant potencies than red wine. (CX1358 (Aviram, Dep. at 6)).

Response to Finding No. 408:
Complaint Counsel does not disagree Dr. Aviram testified as such.

409. Dr. Michael Davidson told Mr. Resnick and Dr. Liker that he believed the data from his CIMT study shows a signal of a benefit in the subgroup and should be presented. (CX1336 (Davidson, Dep. at 182-83).

Response to Finding No. 409:
The proposed finding is incomplete. Dr. Davidson also testified that he expressed that this was an "overall neutral study." (CX1336 (Davidson, Dep. at 183)). Dr. Davidson provided the Respondents with the final CIMT study results in February 2006, which showed that CIMT results were not statistically significant at 18 months. (CCFF ¶ 892).

410. The cardiovascular researchers have not only made statements to Respondents about their belief in the benefits of pomegranates but have also made public statements to reputable newspapers to that same effect. (PX0423-0001).

Response to Finding No. 410:
The proposed finding is unsupported by the cited evidence. The cited article only quotes one cardiovascular researcher, Dr. Davidson. Moreover, the cited evidence does not support the proposed finding about what statements cardiovascular researchers have made to Respondents.

411. For example, Dr. Michael Davidson was quoted in a 2004 article in the Chicago Tribune stating, "It is the concentration of polyphenols that appear to make [pomegranate juice] the most potent antioxidant in nature." (PX0423-0001).

Response to Finding No. 411:
Complaint Counsel does not disagree that the document states as such. *See also* Response to Finding 410.

412. After conducting research, some of the cardiovascular researchers began recommending POM products to their patients because of the benefits shown in the research. (CX1336 (Davidson, Dep. at 225-26)).

Response to Finding No. 412:
The proposed finding that "some of the cardiovascular researchers began recommending POM" is unsupported by the cited evidence. Dr. Davidson testified that he has only "recommended it to patients, . . . who fit [the subgroup] type of profile in my practice." (CX1336 (Davidson, Dep. at 225)).

413. For example, Dr. Davidson stated in deposition that his data supports a possible cardiovascular health benefit from the consumption of pomegranate juice, and he has recommended pomegranate juice or POMx to some of his patients. (CX1336 (Davidson, Dep. at 225-26)).

Response to Finding No. 413:
See Response to Finding 412.

414. POM's cardiovascular advisory panel, who advise Mr. Resnick, also believed that cardiovascular benefits have been shown by the research. (CX1336 (Davidson, Dep. at 224)).

Response to Finding No. 414:
The proposed finding is unsupported by the cited evidence. Rather, Dr. Davidson testified that the advisory board "believed it was a . . . true *signal* of benefit in that subgroup [of the Davidson CIMT Study] . . . *they're always hypothesis-generating*, . . . the belief among the panel members was that . . . the data was convincing that this was a true *signal* that would be supported in a *future trial."* (CX1336 (Davidson, Dep. at 224) (emphasis added); *see also* CCFF ¶ 900 (the probability of successfully testing for this benefit was 20-80%)).

415. For example, Dr. Davidson recalled that members of POM's cardiovascular advisory panel believed that the findings in his CIMT trial were a real, true signal of a benefit in the subgroup. (CX1336 (Davidson, Dep. at 224)).

Response to Finding No. 415:
Complaint Counsel does not disagree Dr. Davidson testified as such. *See* Response to Finding 414.

2. Statements about Prostate Health Research

416. Some of the doctors who researched the prostate benefits from consuming the Challenged Products have also made statements about their own belief that a benefit to the prostate was shown. (CX1350 (Liker, Dep. at 174-75); S. Resnick, Tr. 1734, 1736).

Response to Finding No. 416:
The proposed finding is unsupported and Complaint Counsel disagrees with the conclusion drawn. When asked which scientists conveyed this view, Dr. Liker only identified Dr. Heber. (CX1350 (Liker, Dep. at 174). The cited testimony by Mr. Resnick does not support the proposed finding. (S. Resnick, Tr. 1734, 1736).

417. At trial, Stewart Resnick recalled that doctors reviewing the results of basic and animal studies done on prostate health told him that the results were the best they had ever seen. (S. Resnick, Tr. 1734, 1736).

Response to Finding No. 417:
The proposed finding mischaracterizes Mr. Resnick's testimony in that he testified as follows: "[O]ne of the doctors who worked on the in vitro . . . came to me and said 'We should do this in humans. This is the best result I've ever seen. There is nothing that has had this effect.'" (S. Resnick, Tr. 1734).

418. Dr. Harley Liker told Respondents that Pantuck's Phase II study proves that pomegranate juice slows down the progression PSA. (CX1350 (Liker, Dep. at 174-75)).

Response to Finding No. 418:
The proposed finding mischaracterizes Dr. Liker's testimony in that he did not state that he told Respondents that Pantuck's Phase II study proves that pomegranate juice slows down the progression of PSA.

419. In a January 2007 email, Dr. Heber stated to Mark Dreher, "The prolongation of PSA doubling time is considered clinically significant by urologists and is being confirmed in large multicenter trials." (PX0494).

Response to Finding No. 419:
Complaint Counsel has no specific response except to note that Dr. Heber is neither a urologist nor an expert in the clinical treatment of prostate cancer (CCFF ¶¶ 1008, 1043), and he repeated this statement as an expert endorser in a video on Respondents' POM Wonderful website (CCFF ¶ 476).

420. In deposition, Dr. Liker recalled that Dr. David Heber has shared his view that POM products could contribute to the prevention of prostate cancer. (CX1350 (Liker, Dep. at 174)).

Response to Finding No. 420:
Complaint Counsel has no specific response except to note that Dr. Heber is neither a urologist nor an expert in the clinical treatment of prostate cancer (CCFF ¶¶ 728, 1008, 1043), and that he shared this view as an expert endorser for Respondents' advertising. (*See, e.g.,* CCFF ¶ 476).

421. Like the cardiovascular researchers, the prostate health researchers also made statements in their depositions supporting the research and the conclusion that some benefit to prostate health exists. (CX1341 (Pantuck Dep. at 108, 254-55, 264)).

Response to Finding No. 421:
Complaint Counsel has no specific response except to note that Drs. Pantuck and Carducci did not testify that their studies demonstrated that the POM Products treats, prevents, or reduces the risk of prostate cancer. (*See* CCFF ¶¶ 1000, 1018).

422. For example, Dr. Pantuck, in deposition, stood behind the results of his research and selection of endpoints. (CX1341 (Pantuck Dep. at 108, 254-55).

Response to Finding No. 422:
Complaint Counsel has no specific response except to note that Dr. Pantuck refused to testify that his study demonstrated that POM Juice treated prostate cancer. In addition,

Dr. Pantuck testified that his study did not prove that POM Juice prevented or reduced the risk of prostate cancer. (*See* CCFF ¶ 1000).

423. In his deposition, 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)).

Response to Finding No. 423:
Complaint Counsel has no specific response except to note that Dr. Pantuck refused to testify that his study demonstrated that POM Juice treated prostate cancer. In addition, Dr. Pantuck testified that his study did not prove that POM Juice prevented or reduced the risk of prostate cancer. (*See* CCFF ¶ 1000).

424. In his deposition, 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 254-55)).

Response to Finding No. 424:
The proposed finding is incomplete in that Dr. Pantuck also testified 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." (CX1341 (Pantuck, Dep. at 255)).

425. Dr. Pantuck stated in his deposition that from a patient care standpoint PSA doubling time is extremely important. (CX1341 (Pantuck Dep. at 255)).

Response to Finding No. 425:
The proposed finding is incomplete in that Dr. Pantuck also testified 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." (CX1341 (Pantuck, Dep. at 255)).

426. Dr. Pantuck also stated in his deposition that he consumes POM Wonderful pomegranate juice a few times a week. (CX1341 (Pantuck, Dep. at 264)).

Response to Finding No. 426:
Complaint Counsel has no specific response.

427. Like the cardiovascular researchers, the researchers looking at prostate health benefits have also made public remarks that the research shows a benefit. (PX0428-0001).

Response to Finding No. 427:
Complaint Counsel has no specific response.

428. For example, Dr. Pantuck has publicly made positive remarks about the findings in his research done for Respondents. (PX0428-0001).

Response to Finding No. 428:
Complaint Counsel has no specific response.

429. 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 270-71)).

Response to Finding No. 429:
Complaint Counsel has no specific response except to note that Dr. Pantuck also stated:

"This is not a cure, but we may be able to change the way prostate cancer grows."

(CX1341 (Pantuck, Dep. at 118)).

430. Like some of the cardiovascular researchers, the researchers looking at prostate health discuss the findings of their results with their patients. (CX1341 (Pantuck, Dep. at 270-71)).

Response to Finding No. 430:
Complaint Counsel has no specific response.

431. For example, Dr. Pantuck discusses the benefits of pomegranate juice with his patients. (CX1341 (Pantuck, Dep. at 270-71)).

Response to Finding No. 431:
The proposed finding is incomplete in that Dr. Pantuck testified that it is reasonable to discuss POM 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. (*See* CCFF ¶ 1040).

3. Statements about Erectile Health Research

432. Scientists have also represented to Respondents and to Complaint Counsel in deposition that a benefit to erectile health exists. (CX1363 (S. Resnick, Coke Dep. at 77-78); CX1372 (S. Resnick, Tropicana Dep. at 44); PX0484; CX1350 (Liker, Dep. at 190-91)).

Response to Finding No. 432:
The proposed finding is based on hearsay that lacks satisfactory indicia of reliability pursuant to 16 C.F.R. § 3.43(b). The finding is not a statement by Dr. Ignarro, Dr. Padma-Nathan, or Mr. Forest during a deposition, investigational hearing, prior testimony in Commission or other proceedings, or an expert report, and is instead testimony by Dr. Liker and Mr. Resnick as to what they recall Dr. Ignarro, Dr. Padma-Nathan, or Mr. Forest said. Respondents chose not to call Dr. Ignarro, Dr. Padma-Nathan, or Mr. Forest, who were on their Final Proposed Witness List and, therefore, reliance on these out of court statements is unfair. Furthermore, the proposed finding is incomplete because the Forest/Padma-Nathan RCT Study stated that "[f]urther studies are warranted to clarify the efficacy and clinical role of POM [Juice] on male ED." (CCFF ¶ 1074). Dr. Padma-Nathan and Mr. Forest testified that their study did not conclude that pomegranate juice treats, prevents, or reduces the risk of erectile dysfunction. (CCFF ¶ 1074).

433. Nobel Laureate Louis Ignarro represented to Stewart Resnick that he strongly believes pomegranate juice was 40% as effective as Viagra in helping with erectile dysfunction. (CX1363 (S. Resnick, Coke Dep. at 77-78); CX1372 (S. Resnick, Tropicana Dep. at 44)).

Response to Finding No. 433:
The proposed finding is based on hearsay that lacks satisfactory indicia of reliability pursuant to 16 C.F.R. § 3.43(b). The finding is not a statement by Dr. Ignarro during a deposition, investigational hearing, prior testimony in Commission or other proceedings, or an expert report, and is instead testimony by Mr. Resnick as to what he recalls Dr.

Ignarro said. Respondents chose not to call Dr. Ignarro, who was on their Final Proposed Witness List and, therefore, reliance on this out of court statement is unfair.

434. Louis Ignarro also told Respondents, "Based on studies conducted in my laboratory, pomegranate juice was 20 times better than any other fruit juice at increasing nitric oxide. It's astonishing – I've been working in this field for 20 years and I have never seen anything like it. I drink it 3 times a day without fail." (PX0484).

Response to Finding No. 434:
Complaint Counsel disagrees with the proposed finding's characterization that Dr. Ignarro "told" Respondents. The citation is a quote in an email from Dr. Ignarro's assistant for use in POM marketing.

435. Dr. Liker, in his deposition, stated that he, Dr. Padma-Nathan, and Mr. Forest concluded that the Forest Padma-Nathan erectile study showed a clinically significant benefit to erectile health. (CX1350 (Liker, Dep. at 190-91)).

Response to Finding No. 435:
The proposed finding is based on hearsay that lacks satisfactory indicia of reliability pursuant to 16 C.F.R. § 3.43(b). The finding is not a statement by Dr. Padma-Nathan or Mr. Forest during a deposition, investigational hearing, prior testimony in Commission or other proceedings, or an expert report, and is instead testimony by Dr. Liker as to what he recalls Dr. Padma-Nathan or Mr. Forest said. Respondents chose not to call Dr. Padma-Nathan or Mr. Forest, who were on their Final Proposed Witness List and, therefore, reliance on these out of court statements is unfair. Furthermore, the proposed finding is incomplete because the Forest/Padma-Nathan RCT Study stated that "[f]urther studies are warranted to clarify the efficacy and clinical role of POM [Juice] on male ED." (CCFF ¶ 1074). Dr. Padma-Nathan and Mr. Forest testified that their study did not conclude that pomegranate juice treats, prevents, or reduces the risk of erectile dysfunction. (CCFF ¶ 1074).

C. Respondents' Insistence on Scientific Rigor and Integrity

436. Notwithstanding the enthusiasm for the research by the scientists, Stewart Resnick double-checks both positive and negative results. (CX1360 (S. Resnick, Dep. at 200-01); (Liker, Tr. 1903-04); Liker, Tr. 1903; (S. Resnick, Tr. 1693; Liker, Tr. 1904; PX0023).

Response to Finding No. 436:
Complaint Counsel does not disagree that Dr. Liker and Mr. Resnick testified as such.

437. Respondents independently verify research results to ensure the information is accurate before it was published or placed in the public realm. (CX1360 (S. Resnick, Dep. at 200-01); Liker, Tr. 1903-04).

Response to Finding No. 437:
Complaint Counsel does not disagree that Dr. Liker and Mr. Resnick testified as such.

438. For example, Respondents delayed the publication of Dr. Aviram's study that showed an amazing 30% reduction of arterial plaque in order to have the data re-read to ensure Dr. Aviram's conveyed a correct interpretation of the results. (Liker, Tr. 1903).

Response to Finding No. 438:
Complaint Counsel does not disagree that Dr. Liker testified as such.

439. Respondents also delayed the publication of Dr. Ornish's study on myocardial perfusion, which showed a statistically significant benefit, so that an independent party could double-check the results. (S. Resnick, Tr. 1693; Liker, Tr. 1904; PX0023).

Response to Finding No. 439:
Complaint Counsel agrees that Dr. Liker and Mr. Resnick so testified, but refers to CCFF

¶¶ 822-53 with regard to the proper interpretation and reliability of those study results.

D. POM's Policy with Regard to Publishing the Research

440. Complaint Counsel have produced no evidence that the delay in the publication of the Davidson CIMT study was nefarious or motivated by a desire to hide the results. In fact, the evidence shows the exact opposite. (Liker, Tr. 1903); CX1372 (S. Resnick, Tropicana Dep. at 33); CX1360 (S. Resnick, Dep. at 75); CX1358 (Aviram Dep. at 76); CX1336 (Davidson, Dep. at 230)).

Response to Finding No. 440:
The proposed finding mischaracterizes the evidence. (*See* CCFF ¶¶ 892-98 (describing

Respondents' reaction and conduct after receiving Davidson results)).

441. Respondent Stewart 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)).

Response to Finding No. 441:
Complaint Counsel does not disagree that Mr. Resnick testified as such, but his testimony is unsupported by the record as a whole. *See* Response to Finding 392.

442. Respondent Stewart 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)).

Response to Finding No. 442:
Complaint Counsel does not disagree that those witnesses testified as such, but their testimony is unsupported by the record as a whole. *See* Response to Finding 392.

443. The delay of the publication of Dr. Davidson's CIMT study was caused by confusion on the part of POM's internal scientific team. Specifically, the delay in publication was due to having the results of the study re-read by a blinded independent group. (Liker, Tr. 1895-96; CX1350 (Liker, Dep. at 146, 149-50, 163-64)).

Response to Finding No. 443:
The proposed finding mischaracterizes the evidence. Dr. Davidson's results were provided to Respondents in February 2006, but the report was not submitted to the *American Journal of Cardiology* until May 2009. (CCFF ¶¶ 892-98). Dr. Davison presented the final results of the study, including the subgroup data, at the February 2007 POM Summit. (*See* CX0867). The cited pages do not support the conclusion that Dr. Liker testified that having the study results reread caused the two year delay in publication. Rather, Dr. Liker's testimony supports the conclusion that Respondents were reluctant to publish a study showing no effect on CIMT at 18 months. (*See* Liker, Tr. 1895-1900; CX1350 (Liker Dep. at 146-64); CCFF ¶¶ 892-98).

444. 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)).

Response to Finding No. 444:
The proposed finding mischaracterizes the evidence. *See* Response to Finding 443.

445. Individuals at POM, including Matt Tupper and Stewart Resnick, collectively made the decision to go forward with the publication of Dr. Davidson's CIMT study. (CX1350 (Liker, Dep. at 165-66)).

Response to Finding No. 445:
Complaint Counsel has no specific response, except to refer to CCFF ¶¶ 892-98

(describing Respondents' reaction and conduct after receiving Davidson results).

446. Respondents did not try to hide the 18 month results of the Davidson CIMT study. (Liker, Tr. 190).

Response to Finding No. 446:
Complaint Counsel has no specific response except to refer to CCFF ¶¶ 892-98

(describing Respondents' reaction and conduct after receiving Davidson results).

447. Both 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).

Response to Finding No. 447:
Complaint Counsel has no specific response except to note that Dr. Davidson's data,

showing only a *trend* toward improvement in CIMT *progression* at 12 months

(p=0.0544) was not included in the manuscript that was published. (*See* CCFF ¶ 886).

Instead, the published report discussed the difference in absolute CIMT *values* at 12

months, an irrelevant data point. (*See* CCFF ¶¶ 885, 906).

VIII. RESPONDENTS' CARE IN ADVERTISING AND CHANGES IN POM'S ADVERTISING OVER TIME

448. POM selected studies to discover the truth about the health benefits of the pomegranate. (S. Resnick, Tr. 1859).

Response to Finding No. 448:
Complaint Counsel has no specific response.

449. POM did not select studies based on whether or not they would produce a positive result. (S. Resnick, Tr. 1860).

Response to Finding No. 449:
Complaint Counsel has no specific response.

450. POM endeavored to sponsor high quality science and sought the best scientists in their respective fields. (S. Resnick, Tr. 1857).

Response to Finding No. 450:
Complaint Counsel has no specific response.

451. POM has sponsored over one hundred scientific studies at 44 different institutions and universities with some of the best scientists throughout the world. (Liker, Tr. 1887-88).

Response to Finding No. 451:
Complaint Counsel does not disagree that Dr. Liker testified as stated about the number of studies and institutions, except to note that he testified that "the Resnicks" sponsored the studies. Moreover, Complaint Counsel notes that approximately 40% of the studies were conducted at only two institutions. *See* Responses to Findings 268 and 280.

452. Even though very encouraging research has been completed and published on many areas of science, such as immunity, cold and flu, cognitive function, skin and dental health, POM has been somewhat conservative and has chosen not to discuss those results in advertising. (Tupper, Tr. 2979-81)

Response to Finding No. 452:
Complaint Counsel does not disagree that Mr. Tupper testified as stated, but notes that the implication that POM's research has been uniformly positive in these areas is contradicted by the record. POM's internal research assessment notes for cold and flu / immunity, for example, that POM's "clinical data is not sufficiently compelling to warrant additional research." (CX1029_0008).

453. Even when initial research results are positive, POM delays sharing the results with the public until the science is sufficiently developed. (Tupper, Tr. 2979).

Response to Finding No. 453:
Complaint Counsel agrees that Mr. Tupper testified as stated, but notes that he was referring only to research in certain areas. *See* Response to Finding 452.

454. POM's policy is that a body of science must be developed and the physiological effects of pomegranates on any studied structure or function must be well understood before Respondents will use such research results in advertising. (Tupper, Tr. 2981).

Response to Finding No. 454:

Complaint Counsel has no specific response.

455. In its early years from 2003 through 2006, the language and graphics in POM's advertisements regarding the health benefits of POM Juice were more aggressive. (*See infra* (XVII(E)).

Response to Finding No. 455:
Complaint Counsel agrees that POM's advertisements during the time period were "aggressive." *See also* responses to findings in the cross-referenced section.

456. Since those early years, POM's advertisements have evolved and changed significantly, largely as a result of the NAD decisions in 2005 and 2006 described below. (L. Resnick, Tr. 162, 168).

Response to Finding No. 456:
Complaint Counsel agrees that Mrs. Resnick testified that POM's ads have changed over time, but the assertion that it was largely a result of the NAD decisions is unsupported by the cited evidence.

457. In 2005, POM's advertising was the subject of an inquiry by the National Advertising Division ("NAD"). (CX0037_0001).

Response to Finding No. 457:
Complaint Counsel agrees.

458. The NAD found that many of the advertisements promoting POM Juice could be deemed mere puffery. (CX0037_0006; Tupper, Tr. 2983).

Response to Finding No. 458:
This proposed finding mischaracterizes the evidence. Specifically, the 2005 NAD decision (CX0037) only reviewed two specific advertising claims and did not review, or find that, the images and headlines in Respondents' ads were puffery. The only individual ads it ruled on were "Amaze your cardiologist" and "Floss your arteries daily," and it recommended that the claims under review for both ads be modified or discontinued. (CX0037_0001, 0010). While the 2005 NAD decision stated, in a footnote, that some ads "*could be* deemed mere puffery," the NAD made clear that it was only reviewing POM's claim of quantified product performance; of the seven headlines

listed in this proposed finding, the only one mentioned was "Life Preserver." (CX0037_0006 and n.21 (emphasis added); *see also* CX0055_0020 (2005 NAD review only reviewed one quantified claim and "not any claims of puffery")).

459. There were, however, two advertisements that the NAD believed extended beyond puffery: 1) "Amaze your cardiologist" and 2) "Floss your arteries," both of which made quantified performance claims. (CX0037_0008; CX0034; CX0031).

Response to Finding No. 459:
This proposed finding that the 2005 NAD decision reviewed or ruled on any claims of puffery is unsupported by the cited evidence. *See* Response to Finding 458. Complaint Counsel agrees that the 2005 NAD decision specifically ruled on claims made in the two specified ads.

460. Both advertisements cited Dr. Aviram's 2004 study titled Pomegranate juice consumption for 3 years by patients with carotid artery stenosis reduces common carotid intimamedia thickness, blood pressure and LDL oxidation. (CX0611).

Response to Finding No. 460:
Complaint Counsel agrees.

461. The NAD found that Dr. Aviram's 2004 study was reliable, sufficiently powered and had produced encouraging results concerning the antioxidant attributes of POM Juice. (CX0037_0007).

Response to Finding No. 461:
Complaint Counsel does not disagree that the NAD stated as such, except to note that NAD also determined that POM did not sufficiently qualify its ad claims to communicate the preliminary nature of the findings and the specifics of the study population. (CX0037_0008-09).

462. The NAD further acknowledged the prominent role that the antioxidants found in pomegranate juice can play in reducing the risk of free radical-related diseases, and in particular, the reduction of artery-clogging plaque. (CX0037_0010).

Response to Finding No. 462:
Complaint Counsel has no specific response.

463. The NAD, however, found that POM did not adequately qualify the science that was being described in the "Amaze your cardiologist" and "Floss your arteries" advertisements. (Tupper, Tr. 2983; CX0037_0010).

Response to Finding No. 463:
Complaint Counsel agrees that these were among the findings in the 2005 NAD decision.

464. POM disagreed with the NAD's 2005 ruling. (Tupper, Tr. 2984; CX0037_011).

Response to Finding No. 464:
Complaint Counsel agrees.

465. POM believes that it appropriately and accurately portrayed the results of the science on pomegranate juice in its advertisements. (Tupper, Tr. 2984-86; CX0037_0011).

Response to Finding No. 465:
Complaint Counsel agrees that this is POM's stated belief.

466. Nevertheless, POM took the NAD's 2005 findings into account with respect to its future advertising. (CX0037_0011).

Response to Finding No. 466:
Complaint Counsel agrees that POM stated it *would* take the findings in account in a statement to the NAD, but the finding that POM took the NAD's findings into account is unsupported by the cited evidence and the record as a whole. Indeed the 2006 NAD decision stated it was "particularly disturbed that not only did the advertiser fail to discontinue or take any corrective measure to avoid the implied preventative claim but, since that time, has promulgated new advertising (although avoiding the quantified 30% reduction claim) *expressly* claiming to the general public that drinking 8 ounces of POM Wonderful a day can prevent arterial plaque buildup." (CX0055_0044) (emphasis in original); *see also* CCFF ¶ 666).

467. POM stopped running the "Floss your arteries" advertisement in 2004 and has not disseminated it since that time. (Tupper, Tr. 2996).

Response to Finding No. 467:
Complaint Counsel has no specific response.

468. POM stopped running the "Amaze you cardiologist" advertisement in 2005 and has not disseminated it since that time. (Tupper, Tr. 2996-2997; CX1353 (Tupper, Dep. at 131).

Response to Finding No. 468:
Complaint Counsel agrees that Mr. Tupper testified as stated in the trial in this matter, but this proposed finding is unsupported by the cited deposition testimony. Moreover, Complaint Counsel objects to the deposition testimony as non-designated testimony.

469. Despite those changes, POM's advertising was the subject of an inquiry by the NAD in 2006. (CX0055).

Response to Finding No. 469:
Complaint Counsel agrees that POM's advertising was the subject of a 2006 NAD inquiry.

470. As in 2005, the NAD found that many of POM's advertising headlines and imagery could be deemed puffery. (Tupper, Tr. 2983-84; CX0055_0047).

Response to Finding No. 470:
This proposed finding mischaracterizes the 2005 NAD decision, which as stated in the Response to Finding 459, did not review any claims of puffery. Moreover, this proposed finding mischaracterizes the 2006 NAD finding, which stated that the advertisements cited in the prior decision were only *possible* examples of puffery, not that there was any such finding. (CX0055_0021). The NAD also emphasized that it reviewed claims "in the context of the entire advertisement in which it appears" and that even if the headlines were "fanciful" *in isolation*, "when accompanied by language that . . . POM Wonderful prevents or reduces the risk of heart disease, Alzheimer's, stroke, heart disease, premature aging, cancer, etc. and viewing these advertisements as a whole, these claims are beyond the realm of puffery and hyperbole[.]" (CX0055_0047). The NAD also questioned whether, "having so pervasively promoted its campaign before the public for such a lengthy period of time, it is possible to step back once again, to . . . fanciful puffing advertising copy[.]" (CX0055_0023).

471. The NAD, however, did not make any findings about the validity of the underlying science that had been referenced in POM's advertising. (Tupper, Tr. 2983-2984; CX0055_0038-39).

Response to Finding No. 471:
This proposed finding is incomplete. While the NAD did not criticize the studies themselves, it stated that the studies' "results were not sufficient to support the advertiser's claims." (CX0055_0038).

472. The NAD did acknowledge, however, that numerous studies have touted the benefits of eating foods high in antioxidants and that POM produced a "high quality, healthful drink demonstrating a high level of antioxidants." (CX0055 at 0025).

Response to Finding No. 472:
Complaint Counsel agrees.

473. The NAD further stated that POM Juice is an excellent source of antioxidants and did not dispute that antioxidants may be beneficial to one's health. (CX0055_0039).

Response to Finding No. 473:
Complaint Counsel agrees.

474. The NAD found that the language "[POM] can help prevent premature aging, heart disease, stroke, Alzheimer's, even cancer. Eight ounces a day is all you need," when discussing the benefits of POM Juice, was too general and/or overly broad, and that POM had not sufficiently qualified the results of the scientific studies. (CX0055_0039, 0047).

Response to Finding No. 474:
Complaint Counsel agrees.

475. Notably, the NAD found that POM's scientific evidence on cardiovascular health might be sufficient to support more narrowly tailored qualified claims. (CX0055_0047).

Response to Finding No. 475:
Complaint Counsel agrees that the NAD decision stated that "perhaps the evidence might permit a carefully worded claim[.]" (CX0055_47).

476. POM disagreed with the NAD's ruling that its claims were too broad. (Tupper, Tr. 2984; CX0055_48).

Response to Finding No. 476:
Complaint Counsel agrees that this was POM's position.

477. POM believes that the scientific studies have been appropriately portrayed in advertisements. (Tupper, Tr. 2984-86; CX0055_0048).

Response to Finding No. 477:
Complaint Counsel agrees that this is POM's stated belief.

478. Nevertheless, POM deferred to the NAD's ruling and discontinued and/or modified certain claims in its advertising that the NAD had taken issue with. (CX0055_0048; Tupper, Tr. 2984-85).

Response to Finding No. 478:
Complaint Counsel agrees that POM *stated* it would take the findings in account in a statement to the NAD, but the proposed finding's assertion that POM took the NAD's findings into account is unsupported by the cited evidence or the record as a whole. (*See* CCFF ¶¶ 673-74).

479. Beginning in 2006, largely as a result of the two NAD decisions, POM stopped making generalized statements in advertisements about the science it had done. (Tupper, Tr. 2986-87).

Response to Finding No. 479:
Although Complaint Counsel agrees that Mr. Tupper testified this, his testimony is unsupported and contradicted by the record as a whole on POM's conduct. (*See* CCFF ¶¶ 665-674) (showing that POM continued to make plaque reduction claims, citing the Aviram study, after the NAD rulings)).

480. Since 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).

Response to Finding No. 480:
Although Complaint Counsel agrees that Mr. Tupper testified as stated, his testimony is unsupported and contradicted by the record on POM's conduct. (*See* CCFF ¶¶ 665-674) (showing that POM continued to make plaque reduction claims, citing the Aviram study, after the NAD rulings).

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).

Response to Finding No. 481:
Complaint Counsel agrees that this language was part of the body copy used in an ad (CX0471_0028; CX0260), but disagrees with this proposed finding as to the net impression and meaning of the ad. (*See* CCFF ¶¶ 368-371).

482. Additionally, as a result of the NAD's decisions, in some of their ads, Respondents would direct people back to their website to read the full scientific study. (Tupper, Tr. 2985).

Response to Finding No. 482:
Complaint Counsel has no specific response.

483. Importantly, since 2007 POM has implemented a more formalized and well-defined vetting process for advertisements relating to the health benefits of its products. This process requires multiple stages of review that ultimately culminate in approval by the legal department before any advertisement is run. This formalized process ensures that accurate information is presented to the public. (Tupper, Tr. 2977-78).

Response to Finding No. 483:
Complaint Counsel agrees that Mr. Tupper testified as stated, but the finding that this process "ensures that accurate information is presented to public" is unsupported by the record as a whole. Complaint Counsel has challenged numerous ads that were disseminated after this process was purportedly implemented. (*See* CCFF Section V; *see also* Response to Finding 2260).

484. Respondents' continued policy regarding the relationship between scientific studies and advertisements is to ensure that what is portrayed in the advertisements is consistent and accurate with results of the scientific studies themselves. (Tupper, Tr. 2979).

Response to Finding No. 484:
Complaint Counsel has no specific response.

485. Respondents firmly believe that everything that has been said in any of their advertising regarding the health benefits of their products is more than adequately supported by

published research that has been conducted over the past 10 to 15 years. (Tupper, Tr. 2986).

Response to Finding No. 485:
Complaint Counsel agrees that Mr. Tupper testified as stated and that this is

Respondents' stated belief.

486. POM would never knowingly publish any advertisement that the company did not believe was adequately supported by the body of science. (Tupper, Tr. 3015).

Response to Finding No. 486:
Complaint Counsel agrees that Mr. Tupper testified as stated, but states that this proposed

finding is irrelevant.

487. Likewise, Dr. Dreher, who was formerly POM's VP of Scientific Affairs in charge of overseeing POM's research program, entered into a settlement agreement with the FTC. (Dreher, Tr. 527-28, 587).

Response to Finding No. 487:
Complaint Counsel agrees.

488. Dr. Dreher's settlement agreement with the FTC does not in any way, shape, or for suggest that Dr. Dreher believes that he did anything wrong. (Dreher, Tr. 587).

Response to Finding No. 488:
Complaint Counsel has no specific response.

489. Dr. Dreher did not enter into a settlement agreement with the FTC because he believed he did anything wrong. (Dreher, Tr. 587).

Response to Finding No. 489:
Complaint Counsel has no specific response.

490. Two newsletters authored by Dr. Dreher are the basis for Dr. Dreher's settlement agreement. One discussed prostate health and the other heart health. (Dreher, Tr. 587).

Response to Finding No. 490:
Complaint Counsel agrees that Dr. Dreher testified as stated, but notes that the Complaint

and Decision and Order with respect to Dr. Dreher speak for themselves.

491. 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).

Response to Finding No. 491:
Complaint Counsel has no specific response.

492. Dr. Dreher does not believe there is anything false or misleading about the newsletters despite the FTC's accusations against him in connection with 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).

Response to Finding No. 492:
Complaint Counsel has no specific response.

IX. THE MANUFACTURE AND SALE OF POM JUICE AND POMX EXTRACT AND LIQUID

A. 100% Pomegranate Juice And POMx Are Wholly Derived From The Fruit

493. 100% POM Juice is a 100% juice product derived from whole pomegranate fruits. (PX0353 (Heber, Dep. at 124) CX1362 (L. Resnick, Dep. at 85-86); CX1363 (S. Resnick, Dep. at 46-47)).

Response to Finding No. 493:
Complaint Counsel has no specific response, except to refer to CCFF ¶¶ 124-29, which describe the manufacturing process for POM Juice and its composition.

494. POMx is an extract from the pomegranate, made through a process by which POMx Liquid is first derived from the whole fruit, and then POMx is extracted from the POMx Liquid. (CX1363(S. Resnick, Dep. at 46-47)).

Response to Finding No. 494:
Complaint Counsel has no specific response, except to refer to CCFF ¶¶ 130-35, which describe the manufacturing process for the extracts.

495. POM has never advertised its products as a drug. (Tupper, Tr. 3008).

Response to Finding No. 495:
The proposed finding mischaracterizes the record. Under Section 12 of the FTC Act, a drug is a product that is "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease." (*See* Complaint Counsel's Conclusions of Law ¶ 5). Respondents' advertising represented its products for such use (*see* CCFF ¶ 625); hence, they are "drugs" for the purposes of the FTC Act.

496. POM has never intended to advertise its products as a drug. (Tupper, Tr. 3008).

Response to Finding No. 496:
The proposed finding mischaracterizes the record. *See* Response to Finding 495.

497. POM Juice is sold in the refrigerated produce section of the grocery store. (CX1367 (S. Resnick Welch Dep. at 122); CX1374 (Tupper Ocean Spray Dep. at 56-57)).

Response to Finding No. 497:
Complaint Counsel agrees.

498. POM Juice is not sold in the "drug" or "over the counter" section of any establishment, or advertised or marketed in conjunction with or in comparison to any drug product. (CX1362 (L. Resnick Coke Dep. at 135-136); CX1367 (S. Resnick Welch Dep. at 122; CX1374 (Tupper Ocean Spray Dep. at 56-57)).

Response to Finding No. 498:
Complaint Counsel agrees.

499. Consumers must go to the fresh produce aisle of a store to purchase any POM Juice product. (CX1362 (L. Resnick Coke Dep. at 135-136).

Response to Finding No. 499:
Complaint Counsel agrees.

500. The Challenged Products do not state on their face that they "treat" or "prevent" some disease or condition, like products in the drug aisles of a grocery store such as "Tough Actin' Tinactin," that states on the product that it "prevents" or "cures" most athlete's foot, or Bengay that says it "stops pain" and provides "fast relief from minor arthritis, backache, muscle & joint pain." (Appendix of Advertisments).

Response to Finding No. 500:
Complaint Counsel has no specific response.

501. POMx caters to those consumers who want the benefits of the juice, without the calories or sugar to get, "The Power of Pom, now in a Pill." (CX0169_0001).

Response to Finding No. 501:
The proposed finding is unsupported by the cited evidence, which is an advertisement.

Complaint Counsel disagrees that this is the only target audience of POMx pills. (*See* CCFF ¶¶ 303-04, 307 (creative briefs identifying target audiences of POMx pills as those "seeking a natural cure for current ailments or to maintain health and prevent future ailments" and "men who are scared to get prostate cancer").

X. RESPONDENTS' GENUINE BELIEF IN THE HEALTH BENEFITS OF THE PRODUCTS AND ITS ADVERTISING

A. Respondents' Personal Belief in the Health Benefits

502. Respondents genuinely believe in the integrity of POM's research program and the health benefits of the Challenged Products. (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)).

Response to Finding No. 502:
Complaint Counsel has no specific response.

B. Belief in the Research

503. Based upon his belief and knowledge gained from statements made by POM's consulting doctors and POM's research studies, Respondent Matt Tupper advised members of his families with prostate cancer to consume pomegranate. (CX1406 (Tupper, Tropicana Tr.182-83).

Response to Finding No. 503:
Complaint Counsel has no specific response.

504. Respondent Stewart Resnick personally believes that the research supports the conclusion that pomegranate prevents certain people from getting prostate cancer and in others it may prolong life. (CX1363 (S. Resnick, Coke Dep. at 83; CX1360 (S. Resnick, Dep. at 229)).

Response to Finding No. 504:
Complaint Counsel does not disagree with this statement, except to note that Mr. Resnick further testified that he does not have the research to "make a medical claim of that sort." (CX1363 (S. Resnick, Coke Dep. at 83)).

505. Respondent Stewart Resnick personally believes that consuming pomegranate juice helps with erectile dysfunction and that POM's research supports his belief. (CX1376 (S. Ocean Spray Dep. at 162)).

Response to Finding No. 505:
Complaint Counsel does not disagree with the statement that Mr. Resnick believes that consuming pomegranate juice helps with erectile dysfunction, but the statement that he believes POM's research supports his belief is unsupported by the cited evidence.

506. Stewart Resnick personally believes that the consumption of pomegranate juice is beneficial in the fight against cardiovascular disease and POM's research supports his belief. (CX1360 (S. Resnick, Dep. at 246); CX1360 (S. Resnick, Dep. at 200); (CX1372 (S. Resnick, Tropicana Dep. at 42-43)).

Response to Finding No. 506:
Complaint Counsel has no specific response.

507. Respondent Matt Tupper stated at trial that Respondents believe that the body of science undertaken in the area of prostate health is sufficiently rigorous to lower the amount of future research that would need to be undertaken in order to obtain FDA approval for a claim that POMx pills prevent or treat prostate cancer. (Tupper, Tr. 991-92).

Response to Finding No. 507:
Complaint Counsel has no specific response.

508. Respondents have stated that they believe that PSA doubling time is a valid and appropriate endpoint in research whether its products prevent or treat prostate cancer. (Tupper, Tr. 991-92).

Response to Finding No. 508:
Complaint Counsel has no specific response.

509. Respondent Matt Tupper personal belief in the integrity of the research is evidenced by the high grade that he attaches to the disputed areas of science. He personally grades POM's erectile, prostate, and cardiovascular research each as eight-out-of-ten. (Tupper, Tr. 3012-14).

Response to Finding No. 509:
Complaint Counsel agrees that this is Mr. Tupper's view as he testified and a reason the

remedy against Mr. Tupper is appropriate.

C. Belief in the Health of the Products

510. Despite the fact that POM as a company is losing money, Respondents have chosen to stay in business because they believe that the product does provide all the health benefits that have been advertised. (S. Resnick, Tr. 1867).

Response to Finding No. 510:
Complaint Counsel has no specific response.

511. Respondents genuinely believe that pomegranates are, in fact, "good medicine," in the sense that broccoli and a generally healthy lifestyle are good medicine. (Tupper, Tr. 2991-92).

Response to Finding No. 511:

Complaint Counsel has no specific response.

512. Respondent Matt Tupper testified that Respondents believe that pomegranate is "good medicine" much in the same way that Hippocrates believed that food is medicine. Mr. Tupper recited a Hippocrates quote and said, "Our food should be our medicine, and our medicine should be our food." (Tupper, Tr. 2992).

Response to Finding No. 512:
Complaint Counsel has no specific response.

513. Respondent Matt Tupper testified that Respondents believe that pomegranate juice is "good medicine" in the same way that a quote that has been out in the press states that food is medicine—"the medicine chest of the 21st century can be found in the produce department of your local supermarket." (Tupper, Tr. 2992).

Response to Finding No. 513:
Complaint Counsel has no specific response.

514. Mr. Tupper in other litigation matters stated that he passionately believes pomegranate juice is incredibly healthy and that the power of a good plant-based diet can have a dramatic effect on one's long term health. (CX1371 (Tupper, Tropicana Dep. at 171)).

Response to Finding No. 514:
Complaint Counsel has no specific response.

515. Respondent Stewart Resnick has stated that he believes that pomegranates are a uniquely healthy food. (CX1363 (S. Resnick, Coke Dep. at 50-52)).

Response to Finding No. 515:
Complaint Counsel has no specific response.

516. Respondent Lynda Resnick stated that she personally believes pomegranates and pomegranate juice have unique health-giving properties. (CX1362 (L. Resnick, Coke Dep. at 51, 80); CX1375 (L. Resnick, Dep. at 8, 209).

Response to Finding No. 516:
Complaint Counsel has no specific response.

517. Respondent Lynda 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)).

Response to Finding No. 517:

Complaint Counsel agrees that this is what Mrs. Resnick thinks and has communicated to the public. In fact, she has stated "it's the magic elixir of our age and of all ages." (CX0473 (Compl. Ex. E-6)).

518. Respondent Lynda Resnick believes "with all her heart" that if you lead a healthy lifestyle and consume pomegranate juice, you will be healthier. (CX1362 (L. Resnick, Dep. at 51)).

Response to Finding No. 518:
Complaint Counsel has no specific response.

519. Respondent Lynda Resnick believes that part of POM juice's intrinsic value is that it has been shown to reduce arterial plaque and have a powerful effect against prostate cancer. (L. Resnick, Tr. 76; PX1359 (L. Resnick Dep. at 18)).

Response to Finding No. 519:
Complaint Counsel agrees.

520. Respondents genuinely believe that the consumption of pomegranate juice improves one's odds in combating disease. (Tupper, Tr. 3011-13; CX1363 (S. Resnick, Coke Dep. at 83; CX1360 (S. Resnick, Dep. at 229); CX1376 (S. Ocean Spray Dep. at 162); CX1360 (S. Resnick, Dep. at 246); CX1360 (S. Resnick, Dep. at 200); (PX1372 (S. Resnick, Tropicana Dep. at 42-43); CX1406 (Tupper, Tropicana Tr.182-83)).

Response to Finding No. 520:
Complaint Counsel agrees.

D. Respondents Belief in the Science is Justified by the High Level of Scientific Integrity

521. Respondents are justified in their belief in the integrity of the research program, in part, because of the level of scientific rigor that they have insisted upon in sponsoring research. (Liker, Tr. 1887-89; (S. Resnick, Tr.1857; Liker, Tr. 1878-80; CX1350 (Liker, Dep. at 32-33)).

Response to Finding No. 521:
This proposed finding mischaracterizes the testimony. The cited testimony does not address the "level of scientific rigor" for any particular research. Moreover, Complaint Counsel disagrees with the conclusion that Respondents "are justified in their belief in the integrity of [their] research program."

522. Respondents have sponsored research at the finest medical and research institutions, including, UCLA, Johns Hopkins, M.D. Anderson in Houston, the Mayo Clinic, the Cleveland Clinic, and UC San Francisco. (Liker, Tr. 1887-89).

Response to Finding No. 522:
Complaint Counsel has no specific response.

523. Respondents have also sought out the very best researchers in their respective fields to guide them in their decisions to explore different health conditions and areas and to conduct the research. (S. Resnick, Tr.1857; Liker, Tr. 1878-80; CX1350 (Liker, Dep. at 32-33)).

Response to Finding No. 523:
Complaint Counsel has no specific response.

E. Respondents Do Not Believe Their Advertisements Regarding the Challenged Products Are Deceptive or Misleading

1. The Individual Respondents Never Believed or Suggested That Their Advertisements Were Meant to Convey the Message That The Challenged Products Are or Should Be "Silver Bullet" Against Disease Or Substitute for Conventional Medical Treatment

524. 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).

Response to Finding No. 524:
Complaint Counsel has no specific response.

525. Mr. Resnick is not aware of anyone associated with POM or Roll who suggests that people should drink POM instead of following their doctor's advice. (S. Resnick, Tr. 1870-71).

Response to Finding No. 525:
Complaint Counsel has no specific response.

526. If Mr. Resnick found out an employee was recommending that a consumer drink POM instead of following his or her doctor's advice, Mr. Resnick 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. (S. Resnick, Tr. 1871).

Response to Finding No. 526:
Complaint Counsel has no specific response.

527. 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).

Response to Finding No. 527:
Complaint Counsel has no specific response.

528. Mr. Tupper is unaware of any instance in which any employee told anyone to drink pomegranate juice as a substitute for consulting with a doctor and taking his or her advice. (Tupper, Tr. 3018).

Response to Finding No. 528:
Complaint Counsel has no specific response.

529. Mr. Tupper testified that it is absolutely against company policy for a POM employee, when responding to consumer health inquiries, to remain silent and not inform the consumer that he or she consult his or her doctor. (Tupper, Tr. 3018-19).

Response to Finding No. 529:
Complaint Counsel does not disagree that this was Mr. Tupper's testimony, but disagrees with the conclusion that POM's responses to consumer inquiries about the use of POM's products to treat or prevent disease included information that the consumer should consult his or her doctor. (*See, e.g.,* CCFF ¶¶ 616 -17; CX0485_0083, 0155, 0165, 0192-93, 0384, 0510-11, 0649, 1049-50, 1339-40, 1390, 2296).

530. 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).

Response to Finding No. 530:
See Response to Finding 529.

2. The Individual Respondents Never Believed or Suggested That Their Advertisements Were Meant To Convey the Message That the Challenged Products Could Treat or Prevent Any Disease

(a) Lynda Resnick

531. Mrs. Resnick never believed the "I'm off to save prostates" advertisement was intended to mean that POM Juice would treat prostate cancer. (L. Resnick, Tr. 217-18; CX 1426_0009).

Response to Finding No. 531:
The proposed finding is supported by the transcript cite, but is unsupported by CX1426_0009, in which Mrs. Resnick stated in an interview that every man should be

drinking eight ounces day of pomegranate juice because "what it does for prostate cancer is amazing."

532. With respect to the "cheat death" advertisement, Mrs. Resnick was told from scientists that pomegranate juice has more antioxidants than any other drink, can help prevent premature aging, heart disease, stroke, Alzheimer's, even cancer". (CX471_0002; L. Resnick, Tr. 152).

Response to Finding No. 532:
This proposed finding is unsupported by the cite CX471_0002. Moreover, this finding mischaracterizes Mrs. Resnick's testimony to the extent it implies she heard this from objective third party scientists. Her testimony is that she was told this by the scientists who were working on her business. (L. Resnick, Tr. 152).

533. In her Tropicana deposition, Mrs. Resnick testified that she did not feel comfortable and confident telling consumers that POM can help prevent Alzheimer's in an ad because she does not think the research is exhaustive enough. (L. Resnick, Tr. 155-56).

Response to Finding No. 533:
Complaint Counsel agrees.

534. At the time she gave an interview to Martha Stewart, Mrs. Resnick stated that she believed POM Juice was helpful for Alzheimer's – that is what she believed then and now. (L. Resnick, Tr. 156).

Response to Finding No. 534:
Complaint Counsel agrees.

535. The purpose of the "Cheat death" advertisement is not to prevent heart disease, but rather is to make the reader laugh; it is puffery. (L. Resnick, Tr. 194; 196-97).

Response to Finding No. 535:
This proposed finding is a correct summary of Mrs. Resnick's testimony but it is an incorrect and incomplete conclusion. The "Cheat Death" ad was created with the intent of using imagery that irreverently and boldly conveys to consumers that drinking POM Juice "may help prevent disease." (*See* CCFF ¶ 355; CX0456_0002-03; CX0454_0009-10).

536. Although she states that POM did tell consumers in 2006 that POM Juice could prevent Alzheimer's, Mrs. Resnick believes the statement to be true and that POM would not have made the statement if there was no scientific evidence to support it. (L. Resnick, Tropicana, Dep. at 100-101).

Response to Finding No. 536:
Complaint Counsel has no response except to note that this proposed finding is contradicted by Finding 533.

537. Mrs. Resnick did not intend to use Dr. Pantuck's prostate study to communicate to consumers that POM Juice would treat prostate cancer. (L. Resnick, Tr. 218-19).

Response to Finding No. 537:
The proposed finding is unsupported by the cited evidence, which relates only to the "Off to Save Prostates" ad. *See* Response to Finding 531.

(b) Stewart Resnick

538. In his Coke deposition, Mr. Resnick testified that POM's marketing did not indicate that POM Juice could "prevent any health conditions." (S. Resnick, Coke, Dep. at 81).

Response to Finding No. 538:
Complaint Counsel has no specific response, except to note that no exhibit number cite is provided.

539. By drinking POM Juice, Mr. Resnick does not believe that you can completely prevent getting prostate cancer, but you might be able to slow its recurrence. (S. Resnick, Coke, Dep. at 81-82).

Response to Finding No. 539:
Complaint Counsel has no specific response except to note that no exhibit number cite is provided.

540. During the time the NAD issued its decision, Mr. Resnick did not believe that POM's advertisements claimed that POM Juice prevented or treated heart disease. (S. Resnick, Ocean Spray, Dep. at 135).

Response to Finding No. 540:
Complaint Counsel has no specific response, except to note that no exhibit number cite is provided.

541. Assuming the advertisements did communicate to consumers that POM can prevent or delay the onset of prostate cancer, Mr. Resnick is still comfortable with the scientific evidence. (S. Resnick, Ocean Spray, Dep. at 155-156).

Response to Finding No. 541:
Complaint Counsel has no specific response, except to note that no exhibit number cite is provided.

542. 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).

Response to Finding No. 542:
Complaint Counsel has no specific response, except to note that no exhibit number cite is provided.

543. POM publishes the results of its research because it believes in the effects of pomegranate juice and people should try to both prevent and cure disease as they can. It is up to the individual to make their own decisions. (S. Resnick, Tropicana, Dep. at 43).

Response to Finding No. 543:
Complaint Counsel has no specific response, except to note that no exhibit number cite is provided.

544. POM believes that pomegranate juice is beneficial for prevention and treatment of prostate cancer. (S. Resnick, Tropicana, Dep. at 48).

Response to Finding No. 544:
Complaint Counsel has no specific response, except to note that no exhibit number cite is provided.

545. POM is not attempting to influence consumers to believe that pomegranate juice prevents prostate cancer or making a drug claim, but rather letting them make their own decisions. (S. Resnick, Tropicana, Dep. at 52).

Response to Finding No. 545:
Complaint Counsel has no specific response, except to note that no exhibit number cite is provided.

546. Mr. Resnick does not believe that POM has made prevention claims, other than for prostate cancer, but this "prevent" really means "prolong" in this context. (S. Resnick, Tropicana, Dep. at 56-57).

Response to Finding No. 546:
Complaint Counsel has no specific response, except to note that no exhibit number cite is provided.

547. 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).

Response to Finding No. 547:
Complaint Counsel has no specific response, except to note that no exhibit number cite is provided.

(c) Matthew Tupper

548. POM would never market a drug without FDA approval, regardless of what the indication. (Tupper, Tr. 992).

Response to Finding No. 548:
Complaint Counsel does not disagree Mr. Tupper testified as stated, but disagrees with any implication that POM would not market a product making drug claims without FDA approval, as Mr. Tupper repeatedly failed to answer that question. (Tupper, Tr. 992-94).

549. In POM's advertising, Mr. Tupper testified that POM never claimed that POM Juice can prevent, treat, cure, or mitigate any diseases. (Tupper, Coke, Dep. at 297, 299).

Response to Finding No. 549:
Complaint Counsel has no specific response, except to note that no exhibit number cite is provided.

550. Mr. Tupper believes that POM does not claim that POM cures, prevents, or treats disease and has not made any such representations to any office or department of the U.S. government. (Tupper, Ocean Spray, Dep. at 6).

Response to Finding No. 550:
Complaint Counsel has no specific response, except to note that no exhibit number cite is provided.

XI. HOW TO EVALUATE THE SCIENCE BEHIND THE CHALLENGED PRODUCTS

A. In Evaluating the Potential Health Benefits of a Natural and Safe Food, the Totality of the Scientific Evidence Should Be Considered, Including Basic Science, Animal Research, and "Pilot" Studies

568. The totality of scientific evidence can and should be considered in determining what constitutes competent and reliable scientific evidence, to prove the health benefits of the Challenged Products, given that: (1) pomegranate juice and its extracts are safe; and (2) no one suggests that pomegranate juice or extracts should be offered in lieu of conventional medical treatment. (Heber, Tr. 1948-49, 2166, 2182; Miller, Tr. 2194; PX0206-0007, 15; Ornish, Tr. 2327-31).

Response to Finding No. 568:
Complaint Counsel disagrees with the conclusion drawn. 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, double-blinded human clinical studies. (CCFF ¶¶ 1102, 1108). The level of evidence required depends on the claim being made; for claims that a product can treat, prevent, or reduce the risk of a disease, RCTs are "the best study design that permits a strong causal inference concerning the relationship between an administered agent (whether a drug or nutrient) and any specific outcome." (CX1293 (Stampfer, Report at 0030); Stampfer, Tr. 830-31 ("If the claim implies that a causal link has been established, then you have to have evidence to back it up."); CCFF ¶¶ 1102-08)).

1. Basic and Animal Science Provide Valuable Scientific Information

569. Basic scientific evidence provides powerful scientific support and should not be disregarded. (PX0349 (Burnett, Dep. at 116 -117); PX0352 (Goldstein, Dep. at 118, 133); 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).

Response to Finding No. 569:
Complaint Counsel does not disagree, except to note that many findings in basic scientific studies such as *in vitro* and animal studies cannot be replicated in humans. (*See* CCFF ¶¶ 763-64). Data from RCTs provide the best evidence of a causal relationship between a nutrient and a disease outcome in humans. (CCFF ¶ 771; *see also* Stampfer, Tr. 192 ("The in vitro studies, the animal studies, the observational studies, they're all providing useful, important scientific information. . . . *But when you want to draw a causal conclusion* [such as a claim that a product treats, prevent, or reduces the risk of a disease], you have to have the accumulation of data that's really sufficient to support that kind of claim. *Randomized trials provide the best tool* that we have to do that.") (emphasis added)).

570. Animal studies are very informative as it can characterize what's going on at the human level, and provide for some clinical insights. (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).

Response to Finding No. 570:
Complaint Counsel has no specific response. (*See also* CCFF ¶ 764).

571. In some instances, basic science is enough to provide sufficient substantiation for a health claim. (PX0206-0010-0011, 0013; Miller Tr. 2194; 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).

Response to Finding No. 571:
Complaint Counsel has no specific response, except to note that many findings in basic scientific studies such as *in vitro* and animal studies cannot be replicated in humans. (*See* CCFF ¶¶ 763-64). Data from RCTs provide the best evidence of a causal relationship between a nutrient and a disease outcome in humans. (CCFF ¶ 771).

572. Results from animal studies have some potential for benefit of therapy at the human level. (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).

Response to Finding No. 572:
Complaint Counsel does not disagree that Dr. Burnett testified as such, but the proposed finding is incomplete. Dr. Burnett testified that that "animal studies do allow us to carry away some clinical insights and as to whether animal studies alone would allow you to move forward with saying this is a treatment for ED . . . is a concern to me. I don't think you can rely entirely on animal studies to go that far . . . to claim it is a treatment for ED . . . is not necessarily at all supported just by animal studies alone. I think you need to get two or three clinical [human] studies." (PX0349 (Burnett, Dep. at 112-13)). In addition, this proposed finding is unsupported by the cited evidence CX1352 (Heber, Dep. at 243), Heber Tr. 2086, 2149, 8182, and PX192-0011, 0037, 0038, 0047-0055.

573. Dr. Burnett testified that "there are interventions that [he would] think have some potential benefit on the basis of animal studies or in vitro studies . . . ." (Burnett, Tr. 2262-63).

Response to Finding No. 573:
Complaint Counsel does not disagree that Dr. Burnet said such, but the proposed finding is incomplete. Dr. Burnett also testified that "in terms of the finding of treating erectile dysfunction, . . . we need more than just animal studies." (Burnett, Tr. 2264).

574. 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. (PX0025-0007).

Response to Finding No. 574:
Complaint Counsel does not disagree this is Dr. Ornish's opinion.

575. 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. (PX0025-0007).

Response to Finding No. 575:
Complaint Counsel does not disagree that this is Dr. Ornish's opinion.

576. 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. (Sacks, Tr. 1578; PX0361 (Sacks, Dep. at 123-124)).

Response to Finding No. 576:
The proposed finding mischaracterizes Dr. Sacks' testimony. Dr. Sacks testified that Respondents' *in vitro* studies do not provide competent and reliable scientific evidence of a result in *humans*." (Sacks Tr. 1622 (emphasis added); CCFF ¶¶ 763, 1103-08; CX1291 (Sacks, Report at 0015-16) ("none of these *in vitro* studies are capable of substantiating the kinds of heart disease benefit claims at issue in this case")).

577. Dr. Sacks admits there is value in conducting in vitro studies and animal studies because you can isolate mechanisms of action and accomplish toxicity or safety testing. (PX0361 (Sacks, Dep. at 89 -91)).

Response to Finding No. 577:
Complaint Counsel does not disagree, except that the proposed finding is incomplete. Dr. Sacks testified that an *in vitro* study would not be more useful in terms of evaluating the effect of a food or nutrient than a human clinical study because the purpose of a clinical study is to evaluate "the *sum total effect* of all the mechanisms that can be activated or repressed by food or nutrient." (PX0361 (Sacks, Dep. at 91-92) (emphasis added)). An *in vitro* study would be used to understand a mechanism rather than a "total clinical effect." (PX0361 (Sacks, Dep. at 92); s*ee also* CCFF ¶¶ 763-64)).

578. In an animal study, researchers can examine specific mechanisms by taking out their organs and cells, which you cannot do in humans. (PX0361 (Sacks, Dep. at 91).

Response to Finding No. 578:
Complaint Counsel does not disagree. (*See also* CCFF ¶ 764 (noting uses and limitations of animal studies)).

579. Dr. Sacks considers all levels of science in issuing national guidelines for the prevention or treatment of cardiovascular disease. (PX0361 (Sacks Dep. at 71)).

Response to Finding No. 579:

The proposed finding is incomplete. Dr. Sacks testified that "the panel [of the life style working group of the National Heart Lung and Blood Institute] considers all levels of evidence but would not issue [a national guideline for preventing or treating cardiovascular disease] based only on basic science." (PX0361(Sacks, Dep. at 71)).

580. 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. (deKernion, Tr. 3044-45, 3120).

Response to Finding No. 580:
Complaint Counsel does not disagree that Dr. deKernion testified as such, except to note that he also testified that even where the *in vitro* and animal evidence is strong and shows that an agent's mechanism of action works, this evidence does not prove that the agent works in humans. (deKernion, Tr. 3063-64).

581. Dr. Burnett also concluded that the basic scientific evidence alone "has a likely beneficial effect on erectile function" and is sufficient to support the use of pomegranate juice as a potential benefit for vascular blood flow and the vascular health of the penis. (Burnett, Tr. 2255; PX0349 (Burnett, Dep. at 103, 116-118); PX0149-0006-0007).

Response to Finding No. 581:
Complaint Counsel does not disagree that Dr. Burnett testified as such, except to note that Dr. Burnett testified that the standard of evidence depends on the type of claim being made. (Burnett, Tr. 2261). He agreed that animal and *in vitro* studies would not be sufficient to support a claim that a product treats erectile dysfunction. Dr. Burnett agreed that at least two human RCTs would be required to prove that a product treats erectile dysfunction. (Burnett, Tr. 2264).

582. 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. (Heber, Tr. 2081).

Response to Finding No. 582:

Complaint Counsel agrees that Dr. Heber testified as such, but disagrees with the conclusion drawn. The Davidson CIMT Study, Ornish CIMT Study, and "cardiac arm" of the Ornish MP Study all showed no CIMT benefit for patients at mild to moderate risk for coronary heart disease. (CCFF ¶ 951). The uncontrolled and unblinded Aviram CIMT/BP Study results were never replicated by the aforementioned studies. (CCFF ¶ 951). Finally, the Aviram ACE/BP Study, which was a small ten-person study, was unblinded and uncontrolled, which does not provide competent and reliable evidence to support a heart benefit claim. (CCFF ¶ 803).

2. "Pilot" or Small Studies Are Instructive

583. Pilot studies are generally considered by other scientists and clinicians in the scientific community to be perfectly valid, accurate, and reliable studies. (CX1336 (Davidson, Dep. at 232-233); CX1342 (Hill, Dep. at 48, 49, 53); CX1339 (Ornish, Dep. at 23)).

Response to Finding No. 583:

The proposed finding is unsupported by the cited evidence. Dr. Davidson testified as such about his own pilot studies. (CX1336 (Davidson, Dep. at 232)). Dr. Hill testified as to the meaning of "pilot" studies, which are studies that may not have enough subjects to reach statistical significance. (CX1342 (Hill, Dep. at 48-49, 53)). Complaint Counsel objects to the deposition testimony cited in the proposed finding as CX1339 (Ornish, Dep. at 23) as non-designated testimony. Complaint Counsel objects to Dr. Hill's testimony insofar as he offers expert opinion testimony: Dr. Hill was not qualified as an expert, and indeed, Respondents did not produce him for examination at trial, although he was identified on Respondents' witness list. Accordingly, pursuant to Federal Rule of Evidence 701, his testimony must be disregarded to the extent that he attempts to offer opinions that are based on scientific, technical, or other specialized knowledge within the scope of Federal Rule of Evidence 702.

584. 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." (CX0037_0007).

Response to Finding No. 584:
Complaint Counsel does not disagree that the NAD stated as such, but except to note that NAD also determined that the ads reviewed did not sufficiently qualify their claims to communicate the preliminary nature of the pilot study findings and the specifics of the study population. (CX0037_0008-09). Similarly, Complaint Counsel's experts concluded that the small sample size in this study was too small to provide reliable evidence that the observed effects would be applicable to the larger population. (CCFF ¶ 802).

585. A small number of participants, however, do not weaken the importance of the results, especially if they are in agreement with in vitro, mechanistical studies and in animal models. (CX1358 (Aviram, Dep. at 18)).

Response to Finding No. 585:
Complaint Counsel disagrees. A well-designed study must have a sufficient number and diversity of subjects to conclude that any measured effect can be generalized to a larger population. (CX1291 (Sacks, Report at 0014); Eastham Tr. 1265, 1269). A study must have enough participants to be adequately powered to achieve statistical significance in proving or disproving a hypothesis. (Melman, Tr. 1092, 1109).

586. Dr. Heber testified that "sometimes small studies can be more informative than large studies." (Heber, Tr. 1963).

Response to Finding No. 586:
Complaint Counsel has no specific response.

587. Dr. Aviram considers the term "pilot study" to be positive. (CX1358 (Aviram, Dep. at 17).

Response to Finding No. 587:

Complaint Counsel has no specific response. (*See also* CCFF ¶ 770 (describing typical use of pilot or exploratory studies)).

588. A study with a small number of participants, however, may make it more difficult to achieve overall statistical significance. (CX1338 (Padma-Nathan, Dep. at 108-109); PX0349 (Burnett, Dep. at 138-141); Ornish, Tr. 2352-53; Liker, Tr. 1884-86).

Response to Finding No. 588:
The proposed finding is unsupported by the cited evidence.

589. If an under-powered study does achieve statistical significance, however, then the results would be considered to be "fairly dramatic." (Liker, Tr. 1884-85).

Response to Finding No. 589:
The proposed finding is unsupported by the cited evidence.

590. Nonetheless, a study that is under-powered to achieve statistical significance should not be misconstrued to mean that the study was deficient. (CX1338 (Padma-Nathan, Dep. at 108-109).

Response to Finding No. 590:
Complaint Counsel has no specific response, except to note that Dr. Padma-Nathan did describe a pilot study as being deficient. (CX1338 (Padma-Nathan, Dep. at 106)).

591. In Dr. Ornish's Beverage Study Protocol II Study ("BEV II Study"), Dr. Ornish estimated that he would need at least 200 patients to show a statistically significant difference, but due to funding, he was only able to recruit 73 patients, of whom 56 ended up providing pre and post data on. (Ornish, Tr. 2351-52).

Response to Finding No. 591:
Complaint Counsel does not disagree Dr. Ornish testified as such, but notes that Dr. Ornish admits that his hypothesis that he would have shown a significant effect if he had been provided funding for 200 patients is speculation on his part. (CCFF ¶ 872).

592. As a result, Dr. Ornish was able to show an improvement in the carotid artery significant to the 0.13 level as opposed to the 0.15 level. If that degree of change had occurred in the larger number of patients he had initially projected, "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." (Ornish, Tr. 2352-53).

Response to Finding No. 592:

The proposed finding is incomplete. Dr. Ornish testified that "what's unfortunate and perhaps a little ironic is that we did show in *one* of the measures in the carotid artery that there was an improvement, and it was significant to the 0.13 level as opposed to the 0.15 level." (Ornish, Tr. 2352-2353) (emphasis added).

593. With the 73 patients, they showed a definite benefit but did not reach statistical significance. (Ornish, Tr. 2354).

Response to Finding No. 593:
Complaint Counsel does not disagree. (*See* CCFF ¶ 864 (noting additional analysis found nothing significant but several positive "trends")).

594. Dr. Ornish was confident that had he recruited and tested the number of patients in the protocol he originally planned, he would have reached statistical significance because there is no reason to think the next 127 patients would have been different than the first 73. (Ornish, Tr. 2353-54).

Response to Finding No. 594:
Complaint Counsel agrees Dr. Ornish testified as such, but notes this is Dr. Ornish's hypothesis and he admits this is speculation on his part. (CCFF ¶ 872).

595. Similarly, with regard to the Forest/Padma-Nathan RCT Study, which was a percentage point shy of being statistically significant, a larger number of participants may have helped with achieving overall statistical significance. (CX1338 (Padma-Nathan, Dep. at 108-109); PX0349 (Burnett, Dep. at 138 -141); CX1337 (Forest, Dep. at 76); Goldstein, Tr. 2598-99; Heber, Tr. 2001; CX0908_0001).

Response to Finding No. 595:
The proposed finding is unsupported by the cited evidence.

596. Further, 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)).

Response to Finding No. 596:
The proposed finding mischaracterizes the evidence. More accurately, Dr. deGroof and Dr. Davidson's testimony explained that a study population in a clinical trial may require a specific health condition that the study is designed to test in order to see a benefit from the treatment for that health condition. Dr. deGroof's testimony was in response to a

question asked about prerequisite characteristics of the study population in the protocol for the San Diego Study requiring certain levels of BMI and waist measurements. (CX1345 (deGroof, Dep. at 63-66)). Dr. Davidson testified that "to see an effect of an antioxidant therapy like pomegranate, you need to use it in the population that has high oxidative stress . . . the more likely you're going to see a benefit with the treatment." (CX1336 (Davidson, Dep. at 228-229)).

597. 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)).

Response to Finding No. 597:
The proposed finding mischaracterizes the evidence. *See* Response to Finding 596.

598. A benefit or change effected by an intervention on sick patients may be more easily and timely identified. (CX1345 (deGroof, Dep. at 63-66); CX1336 (Davidson Dep. at 228-229)).

Response to Finding No. 598:
The proposed finding mischaracterizes the evidence. *See* Response to Finding 596.

B. The Lack of a Statistically Significant Result Does Not Undermine the Value of the Study and Does Not Mean That Experts Cannot Rely Upon the Study to Infer a Casual Link

599. Complaint Counsel argues under-powered studies should be disregarded in their entirety. (CX1287_0012, 0014; CX1289_0004, 0008, 0010, 0012, 0015; CX1291_0012-0013, 0035, 0038; CX1293_0020-0021; Stampfer, Tr. at 710-11; Melman, Tr. at 1092; Eastham, Tr. at 1273; Sacks, Tr. at 1440).

Response to Finding No. 599:
The proposed finding mischaracterizes Complaint Counsel's position and the cited evidence. Rather, experts agree that a well-designed RCT should have a sufficient sample size to be able to produce clinically significant results and a statistical significance of $p \leq .05$, to prove or disprove a hypothesis. (CCFF ¶¶ 778-79; CX1287 (Eastham, Report at 0012, 14); CX1289 (Melman, Report at 0004); CX1291 (Sacks, Report at 0012-13, 35, 38); Stampfer, Tr. at 710-11; Melman, Tr. 1092, 1102-03, 1109;

Eastham, Tr. 1273; Sacks, Tr. 1440; Ornish, Tr. 2340)). Only if the results of the treatment group are statistically significant from those of the control group at the end of trial can it be concluded that the test product is effective. (CCFF ¶ 778).

600. "Statistical significance" occurs when the results of a study have a p-value of .05 or less, meaning that the results would occur by chance less than 5 times out of a hundred or that there is a 95 percent probability of validity as opposed to chance. (CX1342 (Hill, Dep. at 100); Ornish, Tr. at 2340)).

Response to Finding No. 600:
Complaint Counsel agrees. (*See* CCFF ¶ 779). Complaint Counsel objects to Dr. Hill's testimony insofar as he offers expert opinion testimony. Dr. Hill was not qualified as an expert, and indeed, Respondents did not produce him for examination at trial, although he was identified on Respondents' witness list. Accordingly, pursuant to Federal Rule of Evidence 701, his testimony must be disregarded to the extent that he attempts to offer opinions that are based on scientific, technical, or other specialized knowledge within the scope of Federal Rules of Evidence 702.

601. A "power calculation" occurs when one designs a clinical study to determine the number of participants required to show a statistically significant difference between the treatment group and control group. (Liker,Tr. 1884-85).

Response to Finding No. 601:
Complaint Counsel has no specific response.

602. A study would require fewer participants in order to demonstrate a benefit in a statistically significant manner where that test is expected to produce dramatic results. (Liker, Tr. 1885).

Response to Finding No. 602:
Complaint Counsel has no specific response.

603. Respondents dispute that under-powered studies should be disregarded in their entirety and have presented significant, contrary testimony and evidence that a benefit can be shown from a study without reaching statistical significance. (PX0352 (Goldstein, Dep. at 108-109); Goldstein, Tr. at 2599; PX0189-0013; PX0361 (Sacks, Dep. at 109); CX1350 (Liker, Dep. at 190-191); PX0149-0006; PX0161-0010; Heber, Tr. at 1979; Burnett, Tr. 2255-56; PX0349 (Burnett, Dep. at 138-139)).

Response to Finding No. 603:

The propose finding is unsupported by the cited evidence that Respondents have presented significant "testimony and evidence that a benefit can be shown from a study without reaching statistical significance." On the contrary, Respondents' cited evidence predominately concerns one study, the Forest Erectile Dysfunction Study, which is only "suggestive evidence" that POM Juice would benefit people with this condition. (CCFF ¶ 1090; *see also* CCFF ¶ 1088 (Respondents' experts agree pomegranate juice does not treat, prevent, or reduce the risk of erectile dysfunction)). With regard to Dr. Heber's cited testimony, he testified that a study that did not reach statistical significance "would be strong evidence to now go pursue that lead in a future study with a larger number of subjects." (Heber, Tr. 1979). The cited evidence, PX0161-0010 and PX0361 (Sacks, Dep. at 109), also do not supported the proposed finding. (*See also* CCFF ¶¶ 779, 782).

604. A lack of statistical significance for a positive result is not proof of the opposite or that pomegranate juice has no beneficial effect. (Sacks, Tr. 1608-09; CX1352 (Heber, Dep. at 218); PX0361 (Sacks, Dep. at 223-224, 230, 238, 243); Goldstein, Tr. 2598-99)).

Response to Finding No. 604:

The proposed finding is incomplete. Dr. Sacks agreed that a lack of a statistical significant result means that pomegranate juice was not proven to work in this study. (Sacks, Tr. 1609). Dr. Sacks also testified that when "[p]roving the negative I suppose would be a safety analysis but an efficacy analysis you have to prove the positive . . . if they don't show an effect then you don't have anything . . . to show that it works." (PX0361 (Sacks, Dep. at 223-24)). He also testified that "failure to reach [statistical significance] is simply evidence that in that population and that sample size there is not benefit of the treatment." Dr. Goldstein only testified that the Forest Erectile Dysfunction Study showing results of 94% significance "provides valuable information."

(Goldstein, Tr. at 2599). The cited evidence, CX1352 (Heber, Dep. at 218), does not support the finding.

605. Using statistical significance as the primary gauge in the determination on whether or not pomegranate juice offers a beneficial health property is an arbitrary and unnecessary convention. (Ornish, Tr. at 2340).

Response to Finding No. 605:
Complaint Counsel disagrees. Evaluating data from a clinical trial for statistical significance is the standard practice to demonstrate that a study's hypothesis has been proven and that the result was less likely to have occurred by mere chance. (*See* CCFF ¶ 779).

606. A study may show clinically significant results even where statistical significance is not reached. (PX0352 (Goldstein, Dep. at 108-109); Goldstein, Tr. at 2599; PX0189-0013; PX0361 (Sacks, Dep. at 109); PX0349 (Burnett, Dep. at 138-139)).

Response to Finding No. 606:
The proposed finding is unsupported by PX0361 (Sacks, Dep. at 108-109) or PX0349 (Burnett, Dep. at 138-139)). Dr. Sacks testified that "everything that is clinically significant will be statistically significant but everything that is statistically significant may not necessarily have a clinical impact or be clinically significant." (PX0361 (Sacks, Dep. at 108-109)). "Clinical significance" means that the treatment makes a real difference in a patient's life. (CCFF ¶ 782).

607. 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 off this number can still evidence a clinically meaningful benefit that is scientifically supportable. (PX0352 (Goldstein Dep. at 108-109); Goldstein, Tr. 2599; PX0189-0013; PX0361 (Sacks, Dep. at 109); (Sacks, Tr. at 1608-09).

Response to Finding No. 607:
Complaint Counsel disagrees with this proposed finding that "there is no evidence or argument suggesting that a p-value significantly greater than .05 can show a benefit." On the contrary, record evidence shows that experts, including Respondents' experts, agree

that a well-designed RCT should have a sufficient sample size to be able to produce clinically significant results and a statistical significance of $p \leq .05$, to prove or disprove a hypothesis. (CCFF ¶¶ 778-79; Ornish, Tr. at 2340)). Only if the results of the treatment group are statistically significant from those of the control group at the end of trial can it be concluded that the test product is effective. (CCFF ¶ 778). With regard to Respondents' cite to Sacks, Tr. at 1608-09, Dr. Sacks agreed that a lack of statistical significance is not proof of a negative, but he also testified that "it [ ] means we didn't prove that [pomegranate juice] worked in this experiment." Complaint Counsel agrees that Respondents have presented no evidence suggesting that their studies have reached a *p*-value significantly greater that .05 to show that POM Products treat, prevent, or reduce the risk of a heart disease, prostate cancer or erectile dysfunction.

608. A lack of statistically 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. *Matrixx Initiatives, Inc. v. Siracusano*, 131 S.Ct. 1309, 1319 (2011) ("A lack of statistically significant data does not mean that medical experts have no reliable basis for inferring a causal link between a drug and adverse events."); *Pearson v. Shalala*, 130 F.Supp.2d 105, 130 (D.D.C 2001) ("The mere absence of significant affirmative evidence in support of a particular claim . . . does not translate into negative evidence "against" it.").

Response to Finding No. 608:

The proposed finding is a legal conclusion, which is not supported by any reference to the record in violation of the Court's Order on Post-Trial Briefs.

609. Evidentiary support for POM's advertising claims should not be so narrowly limited as to include only research whose end result reaches statistical significance. *Matrixx Initiatives, Inc. v. Siracusano*, 131 S. Ct. 1309, 1319-1320 (2011) ("Medical professionals and researchers do not limit the data they consider to the results of randomized clinical trials or to statistically significant evidence."); *Pearson v. Shalala*, 130 F.Supp.2d 105, 130 (D.D.C 2001) ("The mere absence of significant affirmative evidence in support of a particular claim . . . does not translate into negative evidence "against" it.").

Response to Finding No. 609:

The proposed finding is a legal conclusion, which is not supported by any reference to the record in violation of the Court's Order on Post-Trial Briefs.

C. The Absence of a Statistically Significant or Positive Result Does Not Prove the Opposite Conclusion

610. Complaint Counsel's experts dispute the health benefits of the Challenged Products because Respondents' scientific research did not produce statistically significant changes in certain and/or all of their studies. (Melman, Tr. 1130-31; Sacks, Tr. 1488-89, 1507, 1512-13, 1516-19).

Response to Finding No. 610:
The proposed finding mischaracterizes the cited evidence. Complaint Counsel's experts testified that Respondents' research that did not produce statistically significant results showed that POM Products did not treat, prevent, or reduce the risk of heart disease, prostate cancer, or erectile dysfunction. (CCFF ¶¶ 950-65).

611. Dr. Heber testified, however, that not finding a statistically significant positive result in a study does not prove the negative; or in other words, the absence of evidence is not evidence of absence. (Heber, Tr. 1981; Sacks, Tr. 1608).

Response to Finding No. 611:
The proposed finding is incomplete. Dr. Heber also agreed that "if your hypothesis is not proved in a particular study, . . .it just means you didn't prove it in that study." (Heber, Tr. 1981). Dr. Sacks agreed that "not finding a statistically significant positive result in a study does not prove the negative" but "it [ ] means we didn't prove that [pomegranate juice] worked in this experiment." (Sacks, Tr. at 1608-1609).

612. If a hypothesis is not proven in a particular study, it does not mean the hypothesis is wrong; it just means that it was not proven in that study. (Heber, Tr. 1981).

Response to Finding No. 612:
Complaint Counsel does not disagree.

613. In science, this is called a Type II error which means there may have been a statistically significant difference, but the sample size was not sufficiently large to detect it. (PX0025-0019; CX1339 (Ornish, Dep. at 70-71)).

Response to Finding No. 613:

Complaint Counsel does not disagree Dr. Ornish stated as such.

614. Complaint Counsel's own expert, Dr. Sacks, concedes that the lack of statistical significance for a positive result is not proof of a negative and does not suggest that pomegranate juice does not cause the intended result. (Sacks, Tr. 1608) (emphasis added).

Response to Finding No. 614:
The proposed finding mischaracterizes the cited evidence. Dr. Sacks did not say that a lack of statistical significance "is not proof of a negative and does not suggest that pomegranate juice does not cause the intended result." Rather, he said that a lack of statistical significance is not proof of a negative, but "it [ ] means we didn't prove that [pomegranate juice] worked in this experiment." (Sacks, Tr. at 1608-09).

615. Complaint Counsel allege that Respondents deliberately violated the FTCA by continuing to make false and misleading representations after studies by Dr. Davidson, Dr. Ornish, and others purportedly "showed no significant difference[s]" following the consumption of pomegranate juice. (CX1426_0017-0018).

Response to Finding No. 615:
The proposed finding mischaracterizes the allegation. The Complaint alleges that "[a]s early as May 2007, respondents knew that . . . [the Davidson Study] showed no significant difference after 18 months . . . Respondents continue to tout POM Wonderful's cardiovascular research and benefits despite the negative results in the Davidson Study." (CX1426_00017). The Complaint also alleges that Respondents represented that clinical studies, research, and/or trial prove that POM Products, treat, prevent, or reduce the risk of heart disease, however, "the Davidson Study showed no significant difference between consumption of pomegranate juice and a control beverage in carotid intima-media thickness progress rates after 18 months; two smaller studies funded by POM Wonderful or its agents showed no significant difference . . . on measures of cardiovascular function; and multiple studies funded by POM . . . did not

show [POM Products] reduce blood pressure." (CX1426_00018). Respondents were aware of their inadequate science. (CCFF ¶¶ 952-53, 962-73,1044-54, 1096-1101).

616. Respondents, however, cannot have deliberately violated the FTCA merely because every study of POM's did not show a benefit, or a benefit by a statistically significant amount, when their scientific research on pomegranate juice and/or its extracts never showed the opposite hypothesis: that pomegranate juice and/or its extracts does not have a positive benefit. (Heber, Tr. 1981; PX0025-0019; Sacks, Tr. 1608-09).

Response to Finding No. 616:
The proposed finding is a legal argument and is unsupported by the cited evidence.

617. Respondents position on this issue is consistent with case law on the subject. *Matrixx Initiatives, Inc. v. Siracusano*, 131 S. Ct. 1309, 1319-1320 (2011) ("Medical professionals and researchers do not limit the data they consider to the results of randomized clinical trials or to statistically significant evidence."); *Pearson v. Shalala*, 130 F.Supp.2d 105, 130 (D.D.C 2001) ("The mere absence of significant affirmative evidence in support of a particular claim . . . does not translate into negative evidence "against" it.").

Response to Finding No. 617:
The proposed finding is a legal argument, which is unsupported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs.

D. RCTs Are Not Required to Substantiate the Health Benefits of Natural Foods Such as the Challenged Products

618. A harmless pure fruit juice, like pomegranate juice, which is not urged as a substitute for proper medical treatment, does not require RCTs to substantiate health claims. (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).

Response to Finding No. 618:
Complaint Counsel disagrees with the conclusion drawn. The level of evidence required depends on the claim being made; such as for claims that a product can treat, prevent, or reduce the risk of a disease, RCTs are "the best study design that permits a strong causal inference concerning the relationship between an administered agent (whether a drug or nutrient) and any specific outcome." (CX1293 (Stampfer, Report at 30); Stampfer, Tr.

830-31 ("If the claim implies that a causal link has been established, then you have to have evidence to back it up."); CCFF ¶¶ 1102-08)).

The proposed finding is not supported by Burnett, Tr. 2272-74, 2303 or Goldstein, Tr. 2600-02. Dr. Burnet testified that if the claim is not about treatment, then an RCT would not be necessary. (Burnett, Tr. 2272-74, 2303). Dr. Goldstein testified that he "[didn't] know that we actually do need to use the standards for pharmacologic drug development with natural fruit juice nutraceutical[.]" (Goldstein, Tr. 2600-02).

619. The level and rigor of substantiation of a health claim is quite different for a food than it is for the approval of a new drug designed for a specific disease indication. (PX0206-0013-0015).

Response to Finding No. 619:
This proposed finding is incomplete. Respondents' expert Dr. Miller agrees that the claim being made about a product is relevant to the level of substantiation required. (Miller, Tr. 2915). For claims that a product can treat, prevent, or reduce the risk of a disease, RCTs are "the best study design that permits a strong causal inference concerning the relationship between an administered agent (whether a drug or nutrient) and any specific outcome." (CX1293 (Stampfer, Report at 0030); Stampfer, Tr. 830-31 ("If the claim implies that a causal link has been established, then you have to have evidence to back it up."); CCFF ¶¶ 1102-08)).

620. A food, like pomegranate juice, is not a drug or a concoction of other herbs and therefore does not require a RCT. (Miller, Tr. 2198-99).

Response to Finding No. 620:
Complaint Counsel does not disagree that Dr. Miller testified as stated, but notes that this is inconsistent with his further testimony in deposition and trial that he has no knowledge of how the POM products are manufactured other than his own assumptions. (PX0354

(Miller, Dep. at 131); Miller, Tr. 2213-14). Moreover, POM Juice is made out of concentrate and 85.4% water and does not contain fiber or vitamin C. (CCFF ¶¶ 125-26).

621. In fact, a RCT is almost unheard of in the food industry. (CX1338 (Padma-Nathan, Dep. at 196); Goldstein, Tr. 2601-02, 2613-14).

Response to Finding No. 621:
Complaint Counsel has no specific response, except to note that "[RCT] trials of reasonable size have been done with pomegranate[s] and show no benefit." (Stampfer, Tr. 836).

622. There is widespread scientific agreement that you look to the totality of science, which does not require RCTs, when determining whether a health claim about a food, like pomegranate juice, is supported by adequate scientific substantiation. (Miller, Tr. 2194; Heber, Tr. 1948-50, 2056, 2166, 2182; Ornish, Tr. 2327-31).

Response to Finding No. 622:
Complaint Counsel disagrees. 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. (CCFF ¶ 1102).

623. Complaint Counsel 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 claims. (PX0268-0016).

Response to Finding No. 623:
Complaint Counsel agrees.

624. Complaint Counsel's own expert, Professor Stampfer, testified that it is appropriate to rely upon evidence short of RCTs for claims regarding nutrients in food. (Stampfer, Tr. 830; PX0362 (Stampfer, Dep. at 73-79)).

Response to Finding No. 624:
The proposed finding mischaracterizes Dr. Stampfer's testimony. Dr. Stampfer testified that "if the health claim . . . presumes a causal link, then in many instances, you would do

a randomized trial." (Stampfer, Tr. 830). Dr. Stampfer further testified that reliance on evidence short of RCT trials "depends on what the claim is . . . [i]f the claim implies that a causal link has been established, then you have to have evidence to back it up." (Stampfer, Tr. 830-31).

625. Professor Stampfer conceded in trial that scientific evidentiary support for nutritional or dietary claims will necessarily be based on observational studies rather than RCT trials. (Stampfer, Tr. 834; PX0362 (Stampfer, Dep. at 73)).

Response to Finding No. 625:
The proposed finding mischaracterizes Dr. Stampfer's testimony. Dr. Stampfer clarifies that "necessarily" means that when claims will necessarily be based on observational studies, if RCTs are not feasible due to "practical constraints." (Stampfer, Tr. 834-35). Dr. Stampfer also testified that "it would have to reduce its claims to match the data . . . you don't just take the best data that you have and say, 'Well, this is the best data that I have so, therefore, I can claim a cause-and-effect relation.' You say, 'This is the best data I have, so, therefore I can claim this but not that.'" (Stampfer, Tr. 835). In addition, Dr. Stampfer testified that "[RCT] trials of reasonable size have been done with pomegranate[s] and show no benefit." (Stampfer, Tr. 836).

626. Professor Stampfer noted in deposition "[t]hat observational studies are superior to randomized trials depends on the context . . . . In principle, they would not be, if there is no limitation of resources, and feasibility issues . . . . There are feasibility limitations … in principle, the randomized trials are best, but as a practical matter, we have to rely on observational studies because of all the constraints that we discussed." (PX0362 (Stampfer, Dep. at 73-79)).

Response to Finding No. 626:
Complaint Counsel agrees Dr. Stampfer testified as such, but notes that in Dr. Stampfer's opinion RCTs make it "possible to conclude a causal link between the nutrient and disease under study." (PX0362 (Stampfer, Dep. at 99)).

627. Professor Stampfer notes that randomized, double-blind, and placebo-controlled clinical trial is not required to conclude a causal link regarding a nutrient and disease. (PX0362 (Stampfer, Dep. at 98)).

Response to Finding No. 627:
The proposed finding is unsupported by the cited evidence, but notes that in Dr. Stampfer's opinion, RCTs make it "possible to conclude a causal link between the nutrient and disease under study." (PX0362 (Stampfer, Dep. at 99); CCFF ¶ 771).

628. In his expert report, Professor Stampfer conceded 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." (CX1293_0029-0030).

Response to Finding No. 628:
The proposed finding is incomplete. Dr. Stampfer also states that "it is undisputable 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. For products such as POM Juice, POM[x] Pills and POM[x] Liquid, claims of efficacy can be made only when a causal relation with human disease is established. The Respondents have failed to provide such evidence." (CX1293 (Stampfer, Dep. at 29-30); CCFF ¶ 771).

629. Professor Stampfer agreed that evidence-based medicine is not restricted to RCTs. (Stampfer, Tr. 837).

Response to Finding No. 629:
Complaint Counsel does not disagree.

1. RCTs Are Sometimes Not Possible or Not Even Better in Evaluating the Health Benefits of a Food or Nutrient

630. Indeed, 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." (Stampfer, Tr. 831; see RX5007 Appendix A hereto).

Response to Finding No. 630:

The proposed finding is mischaracterizes the evidence, insofar as it is intended to support a conclusion that efficacy claims of the type made by Respondents do not require support in the form of RCTs. Complaint Counsel does not disagree that Dr. Stampfer made the cited statement with regard to the evidence required to support a *nutrient requirement or dietary guideline*. As Dr. Stampfer explains, public health recommendations such as these are made by groups of scientists coming together to consider the overall data. In formulating these, the scientists "sift through all of the available evidence . . . and come to a judgment. What can we tell people right now, who are making food choices, as to what they can do, to the best of our knowledge[.]" (Stampfer, Tr. 794). Based on this, the recommendations state things like, "eat more fruits and vegetables." (Stampfer, Tr. 792-93). He also stated that "[t]his advice should distinguish recommendations based on good evidence of a causal relation from those that are based on evidence that is suggestive but falls short of a firm causal connection. (CX1293 (Stampfer, Report at 0030)). Dr. Stampfer consistently made clear that RCTs are needed to show a causal relationship between consumption of a food or nutrient and an endpoint. Indeed, Dr. Stampfer's article states that "it is indisputable that the RCT . . . is the clinical study design that best permits strong causal inference concerning the relationship between an administered agent (whether drug or nutrient) and any specific outcome. Both drug indications and health claims for nutrients that are backed by one or more well-conducted RCTs are appropriately considered to have a more persuasive evidence base than corresponding claims based primarily upon observational data." (RX5007 at p. 479). Finally, RX5007 makes clear that in the absence of RCTs, "evidence with respect to nutrients and nonindex diseases will continue . . . to be observational studies." (RX5007

at page 480). Currently, there are no observational data on pomegranates, pomegranate juice, or extracts. (Heber, Tr. 2168). The article also describes the "level of certainty of evidence provided by various study designs" which are all human study designs—RCTs being the best evidence and two kinds of observational studies. (*See* Table 1 of RX5007 at p. 482; Heber, Tr. 2171).

631. In the article, Professor Stampfer stated that "certain features of [evidence-based medicine] seem ill-suited to the nutrition context." (see RX5007 Appendix hereto).

Response to Finding No. 631:
See Response to Finding 630.

632. Professor Stampfer noted that "[n]utrients are orders of magnitude less expensive than drugs and often exhibit a broader margin between efficacy and toxicity." (see RX5007 Appendix hereto).

Response to Finding No. 632:
Complaint Counsel does not disagree that the article states such, but notes that the article also states that "[t]his is not to suggest that the standards of what constitutes proof ought to be relaxed for nutrients." (RX5007 at p. 481).

633. Professor Stampfer specifically opined that RCTs may not be appropriate for nutrient recommendations to prevent disease, as distinguished from testing drugs used to treat disease. (see RX5007 Appendix hereto).

Response to Finding No. 633:
The proposed finding is unsupported by the cited evidence. *See also* Response to Finding 630.

634. 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." (see RX5007 Appendix hereto; PX0362 (Stampfer, Dep. at 78)).

Response to Finding No. 634:
The proposed finding is incomplete. The article continues to explain that, "[n]evertheless, it is indisputable that the RCT, in one of its variant forms, is the clinical study design that best permits strong causal inference concerning the relationship between an administered agent (whether drug or nutrient) and any specific outcome. Both drug indications and health claims for nutrients that are backed by one or more well-conducted RCTs are appropriately considered to have a more persuasive evidence base than corresponding claims based primarily upon observational data." (RX5007 at p. 479). Complaint Counsel also notes that Respondents represented that their advertising claims were supported by RCTs. (*See* CCFF, Section V.D. - V.E; *see e.g.,* CCFF ¶¶ 1121-22). Therefore, 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, RCTs. (CCFF ¶¶ 1102, 1108).

635. Professor Stampfer also testified that another difference between nutrients and pharmaceutical drugs is that no exclusive intellectual property rights (like a pharmaceutical patent) will result from a trial. (PX0362 (Stampfer, Dep. at 78)).

Response to Finding No. 635:
Complaint Counsel does not disagree Dr. Stampfer testified as such.

636. Other constraints Professor Stampfer testified to include: (1) the difficulty to ensure that large numbers of participants adhere to an altered diet over long-term periods; and (2) that ethical principles do not permit randomizing individuals to diets that may have negative health effects. (PX0362 (Stampfer, Dep. at 75-76)).

Response to Finding No. 636:

Complaint Counsel does not disagree Dr. Stampfer testified as such, but notes the article stated that, "[n]evertheless, it is indisputable that the RCT, in one of its variant forms, is the clinical study design that best permits strong causal inference concerning the relationship between an administered agent (whether drug or nutrient) and any specific outcome. Both drug indications and health claims for nutrients that are backed by one or more well-conducted RCTs are appropriately considered to have a more persuasive evidence base than corresponding claims based primarily upon observational data." (RX5007 at p. 479). In addition, Dr. Stampfer testified that "[RCT] trials of reasonable size have been done with pomegranate[s] and show no benefit." (Stampfer, Tr. 836).

637. For all these reasons, Professor Stampher indicated that "it seemed useful to suggest some ways to advance the current approach to [evidence-based nutrition in] ways which better reflect the unique features of nutrients and dietary patterns, and which also recognize the need to deal with uncertainty in situations in which evidence from RCTs might never be obtained." (see RX5007 Appendix hereto).

Response to Finding No. 637:
See Response to Finding 630.

638. In trial, Professor Stampfer testified that because of feasibility reasons, RCTs, will often not be reached for diet and nutritional substances. (Stampfer, Tr. 834).

Response to Finding No. 638:
The proposed finding is incomplete. Dr. Stampfer testified that "[w]hat I'm saying in the article is that we have to recognize that that high standard to which we should aspire, will . . . because of feasibility reasons, often not be reached for diet and nutritional substances . . . but this does not mean that we should fail to make recommendations based on the best possible evidence. We just need to distinguish the level of evidence that supports those recommendations." (Stampfer, Tr. 834). In addition, Dr. Stampfer testified that "[RCT] trials of reasonable size have been done with pomegranate[s] and show no benefit." (Stampfer, Tr. 836).

639. In the article, Professor Stampfer further noted that "it is unlikely that RCT evidence could feasibly or appropriately be produced with respect to the role of a nutrient for many nonindex-disease endpoints. Therefore, the majority of the evidence with respect to nutrients and nonindex diseases will continue, of necessity, to be derived from observational studies." (see RX5007 Appendix hereto).

Response to Finding No. 639:
Complaint Counsel does not disagree the article states such, but notes that the article also states that "it is indisputable that the RCT . . . is the clinical study design that best permits strong causal inference concerning the relationship between an administered agent (whether drug or nutrient) and any specific outcome." (RX5007 at p. 479). Currently, there are no observational data on pomegranates, pomegranate juice, or extracts. (Heber, Tr. 2168).

640. Professor Stampfer also testified that in a nutritional context, a hypothesis about disease causation can, rarely, if ever, be directly tested in humans using the RCT design. (Stampfer, Tr. 832-33; PX0362 (Stampfer, Dep. at 73, 98); see RX5007 Appendix hereto).

Response to Finding No. 640:
The proposed finding is mischaracterizes Dr. Stampfer's testimony. Dr. Stampfer testified that it may be rare but "not impossible." (Stampfer, Tr. 832). Dr. Stampfer also testified that "if you're going to make a claim based on an establishment of a causal link, then you need evidence that supports that type of claim." (Stampfer, Tr. 876). In addition, Dr. Stampfer testified that "[RCT] trials of reasonable size have been done with pomegranate[s] and show no benefit." (Stampfer, Tr. 836).

641. Professor Stampfer 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." (see RX5007 Appendix hereto).

Response to Finding No. 641:
Complaint Counsel does not disagree the article states such, but notes that Dr. Stampfer also testified that " the issue is making sound [public health] recommendations in the face

of imperfect information . . . which we have to do in the case of diet, because . . . everyone eats, so we want to give the best advice we can with the data at hand . . . the challenge is to distinguish between the findings where a causal link is established between a nutrient and a disease outcome and whether it's just based on lesser evidence . . . but if you're going to make a claim based on an establishment of a causal link, then you need evidence that supports that type of claim." (Stampfer, Tr. 876).

642. In the article, Professor Stampfer stated that "it seems clear that requiring RCT-level evidence to answer questions for which the RCT may not be an available study design will surely impede the application of nutrition research to public health issues." (see RX5007 Appendix hereto).

Response to Finding No. 642:
Complaint Counsel does not disagree the article states such, but notes that Dr. Stampfer testified that "[RCT] trials of reasonable size have been done with pomegranate[s] and show no benefit." (Stampfer, Tr. 836; s*ee e.g.,* CX1198 (Ornish MP Study); CX1065 (Davidson CIMT Study); *see also* CCFF ¶¶ 1119-30).

643. 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.'" (see RX5007 Appendix hereto).

Response to Finding No. 643:
Complaint Counsel does not disagree the article states such, but notes that the article also states that "it is indisputable that the RCT . . . is the clinical study design that best permits strong causal inference concerning the relationship between an administered agent (whether drug or nutrient) and any specific outcome." (RX5007 at p. 479). Complaint Counsel also notes that Respondents represented that their advertising claims were supported by RCTs. (*See* CCFF, Section V.D. - V.E; *see e.g.,* CCFF ¶¶ 1121-22). Therefore, 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, RCTs. (CCFF ¶¶ 1102, 1108).

644. Moreover, in the article, Professor Stampfer further 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." (see RX5007 Appendix hereto).

Response to Finding No. 644:
See Response to Finding 630.

645. Professor Stampfer 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. (Stampfer, Tr. 838).

Response to Finding No. 645:
Complaint Counsel does not disagree, but notes that Dr. Stampfer also testified that "[one] would have to reduce its claims to match the data . . you don't just take the best data that you have and say, 'Well, this is the best data that I have so, therefore, I can claim a cause-and-effect relation.' You say, 'This is the best data I have, so, therefore I can claim this but not that.'" (Stampfer, Tr. 835).

646. Dr. Heber agrees with Complaint Counsel's expert, Professor Stampfer, that in dealing with nutrients, RCTs are often infeasible and too expensive and that the drug standard should not be applied. (Heber, Tr. 1950; see RX5007 Appendix hereto).

Response to Finding No. 646:
Complaint Counsel does not disagree Dr. Heber testified as such, but notes that Dr. Heber also agreed that the article states, "[b]oth drug indications and health claims for nutrients that are backed by one or more well-conducted RCTs are appropriately considered to have a more persuasive evidence base than corresponding claims based primarily upon observational data." (Heber, Tr. 2168)

647. Also, 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. (PX0361 (Sacks, Dep. at 134-135)).

Response to Finding No. 647:

The proposed finding mischaracterizes Dr. Sacks' testimony. When asked whether one could "determine a causal influence between an agent and its effect on humans without the use of [RCTs]," Dr. Sacks testified "*no* but there are some very few exceptions." (PX0361 (Sacks, Dep. at 134-35) (emphasis added)).

648. 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. (Sacks, Tr. 1545-46).

Response to Finding No. 648:

The proposed finding is incomplete. Dr. Sacks testified that "DASH is a diet that was designed to lower blood pressure, and it utilized all the evidence available on foods and nutrients to lower blood pressure . . . this study showed that diets that are *high* in fruits and vegetables, *high* in whole grains, fish, *reduced* in sugar and sugar-sweetened beverages, *reduced* in refined carbohydrates *and* red meat, that diet. . .the diet that is now called the DASH diet, substantially lowered blood pressure compared to the control diet, which was sort of what people eat . . . an average American diet." (Sacks, Tr. 1417-18 (emphasis added)). He further testified, "We tested a diet that had a beneficial effect on *that* diet that had whole food and also some juice, but *we're not going out from the DASH study recommending any particular component. It's a total approach*." (Sacks, Tr. 1544) (emphasis added)). Dr. Sacks stated that although pomegranates were not specifically tested in the DASH diet (Sacks, Tr. 1617), he would include pomegranates as a kind of fruit that can be consumed as a part of the DASH diet (Sacks, Tr. 1546). He did not agree, however, that pomegranate juice fell into this same DASH fruit category. ((Sacks, Tr. 1549-55). Further, the finding is irrelevant as the advertising at issue is not for whole pomegranates but POM juice and supplements, which were advertised as

having unique benefits and not advertised as a fruit that could be consumed as part of the DASH diet.

649. Dr. Miller testified that if a fruit juice were claiming to prevent prostate cancer, and there was reliable scientific data to support that claim, you could make that claim without a RCT. (Miller, Tr. 2201).

Response to Finding No. 649:
Complaint Counsel does not disagree Dr. Miller testified as such, but disagrees with his conclusion. Experts agree that to substantiate a claim that a food or dietary supplement is effective in preventing or reducing the risk of prostate cancer, experts in the fields of prostate cancer would require at least one RCT involving an appropriate sample population and endpoint. (CCFF ¶ 974).

650. 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. (PX0149-0006-0007; Burnett, Tr. 2272-74, 2303; PX0189-0003; Goldstein, Tr. 2600-02, 2611, 2620).

Response to Finding No. 650:
The proposed finding mischaracterizes the evidence. Experts in the erectile dysfunction field would require RCTs before concluding that pomegranate juice treats, prevents or reduces the risk of erectile dysfunction. (CCFF ¶¶ 783, 1055, 1089, 1102; *see also* ¶ 1073). Respondents' and Complaint Counsel's experts testified that pomegranate juice has not been shown to treat erectile dysfunction in humans. (CCFF ¶¶ 1086-90). In addition, Dr. Burnett also testified that RCTs are the standard of evidence for evaluating erectile dysfunction treatment. (Burnett, Tr. 2264). Dr. Goldstein testified that articles he authored state that RCTs are the criterion standard for determining causality. (Goldstein, Tr. 2612-15). Dr. Burnett and Dr. Goldstein also testified that they did not offer any opinions regarding POMx Pills or POMx Liquid. (CCFF ¶¶ 750, 754).

651. 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 erectile dysfunction. (Burnett, Tr. 2272-74, 2303).

Response to Finding No. 651:
See Response to Finding 650.

652. Also, 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. (Heber, Tr. 1948-49, 2166, 2182).

Response to Finding No. 652:
Complaint Counsel agrees that Dr. Heber testified as such, but Complaint Counsel disagrees with the conclusion drawn. 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, double-blinded human clinical studies. (CCFF ¶¶ 1102, 1108). The level of evidence required depends on the claim being made; such as for claims that a product can treat, prevent, or reduce the risk of a disease, RCTs are "the best study design that permits a causal inference concerning the relationship between an administered agent (whether a drug or nutrient) and any specific outcome." (CX1293 (Stampfer, Report at 0030); Stampfer, Tr. 830-31 ("If the claim implies that a causal link has been established, then you have to have evidence to back it up."); CCFF ¶ 771).

653. In fact, 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. (Heber, Tr. 1948-49).

Response to Finding No. 653:
See Response to Finding 652.

654. Further, a study is not thrown out because it is does not have a placebo control. (PX0361 (Sacks, Dep. at 137); CX1342 (Hill, Dep. at 131)).

Response to Finding No. 654:

The proposed finding is incomplete. Dr. Sacks testified that "an uncontrolled study is a prelude to actually investigating it in a way to make a casual inference to which would be in a randomized controlled study." (PX0361 (Sacks, Dep. at 136)). He further testified that a study that is not placebo-controlled is a "considerably lower level of evidence" but it is "taken into account." (PX0361 (Sacks, Dep. at 137)). Complaint Counsel objects to Dr. Hill's testimony insofar as he offers expert opinion testimony. Dr. Hill was not qualified as an expert, and indeed, Respondents did not produce him for examination at trial, although he was identified on Respondents' witness list. Accordingly, pursuant to Federal Rule of Evidence 701, his testimony must be disregarded to the extent that he attempts to offer opinions that are based on scientific, technical, or other specialized knowledge within the scope of Federal Rules of Evidence 702.

655. 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, one group would receive the intervention while another group would receive a placebo. The results of both groups would then be compared. However, no one design is better than the other. (CX1342 (Hill, Dep. at 45)).

Response to Finding No. 655:

The proposed finding mischaracterizes Dr. Hill's testimony, and Complaint Counsel disagrees with the conclusion drawn. Dr. Hill was testifying about an email in which he explained that the intent the study plan was to look for trends and to set up a pilot study design. He testified that his unblinded, uncontrolled, pilot study would give them a "sense of what the effect is [to] allow [them] to design a placebo-controlled trial." (CX1342 (Hill, Dep. at 45-46)). Complaint Counsel objects to Dr. Hill's testimony insofar as he offers expert opinion testimony. Dr. Hill was not qualified as an expert, and indeed, Respondents did not produce him for examination at trial, although he was identified on Respondents' witness list. Accordingly, pursuant to Federal Rule of

Evidence 701, his testimony must be disregarded to the extent that he attempts to offer opinions that are based on scientific, technical, or other specialized knowledge within the scope of Federal Rules of Evidence 702.

656. 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. (CX1342 (Hill, Dep. at 131)).

Response to Finding No. 656:

The proposed finding mischaracterizes Dr. Hill's testimony, and Complaint Counsel disagrees with the conclusion drawn. Dr. Hill testified that to confirm the results of his unblinded, uncontrolled study he would choose either a placebo-controlled or pre/post study, but he also stated that "if money were unlimited, I would probably do a [placebo-controlled] crossover, where you give people POM, followed by a placebo, versus placebo followed by POM." (CX1342 (Hill, Dep. at 131)). Complaint Counsel objects to Dr. Hill's testimony insofar as he offers expert opinion testimony. Dr. Hill was not qualified as an expert, and indeed, Respondents did not produce him for examination at trial, although he was identified on Respondents' witness list. Accordingly, pursuant to Federal Rule of Evidence 701, his testimony must be disregarded to the extent that he attempts to offer opinions that are based on scientific, technical, or other specialized knowledge within the scope of Federal Rules of Evidence 702.

2. A Balancing of Factors Favors Disclosure of Potential Health Benefits to the Public in the Absence of RCTs

657. Respondent's expert, Dr. Miller, confirms that when a food product is absolutely a 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. (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).

Response to Finding No. 657:

Complaint Counsel does not disagree that Dr. Miller's testified generally as stated, but disagrees with his conclusions. (*See* CCFF ¶¶ 784, 974-77, 1055-61 (summarizing expert testimony on standard of evidence required for treat, prevent, or reduce the risk of disease claims)). Moreover, Dr. Miller also testified that the claim being made is relevant to the level of substantiation required. (Miller, Tr. 2195).

(a) Dr. Miller's Qualifications

658. Dr. Miller has been practicing medicine for over 50 years. (Miller, Tr. 2189, 2217).

Response to Finding No. 658:
Complaint Counsel has no specific response.

659. Dr. Miller is a board certified pediatrician and pediatric hematologist/oncologist and is licensed to practice medicine in the state of New Jersey. (PX0206-0001; PX0354 (Miller, Dep. at 16)).

Response to Finding No. 659:
Complaint Counsel has no specific response.

660. Dr. Miller is a Clinical Professor of Pediatrics at Robert Wood Johnson School of Medicine in New Brunswick, New Jersey. (PX0206-0001; PX0354 (Miller, Dep. at 12); Miller, Tr. 2189).

Response to Finding No. 660:
Complaint Counsel has no specific response.

661. Dr. Miller received his AB and MD degrees from Cornell University and completed his residency in Pediatrics and his research fellowship in Pediatric Hematology/Oncology at the Children's Hospital and Harvard Medical School in Boston. (PX0206-0001; Miller, Tr. 2189-90).

Response to Finding No. 661:
Complaint Counsel has no specific response.

662. Dr. Miller was captain in the Air Force as a physician. (Miller, Tr. 2190).

Response to Finding No. 662:
Complaint Counsel has no specific response.

663. Dr. Miller was a Fulbright Scholar and Exchange Registrar, St. Mary's Hospital Medical School and University of London, in London, England. (PX0206-0001).

Response to Finding No. 663:
Complaint Counsel has no specific response.

664. Dr. Miller is an expert in the design of clinical research protocols. (Miller, Tr. 2218).

Response to Finding No. 664:
Complaint Counsel has no specific response.

665. 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. (PX0206-0001; Miller, Tr. 2190).

Response to Finding No. 665:
Complaint Counsel has no specific response.

666. Dr. Miller's major area of clinical and laboratory research when he was 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. (PX0206-0002).

Response to Finding No. 666:
Complaint Counsel has no specific response.

667. Dr. Miller was the recipient of research grants from the National Cancer Institute, private foundations, and other organizations. (PX0206-0002).

Response to Finding No. 667:
Complaint Counsel has no specific response.

668. Dr. Miller, as Chairman of the Department of Pediatrics at MSKCC, directed one of the largest pediatric oncology/hematology programs in the world and held an endowed chair. (PX0206-0002).

Response to Finding No. 668:
Complaint Counsel has no specific response.

669. Dr. Miller, as Chairman of the Department, was heavily engaged in the entire gamut of Phase I through Phase IV research and in non-clinical studies of mechanisms of action of new agents and the biology and molecular pathology of cancer. (PX0206-0002).

Response to Finding No. 669:
Complaint Counsel has no specific response.

670. Many of those investigational agents are now cornerstones of anticancer therapy. (PX0206-0002).

Response to Finding No. 670:
Complaint Counsel has no specific response.

671. Currently, Dr. Miller is the Global Therapeutic Area Leader of Oncology/Hematology at PAREXEL International, one of the world's leading contract research organizations ("CRO") where he leads a twenty member team of full-time oncologists and hematologists who work in clinical drug development, in cancer and in blood diseases. (PX0206-0001; PX0354 (Miller, Dep. at 12)).

Response to Finding No. 671:
Complaint Counsel has no specific response.

672. CROs, and PAREXEL in particular, manage clinical research trials for the pharmaceutical and biotechnology industries and provide them with scientific and medical consultative services and technical and regulatory guidance to facilitate the successful development of new products to treat patients with a wide variety of illnesses and to facilitate the regulatory approval and marketing authorization of these new medications. (PX0206-0001; PX0354 (Miller, Dep. at 12)).

Response to Finding No. 672:
Complaint Counsel has no specific response.

673. A large number of these clinical trials are focused on targeted therapy for prostate cancer, including men who have undergone prostatectomy or radiation therapy but who have "biochemical recurrence" with a rising PSA level. (PX0206-0004).

Response to Finding No. 673:
Complaint Counsel has no specific response.

674. The objective of these studies is to delay the development of locally recurrent or metastatic disease, not necessarily to prolong survival. (PX0206-0004).

Response to Finding No. 674:
Complaint Counsel has no specific response.

675. Dr. Miller served as Vice-Chairman of the Children's Cancer Group (CCG, now COG), the world's first and largest cooperative group organized to treat children with cancer and discover more effective and safer therapies for them. (PX0206-0002).

Response to Finding No. 675:
Complaint Counsel has no specific response.

676. The marked improvement in the survival and cure of children with cancer is attributable in part to the endeavors of CCG/COG and was accomplished with randomized clinical trials. (PX0206-0002).

Response to Finding No. 676:

Complaint Counsel has no specific response.

677. Randomized double-blind, placebo-controlled studies were not the standard, were not required by the NCI or other regulatory agencies, and were not performed to establish that a new regimen was superior to the old standard. (PX0206-0002).

Response to Finding No. 677:
Complaint Counsel has no specific response.

678. From 1990 to 1996, Dr. Miller served as Associate Medical Director of Cancer Treatment Centers of America ("CTCA") and from 1993 to 1996 was the Scientific Director of CTCA's Cancer Treatment Research Foundation. (PX0206-0002-0003; Miller, Tr. 2191).

Response to Finding No. 678:
Complaint Counsel has no specific response.

679. In both capacities, Dr. Miller was involved actively in designing clinical research protocols for adults with a wide variety of malignancies, including prostate, breast, colorectal, and lung cancer, the four most common cancers in humans. (PX0206-0002-0003; Miller, Tr. 2191).

Response to Finding No. 679:
Complaint Counsel does not disagree that Dr. Miller stated as such, but notes that he has never designed clinical research protocols for foods and has never been involved in designing clinical trial to prevent cancer in healthy people. (Miller, Tr. 2218).

680. Dr. Miller, as Scientific Director, supervised the clinical research program, chaired the Scientific Advisory Committee of the Institutional Review Board, and was principal investigator for a number of Phase I/II studies of cancer treatments, including the common malignancies mentioned above. (PX0206-0002-0003).

Response to Finding No. 680:
See Response to Finding 679.

681. These Phase I/II studies included innovative treatment for a wide variety of solid tumors and hematologic malignancies, including new combinations of chemotherapy, immunotherapy, targeted therapy, supportive care to ameliorate the side effects of conventional anticancer therapy, nutritional and psychosocial support, and alternative and complementary medicine. (PX0206-0003).

Response to Finding No. 681:
Complaint Counsel has no specific response.

682. Since joining the pharmaceutical/biotechnology industry, one of Dr. Miller's major responsibilities and activities has been to be familiar with the process of regulatory approval and post-approval fulfillment requirements. (PX0206-0003).

Response to Finding No. 682:
Complaint Counsel does not disagree that Dr. Miller's report stated as such, but notes that his familiarity is with the process of the FDA's regulatory approval and post-approval fulfillment requirements for pharmaceutical and biotechnology drug treatments. (Miller, Tr. 2216-17). He testified he is not familiar with the FDA's regulations governing health claims for foods. (Miller, Tr. 2217).

683. Dr. Miller has participated in meetings with the FDA and EMEA at each phase of the drug development process, including pre-IND (Investigational New Drug), protocol submission and review, end Phase II meetings, Special Protocol Assessment (SPA), submission of dossiers for approval of pivotal trials, and presentations to ODAC (Oncology Drug Advisory Committee) that advises the FDA regarding the approval of a new anticancer agent. (PX0206-0003).

Response to Finding No. 683:
Complaint Counsel has no specific response.

684. Dr. Miller has presented progress reports and has participated in special informational advisory meetings with national regulatory authorities in the United Kingdom, Sweden, France, Denmark, and Germany at which specific questions relating to a drug development strategy or a specific clinical trial are posed by the sponsor and discussed with an expert panel of regulators. (PX0206-0003).

Response to Finding No. 684:
Complaint Counsel has no specific response.

685. Dr. Miller has performed or managed numerous studies in early (Phase I) and later (Phase II through Phase IV) clinical development of new agents for the treatment of cancer and blood diseases. (PX0206-0003).

Response to Finding No. 685:
Complaint Counsel has no specific response.

686. For the past 10 years, Dr. Miller, has been involved in the clinical development of newer anticancer agents called "targeted therapies" because they are directed against receptors, growth factors, or signal transduction pathways that drive the oncogenic genotype and cause cancer cells to behave abnormally and independent of control mechanisms that keep normal cells normal. (PX0206-0003-0004).

Response to Finding No. 686:
Complaint Counsel has no specific response.

687. Dr. Miller in his capacity as Therapeutic Area Leader of Oncology/Hematology at PAREXEL is involved in the entire process of testing and evaluating new agents designed to treat cancer and blood issues.

Response to Finding No. 687:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel has no specific response.

688. A large number of these clinical trials are focused on targeted therapy of prostate cancer, including mean who have undergone prostatectomy or radiation therapy but who have "biochemical recurrence" with a rising PSA level.

Response to Finding No. 688:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel has no specific response.

689. The objective of these studies is to delay the development of locally recurrent or metastatic disease, not necessarily to prolong survival.

Response to Finding No. 689:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel has no specific response.

690. Many of these targeted therapies that give cancer cells a survival advantage, increase their rates of proliferation, multiplication, local spread, and distant metastases, and render them resistant to anticancer therapy. (PX0206-0004).

Response to Finding No. 690:
Complaint Counsel has no specific response.

691. Dr. Miller is currently a member of the American Society of Clinical Oncology, the American Association for Cancer Research, and the American Society of Hematology. (PX0206-0004).

Response to Finding No. 691:
Complaint Counsel has no specific response.

692. Dr. Miller was founding member and past president of the American Society of Pediatric Hematology/Oncology. (PX0206-0004).

Response to Finding No. 692:

Complaint Counsel has no specific response.

693. Dr. Miller was elected to the Society for Pediatric Research, and the American Pediatric Society, societies that recognize one's contributions to pediatric research. (PX0206-0004).

Response to Finding No. 693:
Complaint Counsel has no specific response.

694. Dr. Miller served on the editorial boards of the British Journal of Haematology, the American Journal of Clinical Oncology (Associate Editor, Pediatric Oncology), and the American Journal of Pediatric Hematology/Oncology (co-founder and Associate Editor). (PX0206-0004; Miller, Tr. 2191).

Response to Finding No. 694:
Complaint Counsel has no specific response.

695. Dr. Miller continues to review submitted manuscripts for the British Journal of Hematology. (PX0206-0004).

Response to Finding No. 695:
Complaint Counsel has no specific response.

696. Dr. Miller has authored or co-authored over 300 book chapters, peer-reviewed articles, and abstracts mostly on cancer and blood disorders. (PX0206-0004; Miller, Tr. 2191).

Response to Finding No. 696:
Complaint Counsel has no specific response.

697. Dr. Miller was senior editor to four editions of a classic textbook, *Blood Diseases of Infancy and Childhood*. (PX0206-0004).

Response to Finding No. 697:
Complaint Counsel has no specific response.

698. 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. (PX0206-0005).

Response to Finding No. 698:
Complaint Counsel does not disagree that Dr. Miller's report stated as such, but notes that

he has not treated *prostate* cancer patients in his responsibilities as a practicing physician

or published any articles about the results of *prostate* cancer treatments. (PX0354 (Miller, Dep. at 17, 21)).

699. This knowledge comes from a professional life devoted to patient care and involvement in the various processes, phases, and stages of clinical drug development. (PX0206-0005).

Response to Finding No. 699:
See Response to Finding 698.

700. Thus, based on his training, experience, and ongoing clinical activities, Dr. Miller is well qualified to offer expert opinion in this case. (PX0206-0005).

Response to Finding No. 700:
Complaint Counsel has no specific response, but notes that he was offered as an expert only as to the applicable standards for substantiating evidence for fruit, fruit juice, or food products in general, and not to testify about the scientific studies on POM products. (Miller, Tr. 2192).

(b) Substantiation for Food Products

701. Dr. Miller offers 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).

Response to Finding No. 701:
The proposed finding is unsupported by the cited evidence. In the cited transcript page, Dr. Miller testified that his familiarity *with FDA regulatory requirements* is based on his experience. (Miller, Tr. 2217).

702. It is Dr. Miller's expert opinion that the critical issue is whether a pure food and its derivative require the same standard of substantiation as a drug. (PX0206-0007).

Response to Finding No. 702:
Complaint Counsel has no specific response.

703. The key question for that determination is safety. (PX0206-0007).

Response to Finding No. 703:

Complaint Counsel does not disagree that Dr. Miller's report stated as such, but disagrees with his conclusion. (*See* CCFF ¶¶ 784, 974-77, 1055-61 (summarizing expert testimony on standard of evidence required for treat, prevent, or reduce the risk of disease claims)). Moreover, Dr. Miller also testified that the claim being made is relevant to the level of substantiation required. (Miller, Tr. 2195).

704. If the product is a whole food or a derivative of a whole food and it is obviously safe there should be a cost benefit analysis to determine whether it makes sense to report possible, or probable benefits of consumption and to err on the side of giving more information to the public and medical community, so long as the claim does not suggest (by use of absolutes or in other ways) that an individual should forgo conventional medical care or treatment based on the consumption of the product and the underlying science is valid. (PX0206-0007-0008).

Response to Finding No. 704:
Complaint Counsel does not disagree that Dr. Miller's report stated as such, but disagrees with his conclusion. (*See* CCFF ¶¶ 784, 974-77, 1055-61 (summarizing expert testimony on standard of evidence required for treat, prevent, or reduce the risk of disease claims)).

705. It is Dr. Miller's expert opinion that in dealing with a food product, as opposed to a drug, flexibility should be the guiding principle in determining what is required to comply with the term "sufficient substantiation" of claims of any health benefits. (PX0206-0008).

Response to Finding No. 705:
Complaint Counsel does not disagree that Dr. Miller's report stated as such, but disagrees with his conclusion. (*See* CCFF ¶¶ 784, 974-77, 1055-61 (summarizing expert testimony on standard of evidence required for treat, prevent, or reduce the risk of disease claims)).

(c) Substantiation for Dietary Supplements

706. If a dietary supplement is derived from a pure food it should require the same level of substantiation as a food. (Miller, Tr. 2213).

Response to Finding No. 706:
Complaint Counsel does not disagree that Dr. Miller testified as stated, but disagrees with his conclusion. (*See* CCFF ¶¶ 784, 974-77, 1055-61 (summarizing expert testimony on standard of evidence required for treat, prevent, or reduce the risk of disease claims)).

707. In the alternative, if a dietary supplement is "a mixture of fifty different minerals and elements and vitamins" then it is different than a food and require as a different level of substantiation. (Miller, Tr. 2213).

Response to Finding No. 707:
Complaint Counsel does not disagree that Dr. Miller's report stated as such, but disagrees with his conclusion. (*See* CCFF ¶¶ 784, 974-77, 1055-61 (summarizing expert testimony on standard of evidence required for treat, prevent, or reduce the risk of disease claims)).

(1) POM's Products Are Safe Whole Food Products

708. Pomegranate juice, (and its derivatives) are whole food products (like broccoli or apples) consisting of pure pomegranate juice made from pressing the whole pomegranate including the husk, flesh and the arils (seeds). (PX0206-0009-0010; PX0354 (Miller, Dep. at 136)).

Response to Finding No. 708:
Complaint Counsel does not disagree that Dr. Miller's report stated as such, but notes that this is inconsistent with his testimony in deposition and trial that he has no knowledge of how the POM products are manufactured other than his own assumptions. (PX0354 (Miller, Dep. at 131); Miller, Tr. 2213-14).

709. POMx is an extract from the pomegranate. There are no biological or chemical components added to POMx. (PX0206-0010).

Response to Finding No. 709:
Complaint Counsel does not disagree that Dr. Miller's report stated as such, but notes that this is inconsistent with his testimony in deposition and trial that he has no knowledge of how the POM products are manufactured other than his own assumptions that there are no biological or chemical components added to the pure fruit. (PX0354 (Miller, Dep. at 131); Miller, Tr. 2213-14).

710. Man has eaten pomegranates since Biblical times with no reports of serious adverse medical consequences. (PX0206-0010).

Response to Finding No. 710:

Complaint Counsel has no specific response, except to note that claims for whole pomegranate fruit are not at issue in this matter.

711. Pomegranate juice has been used uneventfully in Persian medicine for thousands of years. There is no reason to believe that there is any material risk involved in consuming POM products. (PX0206-0010).

Response to Finding No. 711:
Complaint Counsel does not disagree that Dr. Miller's report stated as such, but notes that this is inconsistent with his testimony in deposition and trial that he has no knowledge of how the POM products are manufactured other than his own assumptions that there are no biological or chemical components added to the pure fruit. (PX0354 (Miller, Dep. at 131); Miller, Tr. 2213-14).

712. The lack of demonstrable health risk supports the appropriateness of a less rigorous requirement for substantiating claims that the products under discussion and at issue are healthy in some way. (PX0206-0010).

Response to Finding No. 712:
Complaint Counsel does not disagree that Dr. Miller's report stated as such, but disagrees with his conclusion. (*See* CCFF ¶¶ 784, 974-77, 1055-1061 (summarizing expert testimony on standard of evidence required for treat, prevent, or reduce the risk of disease claims)).

713. In Dr. Miller's expert opinion there are essentially no risks in consuming POM Wonderful 100% Juice or POMx. Alternatively virtually every anticancer agent causes adverse events, some of which are serious and life-threatening and require dose reduction or interruption which may cause disease recurrence or induce resistance to the therapy. (PX0206-0010).

Response to Finding No. 713:
Complaint Counsel does not disagree that Dr. Miller's report stated as such, but disagrees with his conclusion. (*See* CCFF ¶¶ 784, 974-77, 1055-61 (summarizing expert testimony on standard of evidence required for treat, prevent, or reduce the risk of disease claims)).

714. The above statement is not offered to imply that POM's products can replace or be substitutes for conventional anticancer therapy but merely that the one size or standard

does not fit all and that a less rigorous standard for making a health claim for a food is reasonable. (PX0206-0010).

Response to Finding No. 714:
Complaint Counsel does not disagree that Dr. Miller's report stated as such, but disagrees with his conclusion. (*See* CCFF ¶¶ 784, 974-77, 1055-61 (summarizing expert testimony on standard of evidence required for treat, prevent, or reduce the risk of disease claims)).

715. However, once the claim is made that a food can replace a proven therapy, that claim should be substantiated by conventional and standard clinical testing, including randomized controlled clinical trials and follow the same arduous pathway of any anticancer agent with similar attributes. (PX0206-0010).

Response to Finding No. 715:
Complaint Counsel agrees that the claim being made is relevant to the level of substantiation required, (*see* CCFF ¶¶ 784, 974-77, 1055-61 (summarizing expert testimony on standard of evidence required for treat, prevent, or reduce the risk of disease claims)), but disagrees with the conclusion that the only claim that can trigger such a requirement is that a food "can replace a proven therapy."

716. It is Dr. Miller's expert opinion that given the obvious safety of pomegranate consumption, and so long as POM's pomegranate products have never been claimed to be a substitute for conventional care or medical therapy, from both a clinical and research perspective, sound basic science is enough to provide sufficient substantiation for a health claim for this natural food product or its derivatives (wherein the consumer is not getting more of some active agent or an additional active agent than what the consumer could find in the fruit). (PX0206-0010-0011; Miller, Tr. 2194).

Response to Finding No. 716:
Complaint Counsel does not disagree that Dr. Miller's report stated as such, but disagrees with his conclusion. (*See* CCFF ¶¶ 784, 974-77, 1055-61 (summarizing expert testimony on standard of evidence required for treat, prevent, or reduce the risk of disease claims)).

717. Dr. Miller testified that you don't need to go through the process of clinical testing and randomized trials to establish the safety and efficacy of a food when there is already reliable scientific evidence supporting that. (Miller, Tr. 2205-06).

Response to Finding No. 717:

Complaint Counsel does not disagree that Dr. Miller's report stated as such, but disagrees with his conclusion. (*See* CCFF ¶¶ 784, 974-77, 1055-1061 (summarizing expert testimony on standard of evidence required for treat, prevent, or reduce the risk of disease claims)).

(2) POM Does Not Claim That Its Products Are A Substitute For Medical Treatment And POM's Has Valid Science Supporting Its Health Claims

718. The science should be valid and peer-reviewed, and whether clinical science is necessary to substantiate a particular claim would vary according to the strengths of the basic science and the particular claim. (PX0206-0011).

Response to Finding No. 718:
Complaint Counsel does not disagree that Dr. Miller's report stated as such, but disagrees with his conclusion. (*See* CCFF ¶¶ 784, 974-77, 1055-61 (summarizing expert testimony on standard of evidence required for treat, prevent, or reduce the risk of disease claims)).

719. For example, in the area of prostate cancer, an unqualified claim that the product has be shown to slow the progression of PSA doubling times should actually be supported by clinical evidence. (PX0206-0011).

Response to Finding No. 719:
Complaint Counsel has no specific response.

720. A qualified claim that POM products may be effective for the treatment or prevention of prostate cancer (or reduce the risks of getting the disease) is reasonable if there is no suggestion that pomegranate alone can 1) absolutely prevent the disease; or 2) that it can serve as a replacement, as distinguished from an adjunct therapy (like exercise, vitamins, etc), in the treatment of a disease. (PX0206-0011).

Response to Finding No. 720:
Complaint Counsel does not disagree that Dr. Miller's report stated as such, but disagrees with his conclusion. (*See* CCFF ¶¶ 974-77 (summarizing expert testimony on standard of evidence required for treat, prevent, or reduce the risk of prostate cancer claims)).

721. A reasonable oncologist or urologist or any other treating physician would not use POM products instead of any approved drug, biological agent, or vaccine that has been approved to treat a given stage of prostate cancer (for those patients where drugs are an

option) because the evidence for these specific indications is not available to support that level of claim or use of pomegranate. (PX0206-0011).

Response to Finding No. 721:
Complaint Counsel objects to consideration of any testimony or evidence from Dr. Miller regarding the strength of the scientific evidence on POM products or the specific studies on POM products, as outside the scope of his designated expert testimony. Dr. Miller was offered *only* as an expert on the level of evidence required, and not on the studies themselves. (Miller, Tr. 2912, 2218-19; PX0354 (Miller, Dep. at 89, 95)). At his deposition, Respondents' counsel repeatedly instructed the Dr. Miller *not* to answer any questions regarding whether the standard has been met. (PX0354 (Miller, Dep. at 92-95, 124, 129, 140, 149)). Complaint Counsel does not disagree with the proposed finding that a reasonable oncologist or urologist or any other treating physician would not use POM products instead of any approved drug, biological agent, or vaccine that has been approved to treat a given stage of prostate cancer (for those patients where drugs are an option).

722. However, 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. (PX0206-0011).

Response to Finding No. 722:
Complaint Counsel does not disagree that Dr. Miller's report stated as such, but notes that was referring to the context of a patient under the active care of an oncologist or oncological surgeon, and that he further testified that "you can't take the physician out of the formula." (Miller, Tr. 2210; PX0354 (Miller, Dep. at 177)).

723. Based on the strength of the reported research, POM products, for example, have demonstrable beneficial effects that are relevant to carcinogenesis and cancer prevention. (PX0206-0011).

Response to Finding No. 723:

Complaint Counsel objects to this proposed finding as outside the scope of Dr. Miller's designated testimony. *See* Response to Finding 721.

724. Critically important would be the demonstration that POM products did not enhance prostate cancer cell growth and progression of disease. (PX0206-0011-0012).

Response to Finding No. 724:
Complaint Counsel objects to this proposed finding as outside the scope of Dr. Miller's designated testimony. *See* Response to Finding 721.

725. Thus, POM would meet the test of "primum non nocere" or first, do no harm. And there is solid evidence that should meet any "reasonable" standard, and that the products may do good, especially in prostate cancer. (PX0206-0012).

Response to Finding No. 725:

Complaint Counsel objects to this proposed finding as outside the scope of Dr. Miller's designated testimony. *See* Response to Finding 721.

(3) A Cost/Benefit Analysis Supports a Finding That It Is in The Public's Best Interest to Be Informed About The Health Benefits of POM's Products

726. Practicing physicians, who have firsthand knowledge regarding the needs and risks faced by their patients, are in the best position to conduct the cost/benefit analysis. (PX0206-0008).

Response to Finding No. 726:
Complaint Counsel does not disagree that Dr. Miller's report stated as such, but notes that was referring to the context of a patient under the active care of an oncologist or oncological surgeon, and that he further testified that "you can't take the physician out of the formula." (Miller, Tr. 2210; PX0354 (Miller, Dep. at 177)). Moreover, Complaint Counsel notes that the POM products were sold directly to consumers.

727. Dr. Miller firmly believes that the public should be aware of potentially beneficial foods that have a salutary effect on health and cause no harm. (PX0206-0012).

Response to Finding No. 727:
Complaint Counsel has no specific response.

728. Informing the public empowers them to add a potentially beneficial, harmless food to their diet that may prevent prostate cancer (and other disorders). (PX0206-0012).

Response to Finding No. 728:
Complaint Counsel has no specific response.

729. Dr. Miller notes that public health and other agencies urge the populace to eat fruits and vegetables because of their beneficial effects. (PX0206-0012).

Response to Finding No. 729:
This proposed finding is irrelevant. This case has to do with commercial advertising for the purpose of selling Respondents' products; not public health recommendations for fruits and vegetables. Public health authorities must sometimes make recommendations based on imperfect evidence. (Stampfer, Tr. 876).

730. Complaint Counsels' expert Professor Stampfer went as far as to say that it is 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 has a right to be given advice based on the best evidence available. (PX0300 (Stampfer, Dep. at 29-30)).

Response to Finding No. 730:
This proposed finding is irrelevant. This case has to do with commercial advertising for the purpose of selling Respondents' products; not public health recommendations for fruits and vegetables. Public health authorities must sometimes make recommendations based on imperfect evidence, but Professor Stampfer noted that "if you're going to make a claim based on an establishment of a causal link, then you need evidence that supports that type of claim." (Stampfer, Tr. 876).

731. When a specific food like POM products have been subjected to rigorous testing and consistently demonstrate potent anticarcinogenic properties, harm can result from recommending its use in men because it may prevent prostate cancer. (PX0206-0012).

Response to Finding No. 731:
Complaint Counsel objects to this proposed finding as outside the scope of Dr. Miller's designated testimony. *See* Response to Finding 721.

732. More likely than not, if POM products are effective in men with biochemical recurrence, it may prevent prostate cancer in an otherwise healthy but at risk individual. (PX0206-0012).

Response to Finding No. 732:
Complaint Counsel objects to this proposed finding as outside the scope of Dr. Miller's designated testimony. *See* Response to Finding 721.

733. It is Dr. Miller's expert opinion that claiming that a fruit juice is good for prostate health or that it may reduce the risk of developing prostate cancer is much more limited in scope than suggesting that it should be used to treat active prostate cancer, or that it be used instead of conventional therapy. (PX0206-0012).

Response to Finding No. 733:
Complaint Counsel does not disagree that Dr. Miller's report stated as such, but notes that this proposed finding is irrelevant because he did not actually evaluate any of the advertising claims made regarding the health benefits of the POM products. (Miller, Tr. 2210).

734. Health professionals are or should be strong advocates of healthy life style practices just as they are or should be to warn the public about unhealthy practices (cigarettes, alcohol, unprotected sex, obesity). (PX0206-0013).

Response to Finding No. 734:
Complaint Counsel has no specific response.

735. Dr. Miller states that claims publicizing general health benefits ("fish oils lower your cholesterol and may protect your heart") or even more specific health benefits ("broccoli may protect one from colorectal cancer")" are rarely, if ever based upon or substantiated by an equivalent body of basic science or non-clinical and clinical data that are available now and support the anticancer activity of POM products. (PX0206-0013).

Response to Finding No. 735:
Complaint Counsel objects to this proposed finding as outside the scope of Dr. Miller's designated testimony. See Response to Finding 721. Moreover, he stated he was not aware of any regulations governing health claims that can be made for foods. (Miller, Tr. 2217-18).

736. In Dr. Miller's expert opinion few scientists or clinicians would deny, if presented with the published data, that POM is beneficial because of its inhibitory effect on such

important mechanisms as oxidative stress, inflammation, apoptosis, signal transduction, cell proliferation, and angiogenesis. (PX0206-0013).

Response to Finding No. 736:
Complaint Counsel objects to this proposed finding as outside the scope of Dr. Miller's designated testimony. *See* Response to Finding 721.

737. Dr. Miller's opinied that retrospective or prospective observational cohort or case-control studies are not feasible to study the benefits of a food. (PX0206-0014).

Response to Finding No. 737:
Complaint Counsel objects to this proposed finding as outside the scope of Dr. Miller's designated testimony. *See* Response to Finding 721. Moreover, he has never designed clinical research protocols for foods and has never been involved in designing clinical trial to prevent cancer in healthy people, so this statement is without any basis. (Miller, Tr. 2218). (*See also* CCFF ¶ 765 (noting that observational studies have been done to study effect of intake of various nutrients over time)).

738. A double-blind, placebo controlled trial evaluating POM products as a prostate cancer protective agents 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, just to mention a few), genetic predisposition, racial and ethnic factors, benign prostatic hypertrophy, and other factors that might have an effect on carcinogenesis of prostate cancer. (PX0206-0014).

Response to Finding No. 738:
Complaint Counsel has no specific response.

739. A food is not patentable and it is not reasonable to require the maker of a potentially beneficial foodstuff to conduct a prohibitively expensive RCT to claim that it is beneficial to health. (PX0206-0016; Heber, Tr. 1949).

Response to Finding No. 739:
Complaint Counsel does not disagree that Dr. Miller's report stated as such, but notes that this proposed finding is irrelevant because he did not actually evaluate any of the advertising claims made regarding the health benefits of the POM products. (Miller, Tr. 2210). Moreover, Dr. Heber's cited testimony is also irrelevant because he was only

referring to POM Juice's "ability to promote health" and not the claims challenged in the Complaint. (*See* CCFF ¶ 730).

740. Even Complaint Counsels' expert, Professor Stampfer, said that observational studies are often superior as the basis for nutritional recommendations because large RCTs are impractical for assessing nutritional benefits. (PX0362 (Stampfer, Dep. at 74-79)).

Response to Finding No. 740:
This proposed finding mischaracterizes Dr. Stampfer's opinion; he testified that "depends on the context and how it's done." Moreover, he further testified that observational studies 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). This proposed finding is also irrelevant because there is no observational study evidence on pomegranates, pomegranate juice, or pomegranate extract. (Heber, Tr. 2168; Stampfer, Tr. 722). *See also* CCFF ¶¶ 765-66.

741. Yet few scientists or clinicians would deny, if presented with the published data, that POM is beneficial because of its inhibitory effect on key oncogenic mechanisms defined above. (PX0206-0014).

Response to Finding No. 741:
Complaint Counsel objects to this proposed finding as outside the scope of Dr. Miller's designated testimony. *See* Response to Finding 721.

742. In fact, Dr. Miller states, that based on the solid nonclinical data, there should be no need to conduct two randomized well controlled trials to publicize that drinking POM products might decrease one's risk of developing prostate cancer. (PX0206-0014).

Response to Finding No. 742:
Complaint Counsel objects to this proposed finding as outside the scope of Dr. Miller's designated testimony. *See* Response to Finding 721. Moreover, Complaint Counsel disagrees with the conclusions in this proposed finding. (*See* CCFF ¶¶ 974-77

(summarizing expert testimony on standard of evidence required for treat, prevent, or reduce the risk of prostate cancer claims)).

743. Such a statement is in the public's best interest and empowers individuals to take control of their own health by drinking and eating healthful foods, engaging in healthy activities, and avoiding potentially or known harmful ones. (PX0206-0014-0015).

Response to Finding No. 743:
Complaint Counsel objects to this proposed finding as outside the scope of Dr. Miller's designated testimony. *See* Response to Finding 721. Moreover, Complaint Counsel disagrees with the conclusions in this proposed finding. (*See* CCFF ¶¶ 974-77 (summarizing expert testimony on standard of evidence required for treat, prevent, or reduce the risk of prostate cancer claims)).

(4) Dr. Miller Concludes That Basic Science Can Constitute Sufficient Substantiation for Health Claims For a Whole Food Product or Its Derivative and RCTs are not Necessarily Required

744. It is Dr. Miller's opinion that the consensus among competent and reliable scientists is that if you are talking a pure food product or its derivative, and that product is not offered as a substitute for proper medical treatment, you look may rely on basic science and RCTs are not required for substantiation. (Miller, Tr. 2194; PX0206-0007, 0015).

Response to Finding No. 744:
Complaint Counsel does not disagree that Dr. Miller testified as stated, but disagrees with his conclusion. (*See* CCFF ¶¶ 784, 974-77, 1055-61 (summarizing expert testimony on standard of evidence required for treat, prevent, or reduce the risk of disease claims)).

E. Public Health Recommendations Are Made and Clinical Practices Followed In the Absence of RCTs

745. Not surprisingly, much of what physicians provide patients in their clinical practices has not been proven to be beneficial in RCTs. (PX0025-0007; Sacks, Tr. 1559; PX0361 (Sacks Dep. at 111); CX1341 (Pantuck, Dep. at 276-277)).

Response to Finding No. 745:

This proposed finding is irrelevant. This case has to do with commercial advertising for the purpose of selling Respondents' products directly to the public, not discussions between a patient and treating physician in the context of a physician's clinical practice.

746. 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. (Eastham Tr. 1331-32; PX0358 (Eastham, Dep. at 154-155)).

Response to Finding No. 746:
This proposed finding is irrelevant. This case has to do with commercial advertising for the purpose of selling Respondents' products directly to the public, not the surgical practice of physicians following the standard of care for treatment of prostate cancer.

747. 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. (Eastham, Tr. 1331-32).

Response to Finding No. 747:
See Response to Finding 746.

748. Also, Dr. Pantuck stated that clinicians remove kidneys without a RCT showing the benefits of nephrectomy. (CX1341 (Pantuck, Dep. at 276-277)).

Response to Finding No. 748:
See Response to Finding 746.

749. Dr. Ornish also notes 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. (PX0025-0007).

Response to Finding No. 749:
This proposed finding is irrelevant. This case has to do with commercial advertising for the purpose of selling Respondents' products directly to the public, not the surgical practice of physicians following the standard of care for treatment of cardiovascular conditions.

750. 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. (PX0206-0012-0013).

Response to Finding No. 750:
This proposed finding is irrelevant. This case has to do with commercial advertising for the purpose of selling Respondents' products directly to the public, not making public health recommendations about fresh fruits and vegetables by health professionals, third party insurance carries, and health related agencies.

751. Further, Complaint Counsel's experts, Professor Stampfer and Dr. Sacks, admitted that they have made public health recommendations that were not supported by RCTs. (Stampfer, Tr. at 810, 813-14; PX0300 (Stampfer, Dep. at 173); PX0361 (Sacks, Dep. at 35-38, 130-131)).

Response to Finding No. 751:
This proposed finding is irrelevant. This case has to do with commercial advertising for the purpose of selling Respondents' products directly to the public, not making public health recommendations. Just as medical professionals must make treatment decisions in the face of imperfect information, public health professionals must make recommendations about types of foods the population should eat based on imperfect information. (Sacks, Tr. 876-77). Moreover, it mischaracterizes Drs. Stampfer's and Sacks' opinions. *See* Responses to Findings 208-209.

752. Moreover, RCTs were not the standard nor required by the National Cancer Institute or other regulatory agencies. (PX0206-0002).

Response to Finding No. 752:
This proposed finding is unsupported by the cited evidence, which states that "[r]andomized, *double-blind, placebo-controlled* [*sic*] were not the standard, were not required by the NCI or other regulatory agencies[.]" (PX0206-0002 (emphasis added)). In fact, Dr. Miller testified that these were "randomized controlled trials," they just used the standard of care treatment as a control arm rather than a placebo control. (PX0354 (Miller, Dep. at 40)).

753. In fact, the success in treating children with cancer at the National Cancer Institute was achieved without RCTs. (PX0206-0002).

Response to Finding No. 753:
This proposed finding is unsupported by the cited evidence, which states that "the success in treating children with cancer was achieved without using *double-blind, placebo controlled trials.*" (PX0206-0002 (emphasis added)). Dr. Miller actually testified that these *were* "randomized controlled trials," which used the standard of care treatment as a control arm rather than a placebo control. (PX0354 (Miller, Dep. at 40)).

754. Also, certain research agencies of the United States government and internationally recognized academic institutions have participated in and publicized their research addressing some of the very same health benefit topics and diseases that Respondents have also explored using in vitro, animal, and small-scale human models as the bases for their scientific inquiries. (PX0301-PX0324).

Response to Finding No. 754:
Complaint Counsel objects to PX0301 – PX0324 cited in this proposed finding because the documents were not produced during discovery in this matter. Complaint Counsel was therefore unable to question any expert witness as to the relevance or applicability of these 24 exhibits to the issue of whether Respondents had sufficient substantiation for their claims, and to consider these exhibits now would be unduly prejudicial. Moreover, this proposed finding is irrelevant. This case has to do with commercial advertising for the purpose of selling Respondents' products directly to the public, not whether government and other institutions have generally researched health benefits of different foods using a variety of scientific studies.

755. For example, the Agricultural Research Service, which is the U.S. Department of less than 1.5%'s chief scientific research agency, has investigated and funded research on fruits, vegetables, and nuts and publicized studies examining various foods and their potential impact on various human ailments based on in vitro, animal, and small-scale human models. (PX0301-PX0318).

Response to Finding No. 755:

Complaint Counsel objects to PX0301 – PX0318 cited in this proposed finding because the documents were not produced during discovery in this matter. Complaint Counsel was therefore unable to question any expert witness as to the relevance or applicability of these 24 exhibits to the issue of whether Respondents had sufficient substantiation for their claims, and to consider these exhibits now would be unduly prejudicial. Moreover, this proposed finding is irrelevant. This case has to do with commercial advertising for the purpose of selling Respondents' products directly to the public, not whether a government agency has studied health benefits of different foods using a variety of scientific studies.

756. Similarly, the National Institutes of Health ("NIH"), which is a component of the U.S. Department of Health and Human Services, has provided, and continues to provide, grants and funding to support basic, clinical and translational medical research, including for research pertaining to pomegranates, in order "to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce the burdens of illness and disability." (PX0392-PX0418; http://www.nih.gov/about/ and http://www.nih.gov/about/mission.htm (last visited, January 8, 2012).

Response to Finding No. 756:

Complaint Counsel objects to PX0392 – PX0418 cited in this proposed finding because the documents were not produced during discovery in this matter. Moreover, the NIH websites cited are not in the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel was therefore unable to question any expert witness as to the relevance or applicability of these 24 exhibits to the issue of whether Respondents had sufficient substantiation for their claims, and to consider these exhibits now would be unduly prejudicial. Moreover, this proposed finding is irrelevant. This case has to do with commercial advertising for the purpose of selling Respondents' products directly to the public, not whether government and other institutions have generally researched health benefits.

757. In many instances, even the FDA has approved pharmaceutical products without requiring the type of rigorous clinical trials the FTC would require of a safe food product. (PX0206-0008-0009).

Response to Finding No. 757:
This proposed finding is unsupported by the cited evidence. Dr. Miller testified that the cancer trials referred to in the cited pages (and in Findings 758-759) *were* randomized controlled trials, with the standard of care as a control arm. (PX0354 (Miller, Dep. at 30-32, 39-40)).

758. Dr. Miller states 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. (PX0206-0008).

Response to Finding No. 758:
Complaint Counsel does not disagree that Dr. Miller's report stated as such, but notes that the cancer trials referred to in the cited pages (and in Findings 758-759) were randomized controlled trials with the standard of care as a control arm. (PX0354 (Miller, Dep. at 30-32, 39-40)).

759. The following table provides a few examples of new anticancer agents and their Phase III pivotal study design that led to regulatory approval in the US (FDA) and in Europe (EMEA) which were done without a placebo control arm. (PX0206-0008).

Indication [subtype, line]	Agent (class of agent)	Randomized Study Design
NHL, [diffuse large B-cell, 1st]	Rituximab (anti-CD20 monoclonal antibody)	R-CHOP vs CHOP
NHL, [follicular, 1st]	Rituximab	R-CVP vs CVP
NHL [indolent, relapsed]	Rituximab	Monotherapy
CLL [1st]	Rituximab	FCR vs FC
Pancreatic cancer [1st]	Gemcitabine	Gemcitabine vs 5-FU
Prostate cancer [stage 4, HRPC, 1st line]	Docetaxel	Docetaxel + prednisone vs mitoxantrone + prednisone
Renal cell carcinoma [stage 4, 2nd line)	Sunitinib	Sunitinib vs IL-2
NSCLC [2nd line, IIIb-IV]	Pemetrexed	Pemetrexed vs docetaxel
CRC [stage IV, 1st line]	Bevacizumab	Bevacizumab + FOLFOX vs FOLFOX

NHL=non-Hodgkin lymphoma; CLL=chronic lymphocytic leukemia; HRPC=hormone refractory prostate cancer; NSCLC=non small cell lung cancer; CRC=colorectal cancer.

Response to Finding No. 759:
Complaint Counsel does not disagree that Dr. Miller's report stated as such, but notes that the cancer trials referred to in the cited pages (and in Finding 758) were randomized controlled trials with the standard of care as a control arm. (PX0354 (Miller, Dep. at 30-32, 39-40)).

760. To reach Phase III, successful Phase I and Phase II studies were also required, but rarely if ever are RCTs trials done in this early stage of drug development. (PX0206-0009; PX0354 (Miller Dep. at 0025-0026)).

Response to Finding No. 760:
Complaint Counsel does not disagree that Dr. Miller's report stated as such, but this proposed finding is unsupported by the cited deposition testimony. In fact Dr. Miller testified in this context that Phase I studies are primarily to "identify the maximum tolerated dose . . . and a dose one could use in the next phase of clinical research development" and that there are many types of Phase II studies, including "randomized clinical trial, and . . . double-blind randomized placebo control." (PX0354 (Miller, Dep. at 26-28)). He further testified that "[g]enerally . . . you satisfy the safety and efficacy in a larger Phase III trial." (PX0354 (Miller, Dep. at 101)).

761. In addition, from 1973 through 2006, the FDA approved 31 oncology drugs without a randomized trial using the Accelerated Approval and Priority Review Program ("Fast Track Program"). (http://jco.ascopubs.org/content/27/36/6243.abstract (last visited, January 8, 2012); http://www.fda.gov/drugs/resourcesforyou/consumers/ucm143534.htm (last visited, January 8, 2012) (FDA guidance explaining the Fast Track Program); http://www.fda.gov/forconsumers/byaudience/forpatientadvocates/speedingaccesstoimportantnewtherapies/ucm128291.htm (last visited, January 8, 2012). (explaining that "Fast Track" drugs may receive approval based on "an effect on a surrogate, or substitute endpoint reasonably likely to predict clinical benefit"); 21 CFR § 314.510 (allowing approval based on a surrogate endpoint or on an effect on a clinical endpoint other than survival or irreversible morbidity).

Response to Finding No. 761:

The proposed finding is unsupported because the evidence cited is not in the record, in violation of the Court's Order on Post-Trial Briefs. Moreover, it is irrelevant, because this case has to do with commercial advertising for the purpose of selling Respondents' products directly to the public.

XII. THE SCIENCE BEHIND THE NUTRITIONAL BENEFITS OF POMEGRANATE JUICE AND EXTRACTS

A. The Nutritional Benefits of the Challenged Products Are Associated with Their High Antioxidant Content and Ability to Neutralize Free Radicals

1. Free Radicals Play an Integral Role in Cardiovascular Disease, Cancer and Other Diseases Caused by Oxidative Stress

745. Normal cellular metabolism or oxidation produces as its by-product various highly reactive molecules, collectively termed "oxidants" or "free radicals." (PX0192-0019; Heber, Tr. 1956).

Response to Finding No. 745:
Complaint Counsel has no specific response.

746. Free radicals are also produced in response to environmental stressor such as air pollution, tobacco smoke, chemicals, stress, ultraviolet light or other forms of ionizing radiation. (CX1293_0010; Stampfer, Tr. 727; PX0192-0020).

Response to Finding No. 746:
Complaint Counsel has no specific response.

747. Free radicals can cause oxidation which initiates a series of damaging effects on tissue and cellular components, including DNA, proteins, cell membranes, carbohydrates and fats. (Heber, Tr. 1956; PX0192-0018-0019; Stampfer, Tr. 727; CX1293_0010).

Response to Finding No. 747:
Complaint Counsel has no specific response.

748. Free radicals and oxidative stress have been implicated in a wide variety of degenerative processes and diseases, including aging and age-related diseases like cancer and cardiovascular disease. (Heber, Tr. 2185; PX0192-0019-0020; Stampfer, Tr. 727).

Response to Finding No. 748:
Complaint Counsel has no specific response, except to note that when asked "has oxidative damage been implicated in diseases associated with aging, such as

cardiovascular disease and cancer," Dr. Stampfer testified "Yes. That is a hypothesis." (Stampfer, Tr. 727).

749. Free radicals are one of the key mechanisms that promote cancer. (Heber, Tr. 1957).

Response to Finding No. 749:
Complaint Counsel has no specific response, except to note that this is Dr. Heber's opinion.

750. Free radicals are one of the key mechanisms that operate to create the cellular basis of atherosclerosis, the buildup of plaque in arteries. This is accomplished by the oxidation of LDL cholesterol that accelerates the inflammatory response which in turns leads to the development of atherosclerotic plaque. (Heber, Tr. 1957; CX1293_0010).

Response to Finding No. 750:
The proposed finding is Dr. Heber's opinion and is unsupported by the citation to Dr. Stampfer's report (CX1293), in which he wrote that "[i]t has been hypothesized" that free radical damage plays a role in the development of chronic disease. (CX1293 (Stampfer, Report at 0010)).

751. Humans are constantly exposed to oxidative stress caused by oxidation. (PX0192-0019).

Response to Finding No. 751:
Complaint Counsel has no specific response.

752. Although the body has many mechanisms to prevent and repair free radical damage, the human body cannot eliminate all oxidative damage by relying on its own antioxidant defenses. (Heber, Tr. 2185; PX0192-0019-0020; Stampfer, Tr. 727; CX1293_0010).

Response to Finding No. 752:
Complaint Counsel agrees that this is Dr. Heber's opinion and notes that the proposed finding is unsupported by the citations to Dr. Stampfer's testimony and report.

753. When free radical levels rise significantly, the body's defenses can become overwhelmed and cellular damage can occur, leading to incidences of cardiovascular disease and cancer. (Heber, Tr. 2185; PX0192-0019-0020; Stampfer, Tr. 727; CX1293_0010).

Response to Finding No. 753:
Complaint Counsel agrees that this is Dr. Heber's opinion and notes that the proposed finding is unsupported by the citations to Dr. Stampfer's testimony and report in that he

opined that the theory of free radical damage leading to cardiovascular disease is a "hypothesis."

754. Free radicals play an important role in cardiovascular disease, cancer and other disease caused by oxidative stress.

Response to Finding No. 754:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. *See also* Response to Finding 753.

2. Antioxidants Protect Cells Against the Effects of Free Radicals

755. Antioxidants neutralize free radicals by inhibiting oxidation at a molecular, cellular and organ level. (PX0192-0015, 0023; CX1293_0010; Stampfer, Tr. 728).

Response to Finding No. 755:
Complaint Counsel has no specific response.

756. The word "antioxidant" is an umbrella term that includes many chemicals which have the power to oppose the effects of oxidation. (PX0192-0023; Heber, Tr. 2003; Stampfer, Tr. 727-729).

Response to Finding No. 756:
Complaint Counsel has no specific response.

757. Antioxidants either help the body repair the damage caused by oxidation or they prevent oxidation by absorbing the energy of free radicals. (Stampfer, Tr. 727; PX0192-0023).

Response to Finding No. 757:
Complaint Counsel has no specific response.

758. The human body has evolved a large array of endogenous antioxidant defenses against oxidative stress, including antioxidant enzymes such as superoxide dismutase, catalase, and various peroxides, as well as the ability to use small molecules with antioxidant activity such as glutathione, the hormone melatonin, and uric acid. (PX0192-0020; Stampfer, Tr. 728-9).

Response to Finding No. 758:
Complaint Counsel has no specific response, except to note that the proposed finding is unsupported by the citation to Dr. Stampfer's testimony.

759. Antioxidation is not a single "druggable target," but rather is a physiologically important variable characterizing a diet that is either rich or poor in antioxidant intake. Consuming foods with increased antioxidant potency (which also have varied physiological effects)

promotes overall health in a number of organ systems by different mechanisms. (PX0192-0022).

Response to Finding No. 759:
Complaint Counsel has no specific response.

760. Although there is some dispute about the extent of the benefits, it is well accepted within the scientific community that antioxidants are impactful to the body in a beneficial way. (Heber, Tr. 1956, 2003; PX0192-0015, 16-18; Stampfer, Tr. 728-29).

Response to Finding No. 760:
The proposed finding is unsupported by the citation to Dr. Stampfer's testimony and the record as a whole. Although it has been hypothesized that diets high in antioxidants may prevent or treat chronic diseases, there is conflicting scientific evidence on the benefits. Observational and laboratory studies suggest that antioxidant nutrients have beneficial effects, but several randomized controlled clinical trials have found no consistent benefit for specific nutrient antioxidants. (*See* CCFF ¶ 1105). Even Respondents' expert Dr. Heber concedes that *in vitro* testing does not show how an antioxidant will work in the body. (*See* CCFF ¶ 1105).

761. Consumption of antioxidant-rich foods is associated with a healthy heart and a reduced risk of cancer. (PX0192).

Response to Finding No. 761:
Complaint Counsel agrees that this is a conclusion that may be drawn from Dr. Heber's report and states the general view that a diet with a variety of antioxidant-rich foods in general may be helpful for a healthy heart and a reduced risk of cancer. However, although observational and laboratory studies suggest that antioxidant nutrients have beneficial effects, several randomized controlled clinical trials have found no consistent benefit for *specific* nutrient antioxidants. (*See* CCFF ¶¶ 1104-05).

762. The few studies that have found antioxidants ineffective for improving human health have generally involved Vitamin C and Vitamin E supplements, not polyphenol antioxidants. (Heber, Tr. 2002-2003; CX1293_0012-0015).

Response to Finding No. 762:
Complaint Counsel does not disagree that Dr. Heber testified as such. However, "the few studies" are large, comprehensive RCTs involving not only Vitamins C and E, but also beta carotene and selenium. (*See* CX1293 (Stampfer, Report at 0012-13 (Vitamins C and E RCTs involved studied nearly 65,000 people), 0013-14 (beta carotene RCTs studied over 50,000 people), 0015 (selenium and Vitamin E RCT studied over 35,000 people)).

3. Research Agencies of the United States Government Recognize the Health Benefits of Antioxidants in Fighting Free Radicals

763. A Center for Disease Control ("CDC") webpage about the dangers of smoking states that the "[t]he body produces antioxidants to help repair damaged cells." (http://www.cdc.gov/tobacco/data_statistics/sgr/2004/highlights/harm/).

Response to Finding No. 763:
The proposed finding is unsupported because the cited evidence is not in the record, in violation of the Court's Order on Post-Trial Briefs.

764. A 2004 Surgeon General's Report, located on the CDC website, recognizes the healing properties of antioxidants. The webpage states "Normally, your body fights damaging oxygen molecules with antioxidants. It fights the destructive enzymes with defensive enzymes." (http://www.cdc.gov/tobacco/data_statistics/sgr/2004/pdfs/whatitmeanstoyou.pdf).

Response to Finding No. 764:
The proposed finding is unsupported because the cited evidence is not in the record, in violation of the Court's Order on Post-Trial Briefs.

765. Several CDC website pages dealing with eye health recommend a diet rich in antioxidants. One such webpage states, "Additional modifiable factors that might lend themselves to improved overall ocular health include a diet rich in antioxidants…" (http://www.cdc.gov/visionhealth/basic_information/lifespan.htm.).

Response to Finding No. 765:
The proposed finding is unsupported because the cited evidence is not in the record, in violation of the Court's Order on Post-Trial Briefs.

766. One CDC webpage lists the study "Chemoprotection by phenolic antioxidants: Inhibition of tumor mecrosis factor alpha induction in macrophages" as a winner of the 2003 Alice

Hamilton Award. This study explores the effect of antioxidants on toxicity and cancer. (http://www.cdc.gov/niosh/awards/hamilton/aliceabs03.html).

Response to Finding No. 766
The proposed finding is unsupported because the cited evidence is not in the record, in violation of the Court's Order on Post-Trial Briefs.

767. The National Institute of Health ("NIH") website has a page dedicated to antioxidants. The NIH defines antioxidants as "substances that may protect your cells against the effects of free radicals. Free radicals are molecules produced when your body breaks down food, or by environmental exposures like tobacco smoke and radiation. Free radicals can damage cells, and may play a role in heart disease, cancer and other diseases." (http://www.nlm.nih.gov/medlineplus/antioxidants.html).

Response to Finding No. 767:
The proposed finding is unsupported because the cited evidence is not in the record, in violation of the Court's Order on Post-Trial Briefs.

768. When clicking on the Start Here link of the previous webpage, the following webpage states that "Antioxidants are substances that may prevent potentially disease-producing cell damage that can result from natural bodily processes and from exposure to certain chemicals." (http://nccam.nih.gov/health/antioxidants/introduction.htm).

Response to Finding No. 768:
The proposed finding is unsupported because the cited evidence is not in the record, in violation of the Court's Order on Post-Trial Briefs.

769. The NIH website has a webpage that links to 548 open studies regarding antioxidants. (http://clinicaltrials.gov/search/open/intervention=antioxidants).

Response to Finding No. 769:
The proposed finding is unsupported because the cited evidence is not in the record, in violation of the Court's Order on Post-Trial Briefs.

770. The National Cancer Institute page of the NIH website contains an antioxidant fact page which states: "Antioxidants are substances that may protect cells from the damage caused by unstable molecules known as free radicals. Free radical damage may lead to cancer. Antioxidants interact with and stabilize free radicals and may prevent some of the damage free radicals might otherwise cause." The webpage goes on to say "Considerable laboratory evidence from chemical, cell culture, and animal studies indicates that antioxidants may slow or possibly prevent the development of cancer." (http://www.cancer.gov/cancertopics/factsheet/prevention/antioxidants).

Response to Finding No. 770:
The proposed finding is unsupported because the cited evidence is not in the record, in violation of the Court's Order on Post-Trial Briefs.

771. The Agricultural Research Service ("ARS") website features a webpage stating that the pomegranate is "good for you" because it is "high in healthful antioxidants." (PX0306).

Response to Finding No. 771:
Complaint Counsel does not disagree that the article states as such, but objects to PX0306 because the document was not produced during discovery in this matter. Complaint Counsel was therefore unable to question any witness as to the relevance of this exhibit to the issue of whether Respondents had sufficient substantiation for their claims, and to consider this exhibit now would be unduly prejudicial..

772. An ARS webpage entitled "Eating is Stressful, But Antioxidants Can Help" states that antioxidants can help neutralize free radicals. The article goes on to say that "omitting antioxidant rich foods from meals could lead to cellular damage by free radicals. Such damage is thought to increase risk of atherosclerosis, cancer and other diseases." (PX0308).

Response to Finding No. 772:
Complaint Counsel does not disagree that the article states as such, but objects to PX0308 because the document was not produced during discovery in this matter. Complaint Counsel was therefore unable to question any witness as to the relevance of this exhibit to the issue of whether Respondents had sufficient substantiation for their claims, and to consider this exhibit now would be unduly prejudicial..

773. An ARS webpage displays a scientific study that states that an antioxidant compound in oats "may help prevent the buildup of plaque in arteries and thus lessen the risk of heart disease." (PX0316).

Response to Finding No. 773:
Complaint Counsel does not disagree that the article states as such, but objects to PX0316 because the document was not produced during discovery in this matter. Complaint Counsel was therefore unable to question any witness as to the relevance of this exhibit to

the issue of whether Respondents had sufficient substantiation for their claims, and to consider this exhibit now would be unduly prejudicial.

774. Another ARS webpage discusses the beneficial antioxidant effects of eating almonds. (PX0318).

Response to Finding No. 774:
Complaint Counsel does not disagree that the article states as such, but objects to PX0318 because the document was not produced during discovery in this matter. Complaint Counsel was therefore unable to question any witness as to the relevance of this exhibit to the issue of whether Respondents had sufficient substantiation for their claims, and to consider this exhibit now would be unduly prejudicial..

775. The ARS website features a study that explores antioxidants' role in protection against colon cancer. (http://www.ars.usda.gov/research/publications/publications.htm?seq_no_115=185492).

Response to Finding No. 775:
The proposed finding is unsupported because the cited evidence is not in the record, in violation of the Court's Order on Post-Trial Briefs.

776. The ARS website contains pages about the high antioxidant content of different food such as strawberries, cocoa, and peanut plants. (PX0309).

Response to Finding No. 773:
Complaint Counsel does not disagree that the article states as such, but objects to PX0309 because the document was not produced during discovery in this matter. Complaint Counsel was therefore unable to question any witness as to the relevance of this exhibit to the issue of whether Respondents had sufficient substantiation for their claims, and to consider this exhibit now would be unduly prejudicial.

777. The FDA has issued a Small Entity Compliance Guide in pursuant to section 212 of the Small Business Regulatory Enforcement Fairness Act (Public Law 104-121) that establishes guidelines for making antioxidant nutrient claims. (http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm063064.htm).

Response to Finding No. 777:
The proposed finding is unsupported because the cited evidence is not in the record, in violation of the Court's Order on Post-Trial Briefs.

778. The United States Department of Agriculture's website contains pages that feature links to articles discussing the health benefits of antioxidants, including, among other pages, (http://riley.nal.usda.gov/nal_display/index.php?info_center=11&tax_level=2&tax_subject=388&level3_id=0&level4_id=0&level5_id=0&topic_id=1668&&placement_default=0; and http://fnic.nal.usda.gov/nal_display/index.php?info_center=4&tax_level=3&tax_subject=358&topic_id=1610&level3_id=5947&level4_id=0&level5_id=0&placement_default=0).

Response to Finding No. 778
The proposed finding is unsupported because the cited evidence is not in the record, in violation of the Court's Order on Post-Trial Briefs.

779. Research agencies of the United States Government recognize the health benefits of antioxidants in fighting free radicals.

Response to Finding No. 779:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs.

4. The Challenged Products Contain Potent Antioxidants that Fight Free Radicals

780. Pomegranate juice is high in polyphenol antioxidants. (PX0192).

Response to Finding No. 780:
Complaint Counsel does not disagree that Dr. Heber's report suggests as much. However the proposed finding is incomplete in that Dr. Heber also wrote that "in vitro antioxidant potency does not prove in vivo biological activity." (PX0192 (Heber Report at 0023)).

781. The consumption of pomegranate juice and extracts containing polyphenols contribute to overall antioxidant intake in the diet. (PX0192-0014; CX1352 (Heber, Dep. at 61)).

Response to Finding No. 781:
Complaint Counsel does not disagree that Dr. Heber opined as such.

782. The antioxidant properties of pomegranates are well understood to be derived from the polyphenols found in the fruit. (PX0192-0016; PX0059; Burnett, Tr. 2290).

Response to Finding No. 782:
Complaint Counsel objects to the term "well understood" as vague and ambiguous.

Complaint Counsel does not disagree that Dr. Heber opined as such that the antioxidant properties of pomegranates are derived from the polyphenols. The proposed finding is unsupported by the citation to Dr. Burnett's testimony.

783. The Challenged Products contain a diverse, complex mixture of antioxidant polyphenols, including hydrolyzable tannins, flavonols, anthocyanins and acids. The hydrolysable tannins include, among others, punicalagins, ellagitannins, punicalins and gallotannins. The acids include ellagic acid, gallic acid and gallagic acid. (PX0192-0016, 0024; PX0074-0002; Heber, Tr. 2001-2002).

Response to Finding No. 783:
Complaint Counsel does not disagree that Dr. Heber opined as such.

784. Punicalagin is a unique compound and is the largest known polyphenol antioxidant molecule in any fruit or vegetable. (PX0192-0021).

Response to Finding No. 784:
Complaint Counsel does not disagree that Dr. Heber opined as such.

785. The Challenged Products contain among the most potent naturally occurring polyphenol antioxidants found in foods. (PX0192-0021, 0024; PX0189-0011; Goldstein, Tr. 2594-2595; Heber, Tr. 1967; PX484; Burnett, Tr. 2254-2255; PX0058; (PX0021-0001).

Response to Finding No. 785:
Complaint counsel has no specific response, except to note that Dr. Heber also opined that "in vitro antioxidant potency does not prove in vivo biological activity." (PX0192 (Heber Report at 0023)).

786. Laboratory examination has demonstrated POM Juice had more polyphenol antioxidants and a higher level of antioxidant activity or potency than the juices of concord grapes, blueberries and acai. (PX0192-0020-0023; CX1352 (Heber, Dep. at 136); PX0098_0001; PX0097-0002; PX0021-0001).

Response to Finding No. 786:
The proposed finding is incomplete; Dr. Heber also opined that "in vitro antioxidant potency does not prove in vivo biological activity." (PX0192 (Heber Report at 0023); *see also* PX0098_0001).

787. Laboratory examination has demonstrated that POM Juice had more polyphenol antioxidants and a higher level of antioxidant activity or potency than red wine or green tea. (PX0192-0020-0023; CX1352 (Heber, Dep. at 136); PX0098_0001; PX0097-0001).

Response to Finding No. 787:
The proposed finding is incomplete; Dr. Heber also wrote that "in vitro antioxidant potency does not prove in vivo biological activity." (PX0192 (Heber Report at 0023); *see also* PX0098_0001).

788. Several *in vitro* studies demonstrated that the Challenged Products reduces the oxidation of LDL better than any other food or beverage tested. (PX0021-0001).

Response to Finding No. 788:
The proposed finding is unsupported by the cited evidence which is a report of a single study. In addition, the proposed finding mischaracterizes the study which examined the effect of POM Juice (not the other POM Products) and found that both POM Juice and black currant juice had the most potent *in vitro* antioxidant effect on LDL.

789. Several human clinical trials demonstrated that the consumption of POM Juice reduces oxidation of LDL cholesterol. (PX0192-0035-0036; Heber, Tr. 2113).

Response to Finding No. 789:
Complaint Counsel does not disagree that Dr. Heber opined as such, but notes the antioxidant effect on LDL cholesterol has not been proven in RCTs. (*See* CCFF ¶¶ 951-54).

790. Several animal studies demonstrated that the consumption of POM Juice reduces both early and late stage plaque development. (PX0192-0035).

Response to Finding No. 790:
Complaint Counsel does not disagree that Dr. Heber opined as such, but notes that the reduction in plaque has not been proven in RCTs. (*See* CCFF ¶¶ 951-54).

791. The polyphenols in pomegranate juice have antioxidant effects such as inhibiting the oxidation of LDL cholesterol. (Heber, Tr. 2113; PX0192-0035-0036).

Response to Finding No. 791:

The proposed finding is incomplete; Dr. Heber also testified that it would be difficult to translate the *in vitro* effect into an effect in humans because "it's still an area of evolving science." (Heber, Tr. 2113). In addition, the antioxidant effect on LDL cholesterol has not been proven in RCTs. (*See* CCFF ¶¶ 951-54).

792. Pomegranate juice has antioxidant and anti-atherosclerotic effects attributable to its high content of polyphenols including ellagitannins. (PX0075-0001, 0005).

Response to Finding No. 792:
Complaint Counsel does not disagree that the cited article states as such, but notes that the anti-atherosclerotic effects have not been proven in RCTs. (*See* CCFF ¶¶ 951-54).

793. The antioxidant potency of POMx has been measured by Brunswick Laboratories, and the results were reported as 2,571 total oxygen radical absorbance capacity ("ORAC"), 6,976 ferric reducing antioxidant power ("FRAP"), 9,824 Trolox equivalent antioxidant capacity ("TEAC"), and 9,506 free radical scavenging capacity by 2,2-diphenyl-1-picrylhydrazyl ("DPPH"), which was exceptionally high relative to other types of dietary supplements. (PX0192-0024).

Response to Finding No. 793:
Complaint Counsel does not disagree that Dr. Heber's report states as such, but notes that his report is not corroborated by a citation to evidence in the record.

794. Hydrolyzable tannins, rather than anthocyanins, are the major compounds contributing to the high antioxidant activity found in POM Juice, POMx Pills and POMx Liquid. (PX0192-0024; Heber, Tr. 2002, 2186; PX0073-0004; PX0107-0005; PX0199_0001).

Response to Finding No. 794:
Complaint Counsel has no specific response, except to note that Dr. Heber testified that anthocyanins "undoubtedly" contribute to the antioxidant capacity of POM Juice. (*See* CCFF ¶ 965).

795. The potent antioxidant effects measured for POMx are consistent with scientific research finding that hydrolysable tannins like punicalagin, rather than anthocyanins, are the major active antioxidant component of pomegranates. (PX0192-0024; PX0107-0005).

Response to Finding No. 795:
Complaint Counsel has no specific response, except to note that Dr. Heber testified that

anthocyanins "undoubtedly" contribute to the antioxidant capacity of POM Juice. (*See* CCFF ¶ 965).

796. There is no significant correlation between anthocyanin levels and antioxidant activity. (Heber, Tr. 2186).

Response to Finding No. 796:
Complaint Counsel does not disagree that Dr. Heber testified as such, except to note that Dr. Heber testified that anthocyanins "undoubtedly" contribute to the antioxidant capacity of POM Juice. (*See* CCFF ¶ 965).

Seeram NP, Aviram M, Zhang Y, Henning SM, Feng L, Dreher M, Heber D, *"Comparison of antioxidant potency of commonly-consumed polyphenol rich beverages in the United States"* J. Agric. Food Chem. 2008; 56:1415-22

797. In 2008, in a study entitled "Comparison of antioxidant potency of commonly-consumed polyphenol rich beverages in the United States," by Seeram NP, Aviram M, Zhang Y, Henning SM, Feng L, Dreher M, Heber D, J. Agric. Food Chem. 2008; 56:1415-22, Dr. Heber and his colleagues examined the antioxidant potency of a number of commonly-consumed polyphenol rich beverages, including: apple juice (3), acai juice (3), black cherry juice (3), blueberry juice (3), cranberry juice (3), Concord grape juice (3), orange juice (3), red wines (3), and iced tea beverages. (PX0192-0023; PX0098_0001).

Response to Finding No. 797:
Complaint Counsel has no specific response.

798. The antioxidant potency of the various juices were measured using TEAC, ORAC, DPPH, and FRAP; a test of antioxidant functionality (inhibition of low-density lipoprotein oxidation by peroxides and malondialdehyde); and an evaluation of the total polyphenol content. (PX0192-0023; PX0098_0001).

Response to Finding No. 798:
Complaint Counsel has no specific response.

799. Pomegranate juice had the greatest antioxidant potency composite index among the beverages tested, and was at least 20% higher than the other beverages. (PX0192-0023; PX0098_0001).

Response to Finding No. 799:
The proposed finding is incomplete; both Dr. Heber and the study authors stated that "in vitro antioxidant potency does not prove in vivo biological activity." (PX0192 (Heber, Report at 0023); PX0098_0001).

800. This study demonstrates that pomegranate juice has higher antioxidant potency than apple juice, acai juice, black cherry juice, blueberry juice, cranberry juice, Concord grape juice, orange juice, red wine and iced tea beverages.

Response to Finding No. 800:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs.

Gil M., Tomas-Barberan F, Hess-Pierce B, Holcroft D, Kader A, *"Antioxidant activity of pomegranate juice and its relationship with phenolic composition and processing"* J. Agric. Food Chem. 2000, 48:4581-4589

801. In 2000, in a study entitled "Antioxidant Activity of Pomegranate Juice and Its Relationship with Phenolic Composition and Processing," by Gil M., Tomas-Barberan F, Hess-Pierce B, Holcroft D, Kader A, J. Agric. Food Chem. 2000, 48:4581-4589, Dr. Gil and her colleagues examined the antioxidant activity of pomegranate juice in comparison with red wine and a green tea infusion. (PX0097-0001).

Response to Finding No. 801:
Complaint Counsel has no specific response.

802. The study applied four methods to test the antioxidant activity of pomegranate juices; free radical scavenging capacity by 2,2'-azinobis (3-ethylbenzothiazoline)-6-sulfonic acid ("ABTS"), free radical scavenging capacity by DPPH, free radical scavenging by N,N-dimethyl-p-phenylenediamine ("DMPD") and FRAP, and then compared this to the antioxidant activity of red wine and a green tea infusion. (PX0097-0001).

Response to Finding No. 802:
Complaint Counsel has no specific response.

803. Commercial pomegranate juices showed an antioxidant activity three times higher than those of red wine and green tea. Antioxidant activity was also higher in commercial juices extracted from whole pomegranates (such as POM Juice) than in experimental pomegranate juice obtained from arils only. (PX0097-0001).

Response to Finding No. 803:
Complaint Counsel has no specific response.

804. This study demonstrates that POM Juice has higher antioxidant potency that red wine, green tea and experimental pomegranate juices.

Response to Finding No. 804:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs.

Rosenblat M, Volkove N, Attias, J, Mahamid R, Aviram M, *"Consumption of polyphenolic-rich beverages (mostly pomegranate and black currant juices) by healthy subjects for a short term increased serum antioxidant status, and the serum's ability to attenuate macrophage cholesterol accumulation"* Food Function, 2010, 1:99-109

805. In 2010, in a study entitled "Consumption of polyphenolic-rich beverages (mostly pomegranate and black currant juices) by healthy subjects for a short term increased serum antioxidant status, and the serum's ability to attenuate macrophage cholesterol accumulation," by Rosenblat M, Volkove N, Attias, J, Mahamid R, Aviram M, Food Function, 2010, 1:99-109, Dr. Aviram and his colleagues compared the polyphenol content of 35 beverages, *in vitro*, then selected the top five and examined their effect on antioxidant status in health humans., *in vivo*. (PX0021-0001).

Response to Finding No. 805:
Complaint Counsel has no specific response.

806. The *in vitro* study beverages tested included, among others, several brands of beverages as follows: pomegranate juice, Concord grape juice, black cherry juice, black currant juice and blends, blueberry juice, yumberry, acai juice blends, "superfruit" blends, green tea and red wines. The *in vivo* study tested five polyphenol rich-beverages; POM Juice, acai juice blend, Concord grape juice, black currant juice and red wine. (PX0021-0001).

Response to Finding No. 806:
Complaint Counsel has no specific response.

807. Dr. Aviram found that after short-term consumption the POM Juice and 100% black currant juices were the most potent antioxidants *in vitro* and also had the greatest impact on measures of antioxidant status in humans. (PX0021-0001).

Response to Finding No. 807:
Complaint Counsel has no specific response.

808. The antioxidant potency and activity was measured by total polyphenol concentration, free radical scavenging capacity, ability to inhibit LDL oxidation or decrease serum susceptibility to AAPH-induced lipid peroxidation, ability to increase paraoxonase 1 ("PON1"), and serum biochemical parameters and basal serum oxidative status. (PX0021-0001).

Response to Finding No. 808:
Complaint Counsel has no specific response.

809. This study demonstrates that POM Juice higher antioxidant potency *in vitro* and the greatest antioxidant activity than the tested beverages.

Response to Finding No. 809:

The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs.

810. In sum, the expert opinions and affirmative evidence presented by Respondents prove that the antioxidants in the Challenged Products protect cells against the free radicals which is beneficial to cardiovascular and erectile health and cancer prevention.

Response to Finding No. 810:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs.

5. Complaint Counsel Failed to Rebut Respondents' Evidence on the Benefits of Antioxidants in Fighting Free Radicals; to the Contrary, Complaint Counsel's Experts Provided Opinions that Supported Respondents' Evidence on Antioxidants

811. Complaint Counsel have presented no expert opinion or competent affirmative evidence rebutting Respondents' evidence that antioxidants inhibit the oxidizing effects of free radicals. (CX1293; PX0362 (Stampfer, Dep. at 1-205); Stampfer, Tr. 689-885; CX1291; PX0361 (Sacks, Dep. at 1-273); Sacks, Tr. 1410-1625; CX1289; PX0360 (Melman, Dep. at 1-141); Melman, Tr. 1069-1197; CX1287; PX0358 (Eastham, Dep. at 1-158); Eastham, Tr. 1204-1351; CX1295; PX0357 (Stewart, Dep. at 1-194); Stewart, Tr. 3158-3242; PX0359 (Mazis, Dep. 1-242); Mazis, Tr. 2651-2761).

Response to Finding No. 811:
The proposed finding mischaracterizes the evidence. Complaint Counsel does not disagree that its experts did not explicitly opine that antioxidants fail to inhibit the oxidizing effects of free radicals. Nevertheless, Complaint Counsel's experts reviewed the totality of the evidence, including the studies cited above, and concluded that there is not enough reliable scientific evidence to substantiate Respondents' claims. (*See* CCFF ¶¶ 962-64, 1037, 1085-86).

812. Complaint Counsel have presented no expert opinion or competent affirmative evidence rebutting Respondents' evidence that free radicals play a role in cardiovascular disease and cancer. (CX1293; PX0362 (Stampfer, Dep. at 1-205); Stampfer, Tr. 689-885; CX1291; PX0361 (Sacks, Dep. at 1-273); Sacks, Tr. 1410-1625; CX1289; PX0360 (Melman, Dep. at 1-141); Melman, Tr. 1069-1197; CX1287; PX0358 (Eastham, Dep. at 1-158); Eastham, Tr. 1204-1351; CX1295; PX0357 (Stewart, Dep. at 1-194); Stewart, Tr. 3158-3242; PX0359 (Mazis, Dep. 1-242); Mazis, Tr. 2651-2761).

Response to Finding No. 812:

The proposed finding mischaracterizes the evidence. Complaint Counsel does not disagree that its experts did not explicitly opine that free radicals play no role in cardiovascular disease and cancer. However, Dr. Stampfer did opine in his report that "[i]t has been *hypothesized*" that free radical damage plays a role in the development of chronic disease. (CX1293 (Stampfer, Report at 0010). Moreover, Complaint Counsel's experts reviewed the totality of the evidence, including the studies cited above, and concluded that there is not enough reliable scientific evidence to substantiate Respondents' claims. (*See* CCFF ¶¶ 962-64, 1037, 1085-86).

813. Complaint Counsel have presented no expert opinion or competent affirmative evidence rebutting Respondents' evidence concerning the antioxidant activity or potency of the Challenged Products. (CX1293; PX0362 (Stampfer, Dep. at 1-205); Stampfer, Tr. 689-885; CX1291; PX0361 (Sacks, Dep. at 1-273); Sacks, Tr. 1410-1625; CX1289; PX0360 (Melman, Dep. at 1-141); Melman, Tr. 1069-1197; CX1287; PX0358 (Eastham, Dep. at 1-158); Eastham, Tr. 1204-1351; CX1295; PX0357 (Stewart, Dep. at 1-194); Stewart, Tr. 3158-3242; PX0359 (Mazis, Dep. 1-242); Mazis, Tr. 2651-2761).

Response to Finding No. 813:

The proposed finding mischaracterizes the evidence. Complaint Counsel does not disagree that its experts did not explicitly opine on the antioxidants activity or potency of the POM Products. Nevertheless, Complaint Counsel's experts reviewed the totality of the evidence, including the studies cited above, and concluded that there is not enough reliable scientific evidence to substantiate Respondents' claims. (*See* CCFF ¶¶ 962-64, 1037, 1085-86).

814. Complaint Counsel have presented no expert opinion or competent affirmative evidence rebutting Respondents' evidence that the Challenged Products contain more antioxidants than comparative fruit juices or supplements. (CX1293; PX0362 (Stampfer, Dep. at 1-205); Stampfer, Tr. 689-885; CX1291; PX0361 (Sacks, Dep. at 1-273); Sacks, Tr. 1410-1625; CX1289; PX0360 (Melman, Dep. at 1-141); Melman, Tr. 1069-1197; CX1287; PX0358 (Eastham, Dep. at 1-158); Eastham, Tr. 1204-1351; CX1295; PX0357 (Stewart, Dep. at 1-194); Stewart, Tr. 3158-3242; PX0359 (Mazis, Dep. 1-242); Mazis, Tr. 2651-2761).

Response to Finding No. 814:

The proposed finding mischaracterizes the evidence. Complaint Counsel does not disagree that its experts did not explicitly opine on whether the POM Products contain more antioxidants than comparative fruit juices. Nevertheless, Complaint Counsel's experts reviewed the totality of the evidence, including the studies cited above, and concluded that there is not enough reliable scientific evidence to substantiate Respondents' claims. (*See* CCFF ¶¶ 962-64, 1037, 1085-86).

815. Complaint Counsel's expert, Professor Meir Stampfer, offered no expert opinion that the Challenged Products do not provide nutritional benefits in regards to cardiovascular, prostate and erectile health. Rather he merely opines that based on the materials Complaint Counsel provided him and that he reviewed, there is no competent or reliable scientific evidence to support Respondents' health-benefit claims. (CX1293_0007, 0016-0024, 0027-0029; Stampfer, Tr. 769-70).

Response to Finding No. 815:

The proposed finding mischaracterizes the evidence. Complaint Counsel does not disagree that Dr. Stampfer did not offer an opinion on the general nutritional benefits of the POM Products. Dr. Stampfer was asked to determine whether the materials submitted by Respondents were sufficient to support Respondents' cardiovascular and prostate cancer claims. (*See* CCFF ¶ 700). To form his opinions, Dr. Stampfer drew upon his own expertise, the materials submitted by Respondents and affiliated researchers, deposition transcripts of researchers who conducted studies for Respondents, information about ingredients contained in the POM products, and materials he found through his independent literature search. (*See* CCFF ¶ 701).

816. Complaint Counsel's expert, Dr. James Eastham, offered no expert opinion that the Challenged Products do not provide the health benefits Complaint Counsel alleges Respondents make about Challenged Products. Rather Dr. Eastham merely opines that based on the materials Complaint Counsel provided him and that he reviewed, there is no competent or reliable scientific evidence to support Respondents' health-benefit claims. (CX1287_0006).

Response to Finding No. 816:

The proposed finding mischaracterizes the evidence. Complaint Counsel does not disagree that Dr. Eastham did not offer an opinion on the health nutritional benefits of the POM Products. Dr. Eastham was asked to determine whether the materials submitted by Respondents were sufficient to support Respondents' prostate cancer claims. (*See* CCFF ¶ 715). To form his opinions, Dr. Eastham drew upon his own expertise, the materials submitted by Respondents and affiliated researchers, information about ingredients contained in the POM products, and materials he found through his independent literature search. (*See* CCFF ¶ 716).

817. Professor Stampfer admits that he is not an urologist or cardiologist. (Stampfer, Tr. 868).

Response to Finding No. 817:

See Response to Finding 206.

818. Professor Stampfer has no opinion about the particular classes of antioxidant compounds within pomegranates. (PX0362 (Stampfer, Dep. at 199)).

Response to Finding No. 818:
Complaint Counsel does not disagree that Dr. Stampfer testified as stated.

819. Professor Stampfer has no opinion about the extent to which the antioxidant effect of pomegranate juice on human health is attributable to anthocyanins as opposed to other antioxidants. (PX0362 (Stampfer, Dep. at 203)).

Response to Finding No. 819:
The proposed finding mischaracterizes Dr. Stampfer's testimony. At his deposition, Dr. Stampfer was asked whether he had "an opinion regarding the extent to which the antioxidant effect of pomegranate juice in the human body are attributable to anthocyanins relative to other forms of antioxidants." (PX0362 (Stampfer, Dep. at 203)). Dr. Stampfer responded that "if you are talking about effects other than human health, then I don't have an opinion." (PX0362 (Stampfer, Dep. at 203)).

820. Professor Stampfer was not asked by Complaint Counsel, and did not prepare, a rebuttal report to Dr. Heber's expert report. (PX0362 (Stampfer, Dep. at 187-88)).

Response to Finding No. 820:
Complaint Counsel has no specific response.

821. Professor Stampfer in preparing his expert report, did not review the expert reports of any of Respondents' experts. (CX1293_0008).

Response to Finding No. 821:
The proposed finding mischaracterizes the record insofar as implies that Dr. Stampfer did not fully address the issues relevant to this matter. Dr. Stampfer's report anticipated the Respondents' arguments and fully addressed them. (CX1293 (Stampfer, Report at 0001-30).

822. Professor Stampfer admits that animal studies "can be very important to help learn about biology, metabolism, biological pathways for the impact of a nutrient." (Stampfer, Tr. 722).

Response to Finding No. 822:
The proposed finding is incomplete. Complaint Counsel does not disagree that Dr. Stampfer testified as stated, however, Dr. Stampfer also testified that the results of animal studies do not always correspond with what occurs in humans. (Stampfer, Tr. 723).

823. Professor Stampfer offered no expert opinion that the compounds that work *in vitro* or in animal cannot work the same way in humans, he only opines that these compounds "often" do not work the same way in humans. (CX1293_, 0008, 0016, 0023). Thus, Professor Meir Stampfer admits that the results of animal studies "sometimes" correspond with what will occur in humans. (Stampfer, Tr. 723).

Response to Finding No. 823:
The proposed finding is incomplete; Complaint Counsel does not disagree that Dr. Stampfer testified that the results of animal studies do not always correspond with what occurs in humans, however, Dr. Stampfer also testified that for nutrients it is difficult to predict whether outcomes observed in animal studies will be replicated in humans because of the "different paths of evolution." (Stampfer, Tr. 723).

824. Professor Stampfer admits that observational studies enable investigators to conclude there is an association between the nutrient and disease of interest. (CX1293_0008).

Response to Finding No. 824:

The proposed finding is incomplete in that Dr. Stampfer opined that "[t]hese studies enable investigators to conclude there is an association between the nutrient and disease of interest, but typically cannot confirm causality due to the potential, even in well-designed studies, for unidentified biases or inadequately controlled confounding." (*See* CCFF ¶ 765).

825. Professor Stampfer did not opine on what is a "sufficient size" for a study to be able to conclude a causal link between a nutrient and disease of interest. (CX1293_0009; PX0362 (Stampfer, Dep. at 1-205); Stampfer, Tr. 689-885).

Response to Finding No. 825:
Complaint Counsel has no specific response, except to note that Dr. Stampfer testified that RCTs are necessary to establish that causal link. (*See* CCFF ¶ 771).

826. Professor Stampfer admits that antioxidant polyphenols have been associated with reduced risk of prostate cancer in various *in vitro* and observational studies. (CX1293_0015).

Response to Finding No. 826:
The proposed finding is incomplete, in that Dr. Stampfer stated that "the suggestive associations between some specific antioxidant nutrients and CVD or prostate cancer observed in observational studies, and the biological plausibility established in *in vitro* and animal studies, has not translated to consistent protective effects in humans." (CX1293 (Stampfer, Report at 0015)). Dr. Stampfer concludes that "[t]his demonstrates the importance of performing randomized, double-blind placebo-controlled trials before drawing firm conclusions regarding causality or making public health recommendations regarding nutrient supplementation." (CX1293 (Stampfer, Report at 0015)).

827. Professor Stampfer admits that Dr. Michael Aviram found that the Challenged Products reduce the size of atherosclerotic lesions in mice. (CX1293_0016; CX0541).

Response to Finding No. 827:
The proposed finding mischaracterizes Dr. Stampfer's expert report in that he wrote that "studies conducted by Dr. Aviram found that POM Juice, POMx Pills, and POMx Liquid

appear to reduce the size of atherosclerotic lesions in mice." (CX1293 (Stampfer, Report at 0016)).

828. Professor Stampfer admits that Dr. Filomena de Nigris found that POM Juice *in vitro* decreases LDL oxidation and the size of plaques in mice. (CX1293_0016; PX0059).

Response to Finding No. 828:
The proposed finding mischaracterizes Dr. Stampfer's expert report in that he wrote that a "study by deNigris, et al, examined the effect of POM Juice *in vitro* and in mice, and found that it *appeared* to decrease LDL oxidation and the size of plaques." (CX1293 (Stampfer, Report at 0016)).

829. Complaint Counsel failed to rebut Respondents' evidence on the benefits of antioxidants in fighting free radicals and, indeed, their experts often provided opinions that supported Respondents evidence on antioxidants effects in the body.

Response to Finding No. 829:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs.

830. Therefore, Complaint Counsel have failed to present expert opinion or affirmative evidence on the benefits of the antioxidants in the Challenged Products in fighting free adicals.

Response to Finding No. 830:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs.

B. Antioxidants Positively Impact the Level and Preservation of Nitric Oxide Which Is Beneficial to Cardiovascular And Erectile Health

1. Respondents Presented Substantial Evidence on the Beneficial Effects of the Challenged Products on Nitric Oxide

831. Antioxidants are well known to enhance the biological actions of nitric oxide ("NO") by virtue of their capacity to improve endothelial NO synthase ("eNOS"). (PX0055-0002; PX0056).

Response to Finding No. 831:
Complaint Counsel has no specific response.

832. Antioxidants are well known to increase and prolong cellular concentrations of NO by protecting it from oxidation. (PX0056-0002; PX0059-001, 0004; PX0149-0005-0006). Antioxidants accomplish this task by neutralizing free radicals. (PX0055-0002; PX0056-0002; PX0057; PX0059-001, 0004; PX0190-0006; PX0149-0005-0006); PX0189-0004-0005; Goldstein, Tr. 2604-2605).

Response to Finding No. 832:
Complaint Counsel has no specific response.

833. The negative effects on NO caused by shear stress (the force of friction caused by perturbed blood flow around atherosclerosis) and on the expression of oxidation-sensitive genes can be mitigated by antioxidants. (PX0055-0002; PX0056).

Response to Finding No. 833:
The proposed finding is unsupported by the cited evidence.

834. Dr. Louis Ignarro, who was awarded the 1998 Nobel Prize in Physiology for demonstrating the signaling properties of NO, demonstrated that POM Juice and POMx were able to attenuate the effects of perturbed shear stress and atherogenisis. However, POMx was significantly more effective at enhancing the expression of endothelial nitric oxide synthase (eNOS – an enzyme necessary for cellular NO production) decreasing oxygen-sensitive gene expression and reducing lesion size. (PX0056).

Response to Finding No. 834
Complaint Counsel has no specific response except to note that the proposed finding's assertion that Dr. Louis Ignarro was awarded the 1998 Nobel Prize is unsupported by the cited evidence.

835. Antioxidants enhance the bioavailability of NO. (CX0908_0001, 0002; PX0058).

Response to Finding No. 835:
The proposed finding is unsupported by the cited evidence.

836. NO helps maintain healthy blood vessels, which improves blood flow to almost every organ in the body, including the heart. (Heber, Tr. 1816, 1969; Burnett, Tr. 2250).

Response to Finding No. 836:
The proposed finding is not supported by the cited evidence; neither Dr. Heber nor Dr. Burnett testified as such.

837. NO plays a key role in inflammation, blood flow regulation, cell growth and smooth muscle relaxation, all of which offer protection against atherosclerosis. (Heber, Tr. 1816, 1969, 1999; PX0149-0004; Burnett, Tr. 2249-2250; PX0189; PX0190-0006; Melman, Tr. 1169).

Response to Finding No. 837:
The proposed finding is unsupported by the cited evidence.

838. Maintaining healthy blood vessels and the flow of blood to the heart and penis are important to cardiovascular health and erectile function. (PX0149 at ¶ 12; Burnett, Tr. 2249-2250; PX0189; PX0190-0006; Heber, Tr. 1999; Melman, Tr. 1169).

Response to Finding No. 838:
The proposed finding is unsupported by the cited evidence. However, Complaint Counsel does not disagree that Dr. Melman testified that blood vessels and the flow of the blood to the penis are important to erectile function. (Melman, Tr. 1169).

839. Competent and reliable basic scientific evidence and clinical evidence shows that the Challenged Products affect NO in that they increase and prolong cellular concentrations of NO by protecting it from oxidation. (Burnett, Tr. 2251-2256; PX0349 (Burnett, Dep. at 103, 116-119, 137); Heber, Tr. 2012; PX0149; PX0189-0011; PX0058; PX0059).

Response to Finding No. 839:
Complaint Counsel has no specific response, except to note that Complaint Counsel's experts reviewed the totality of the evidence, including the studies cited above, and concluded that there is not enough reliable scientific evidence to substantiate Respondents' claims. (*See* CCFF ¶¶ 962-64, 1037, 1085-86).

840. In sum, the expert opinions and affirmative evidence presented by Respondents prove that the antioxidants in the Challenged Products increase and prolong NO in the body which is beneficial to cardiovascular, prostate and erectile health.

Response to Finding No. 840:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs.

2. Complaint Counsel Have Failed to Rebut Respondents' Evidence on the Challenged Products' Effect on Nitric Oxide

841. Complaint Counsel's experts provided no expert opinion that NO does not help maintain healthy blood vessels and blood flow. (CX1293; PX0362 (Stampfer, Dep. at 1-205); Stampfer, Tr. 689-885; CX1291; PX0361 (Sacks, Dep. at 1-273); Sacks, Tr. 1410-1625; CX1289; PX0360 (Melman, Dep. at 1-141); Melman, Tr. 1069-1197; CX1287; PX0358 (Eastham, Dep. at 1-158); Eastham, Tr. 1204-1351; CX1295; PX0357 (Stewart, Dep. at 1-194); Stewart, Tr. 3158-3242; PX0359 (Mazis, Dep. 1-242); Mazis, Tr. 2651-2761).

Response to Finding No. 841:

The proposed finding mischaracterizes the evidence. Complaint Counsel does not disagree that its experts did not explicitly opine that NO does not help maintain healthy blood vessels and blood flow. However, Complaint Counsel's experts reviewed the totality of the evidence, including the studies cited above, and concluded that there is not enough reliable scientific evidence to substantiate Respondents' claims. (*See* CCFF ¶¶ 962-64, 1037, 1085-86). In particular, Dr. Melman opined that basic research studies about antioxidant's effects on nitric oxide levels do not directly involve erectile function in humans and cannot alone prove that POM treats, prevents, or reduces the risk of erectile dysfunction. (*See* CCFF ¶ 1085).

842. Complaint Counsel's experts provided no expert opinion that antioxidants do not protect NO against oxidative destruction. (CX1293; PX0362 (Stampfer, Dep. at 1-205); Stampfer, Tr. 689-885; CX1291; PX0361 (Sacks, Dep. at 1-273); Sacks, Tr. 1410-1625; CX1289; PX0360 (Melman, Dep. at 1-141); Melman, Tr. 1069-1197; CX1287; PX0358 (Eastham, Dep. at 1-158); Eastham, Tr. 1204-1351; CX1295; PX0357 (Stewart, Dep. at 1-194); Stewart, Tr. 3158-3242; PX0359 (Mazis, Dep. 1-242); Mazis, Tr. 2651-2761).

Response to Finding No. 842:

The proposed finding mischaracterizes the evidence. Complaint Counsel does not disagree that its experts did not explicitly opine that antioxidants do not protect NO against oxidative destruction. However, Complaint Counsel's experts reviewed the totality of the evidence, including the studies cited above, and concluded that there is not enough reliable scientific evidence to substantiate Respondents' claims. (*See* CCFF ¶¶ 962-64, 1037, 1085-86).

843. Complaint Counsel's experts provided no expert opinion disputing that NO plays a role in cardiovascular and erectile health. (CX1293; PX0362 (Stampfer, Dep. at 1-205); Stampfer, Tr. 689-885; CX1291; PX0361 (Sacks, Dep. at 1-273); Sacks, Tr. 1410-1625; CX1289; PX0360 (Melman, Dep. at 1-141); Melman, Tr. 1069-1197; CX1287; PX0358 (Eastham, Dep. at 1-158); Eastham, Tr. 1204-1351; CX1295; PX0357 (Stewart, Dep. at 1-194); Stewart, Tr. 3158-3242; PX0359 (Mazis, Dep. 1-242); Mazis, Tr. 2651-2761).

Response to Finding No. 843:

The proposed finding mischaracterizes the evidence. Complaint Counsel does not disagree that its experts did not explicitly dispute that NO plays a role in cardiovascular and erectile health. However, Complaint Counsel's experts reviewed the totality of the evidence, including the studies cited above, and concluded that there is not enough reliable scientific evidence to substantiate Respondents' claims. (*See* CCFF ¶¶ 962-64, 1037, 1085-86). In particular, Dr. Melman opined that while nitric oxide plays an important role in erectile function, nitric oxide alone does not produce erections. (*See* CCFF ¶ 1084). Therefore, basic research studies about antioxidant's effects on nitric oxide levels do not directly involve erectile function in humans and cannot alone prove that POM treats, prevents, or reduces the risk of erectile dysfunction. (*See* CCFF ¶ 1085).

844. Antioxidants positively impact the level and preservation of nitric oxide which is beneficial to cardiovascular and erectile health.

Response to Finding No. 844:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs.

845. Therefore, Complaint Counsel have failed to present expert opinion on the Challenged Products effect on nitric oxide.

Response to Finding No. 845:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs.

C. Antioxidants Lessen Inflammation Which Provides Health Benefits In Regard to Cardiovascular Health, Cancer and Erectile Function

1. Chronic Inflammation Leads to a Variety of Health Problems

846. It is well established in the scientific community that chronic inflammation is a characteristic prostate cancer. (deKernion, Tr. 3046-3047; Heber, Tr. 1957, 1992; CX1352 (Heber, Dep. at 257-258); PX0192-0029-0030, 0045; PX0337a21-0011).

Response to Finding No. 846:
Complaint Counsel does not disagree that Dr. Heber and Dr. deKernion testified that inflammation plays a role in prostate cancer. However, the proposed finding's suggestion that it is well established in the scientific community is not supported by the cited evidence.

847. It is well established in the scientific community that chronic inflammation plays a critical role in atherosclerosis, the narrowing of arteries caused by buildup of cholesterol-based plaques, which is the primary cause of heart disease. (Heber, Tr. 1957; PX0192-0029-0030, 0033, 0045; PX0298a41-0009; PX0337a21-0011).

Response to Finding No. 847:
The proposed finding is unsupported by the cited evidence

848. Because atherosclerosis leads to restricted blood flow, it is a causative factor in erectile dysfunction. (Heber, Tr. 1958-1960; Melman, Tr. 1169).

Response to Finding No. 848:
The proposed finding is unsupported by the cited evidence. Moreover, Dr. Heber does not hold himself out as an expert in cardiovascular disease (CCFF ¶ 728), was not asked to opine on whether the heart benefit claims challenged in the complaint were true or substantiated (CCFF ¶¶ 730-31), and did not consider all of the available clinical evidence when reaching his conclusions (CCFF ¶¶ 849, 874). Furthermore, at his deposition, Dr. Heber testified that he was not an expert in erectile dysfunction treatment. (PX0353 (Heber, Dep. at 11)). *See also* Response to Finding 968.

849. Activation of nuclear factor-*K*B ("NF-*K*B"), the oxidative stress responsive transcription factor, has been linked with a variety of inflammatory diseases, including prostate cancer and cardiovascular disease. (PX0192-0015, 0029-030, 0033-0034; CX1352 (Heber, Dep. at 258); PX0298a41-0009).

Response to Finding No. 849:
Complaint Counsel has no specific response, but objects to the deposition testimony cited in the proposed finding as non-designated testimony.

850. Inflammation itself causes oxidation in the body. (Heber, Tr. 1956-1957).

Response to Finding No. 849:
Complaint Counsel does not disagree that Dr. Heber testified as such.

851. Oxidized LDL cholesterol tends to accumulate in the wall of blood vessels. (Heber, Tr. 1959).

Response to Finding No. 851:
Complaint Counsel agrees that Dr. Heber testified as such, however, Dr. Heber does not hold himself out as an expert in cardiovascular disease (CCFF ¶ 728), was not asked to opine on whether the heart benefit claims challenged in the complaint were true or substantiated (CCFF ¶¶ 730-31), and did not consider all of the available clinical evidence when reaching his conclusions (CCFF ¶¶ 849, 874).

852. Macrophages continuously consume the oxidized LDL cholesterol that accumulates in the blood vessels and become foam cells, resulting in inflammation. (Heber, Tr. 1960; PX0021-0001).

Response to Finding No. 852:
Complaint Counsel has no specific response.

853. Atherosclerotic plaque forms as a result of damage to the blood vessel that begins with the oxidation of LDL cholesterol that accumulates in the vessels. (Heber, Tr. 1959-1960; PX0021-0001).

Response to Finding No. 853:
Complaint Counsel has no specific response.

854. Unstable atherosclerotic plaque, which causes heart disease, contains oxidized LDL cholesterol and macrophages, reft with inflammation. (Heber, Tr. 1960, 2088).

Response to Finding No. 854:
Complaint Counsel has no specific response.

855. High-density lipoprotein ("HDL") contains an antioxidant enzyme called PON1 that protects against oxidation. (Heber, Tr. 1961).

Response to Finding No. 855:
Complaint Counsel has no specific response.

856. Many antioxidants inhibit inflammation in the body. (Heber, Tr. 1957, 2003).

Response to Finding No. 856:
Complaint Counsel has no specific response.

857. It is well established within the scientific community that blocking inflammation or oxidation of cholesterol can stabilize plaque. (Heber, Tr. 1960; PX0192-0033).

Response to Finding No. 857:
Complaint Counsel does not disagree this is Dr. Heber's opinion, but disagrees with the conclusion drawn. Overall, suggestive associations between some specific antioxidant nutrients and CVD observed in observational studies, *in vitro* and animal studies, has not translated to consistent protective effects in humans, which demonstrates the importance of RCTs to establish a causal inference in humans. (CX1293 (Stampfer, Report at 0015)).

858. It is well established within the scientific community that inflammation in the prostate can be reduced if NF-*K*B is inhibited. (deKernion, Tr. 3046-3047; Heber, Tr. 1992; CX1352 (Heber, Dep. at 257-258); PX0192-0029-0030, 0045).

Response to Finding No. 858:
Complaint Counsel does not disagree that Dr. Heber and Dr. deKernion testified as such, but notes that the proposed finding's assertion that "it is well established within the scientific community" is unsupported by the cited evidence.

859. It is well established within the scientific community that the pathway that activates NF-*k*B can be inhibited by phytochemicals, thus providing a beneficial effect against atherosclerosis. (PX0192-0015, 0031; PX0298a41-0009).

Response to Finding No. 859:
The proposed finding's assertion that "it is well established within the scientific community" is unsupported by the cited evidence.

2. Respondents Presented Substantial Evidence of the Challenged Products' Anti-Inflammatory Capabilities

860. Competent and reliable scientific evidence shows that the antioxidants in the Challenged Products inhibit the pathway that activates NF-*k*B, thereby mediating atherosclerosis and improving blood flow to the penis. (PX0192-0015, 0031; PX0341 (Heber, Dep. at 257-258); PX0353 (Heber, Dep. at 122); PX0298a41-0009; Melman, Tr. 1169).

Response to Finding No. 860:

The proposed finding is unsupported by the cited evidence. Moreover, Complaint Counsel's experts opined that *in vitro* and animal studies alone are not sufficient to show that the tested product will prevent or treat human disease. (*See* CCFF ¶¶ 763-64). Data from RCTs provide the best evidence of a causal relationship between a nutrient and a disease outcome in humans. (*See* CCFF ¶ 771).

861. Competent and reliable scientific evidence shows that the antioxidants in the Challenged Products inhibit the pathway that activates NF-*k*B, thereby reducing inflammation which is beneficial to cardiovascular and prostate health. (PX0192-0015, 0031; CX1352 (Heber, Dep. at 257-258); PX0353 (Heber, Dep. at 122); PX0298a41-0009).

Response to Finding No. 861:

The proposed finding is unsupported by the cited evidence. Moreover, Complaint Counsel's experts opined that *in vitro* and animal studies alone are not sufficient to show that the tested product will prevent or treat human disease. (*See* CCFF ¶¶ 763-64). Data from RCTs provide the best evidence of a causal relationship between a nutrient and a disease outcome in humans. (*See* CCFF ¶ 771).

862. Competent and reliable scientific evidence shows that the antioxidants in the Challenged Products increases PON1 association with HDL, thereby reducing inflammation in coronary arteries which is beneficial to cardiovascular health and other inflammatory diseases. (PX0021-0001; PX0192-0038; Heber, Tr. 1961).

Response to Finding No. 862:

The proposed finding is unsupported by the cited evidence. Moreover, Complaint Counsel's experts opined that *in vitro* and animal studies alone are not sufficient to show that the tested product will prevent or treat human disease. (*See* CCFF ¶¶ 763-64). Data from RCTs provide the best evidence of a causal relationship between a nutrient and a disease outcome in humans. (*See* CCFF ¶ 771). Moreover, Respondents' RCTs did not consistently show a positive effect on the PON1 biomarker. *See* Response to Finding 870.

Shukla, M, Gupta K, Rasheed Z, Khan K, Haggi, T, "*Consumption of hydrolysable tannins-rich pomegranate extract suppresses inflammation and joint damage in rheumatoid arthritis,*" Nutrition 24 (2008) 733-743

863. In 2008, in a peer-reviewed study entitled Consumption of hydrolysable tannins-rich pomegranate extract suppresses inflammation and joint damage in rheumatoid arthritis," by Shukla, M, Gupta K, Rasheed Z, Khan K, Haggi, T, (Nutrition 24 (2008) 733-743), Drs. Rasheed and Haqqi and their colleagues evaluated the anti-inflammatory properties of POMx in arthritic mice. (PX0124-0001).

Response to Finding No. 863:
Complaint Counsel has no specific response except to note that the claims challenged in this matter relate to heart disease, prostate cancer, and erectile dysfunction, not arthritis. (*See* CCFF ¶ 3).

864. The consumption of POMx delayed the onset and reduced the incidence of arthritis in mice. It also significantly reduced the disease's severity. In those mice fed POMx, the number of inflammatory cells infiltrating the joints was reduced and there was no destruction of bone or cartilage. (PX0124-0001).

Response to Finding No. 864:
Complaint Counsel does not disagree with the conclusion of the study, but notes that Respondents acknowledged in internal documents there were no pomegranate studies on humans for arthritis. Moreover, Respondents internally considered whether or not to conduct a pilot study costing $500,000 and then, if positive, conduct a further "definitive" study on 100+ patients costing $1-2 million. Respondents further noted that the results of a clinical study would be "difficult to predict" and questioned whether it could be "going too far away from our Cardiovascular / Prostate core message[.]" (CX1029_0007).

865. This study demonstrates that POMx has anti-inflammatory properties.

Response to Finding No. 865:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs.

Rasheed Z, Akhtar N, Anbazhagan A, Ramamurthy S, Shukla M, Haqqi T, "*Polyphenol-rich pomegranate extract (POMx) suppresses PMACI-induced*

***expression of pro-inflammatory cytokines by inhibiting the activation of MAP Kinases and NF-kB in human KU812 cells,"* J. of Inflammation 6:1-12 (2009)**

866. In 2009, in a peer-reviewed study entitled, "Polyphenol-rich pomegranate extract (POMx) suppresses PMACI-induced expression of pro-inflammatory cytokines by inhibiting the activation of MAP Kinases and NF-kB in human KU812 cells," by Rasheed Z, Akhtar N, Anbazhagan A, Ramamurthy S, Shukla M, Haqqi T (J. of Inflammation 6:1-12 (2009), Drs. Rasheed and Haqqi examined the anti-inflammatory properties of POMx. (PX0125-0001).

Response to Finding No. 866:
Complaint Counsel has no specific response.

867. The consumption of POMx inhibited the activation of both mast cells and of NF-kB, a transcription factor that is part of an important signaling pathway involved in inflammatory responses related to several cancers. (PX0125-0001).

Response to Finding No. 867:
Complaint Counsel does not disagree that the article states as such.

868. This study demonstrates that POMx has anti-inflammatory properties.

Response to Finding No. 868:
The proposed finding is not supported by any reference to the record, in violation of the

Court's Order on Post-Trial Briefs.

869. In sum, the expert opinions and affirmative evidence presented by Respondents prove that the antioxidants in the Challenged Products lessen inflammation which is beneficial to cardiovascular health, cancer prevention and erectile function.

Response to Finding No. 869:
The proposed finding is not supported by any reference to the record, in violation of the

Court's Order on Post-Trial Briefs.

3. Complaint Counsel Have Failed to Rebut Respondents Evidence on the Challenged Products' Ability to Lesson Inflammation

870. Complaint Counsel's experts provided no expert opinion disputing the fact that antioxidants inhibit inflammation. (CX1293; PX0362 (Stampfer, Dep. at 1-205); Stampfer, Tr. 689-885; CX1291; PX0361 (Sacks, Dep. at 1-273); Sacks, Tr. 1410-1625; CX1289; PX0360 (Melman, Dep. at 1-141); Melman, Tr. 1069-1197; CX1287; PX0358 (Eastham, Dep. at 1-158); Eastham, Tr. 1204-1351; CX1295; PX0357 (Stewart, Dep. at 1-194); Stewart, Tr. 3158-3242; PX0359 (Mazis, Dep. 1-242); Mazis, Tr. 2651-2761).

Response to Finding No. 870:

The proposed finding mischaracterizes the evidence. Complaint Counsel does not disagree that its experts did not explicitly dispute that antioxidants inhibit inflammation. However, Complaint Counsel's experts reviewed the totality of the evidence, including the studies cited above, and concluded that there is not enough reliable scientific evidence to substantiate Respondents' claims. (*See* CCFF ¶¶ 962-64, 1037, 1085-86). In particular, Complaint Counsel's experts reviewed the results of Respondents' human clinical studies in which the POM Products had no effect on biomarkers (i.e., PON 1, TBARS) for inflammation. (*See* CCFF ¶¶ 825, 884, 915, 928, 933, 949).

871. Complaint Counsel's experts provided no expert opinion disputing the fact that antioxidants inhibit NF-*k*B activation. (CX1293; PX0362 (Stampfer, Dep. at 1-205); Stampfer, Tr. 689-885; CX1291; PX0361 (Sacks, Dep. at 1-273); Sacks, Tr. 1410-1625; CX1289; PX0360 (Melman, Dep. at 1-141); Melman, Tr. 1069-1197; CX1287; PX0358 (Eastham, Dep. at 1-158); Eastham, Tr. 1204-1351; CX1295; PX0357 (Stewart, Dep. at 1-194); Stewart, Tr. 3158-3242; PX0359 (Mazis, Dep. 1-242); Mazis, Tr. 2651-2761).

Response to Finding No. 871:

The proposed finding mischaracterizes the evidence. Complaint Counsel does not disagree that its experts did not explicitly dispute that antioxidants inhibit NF-*k*B activation. However, Complaint Counsel's experts reviewed the totality of the evidence, including the studies cited above, and concluded that there is not enough reliable scientific evidence to substantiate Respondents' claims. (*See* CCFF ¶¶ 962-64, 1037, 1085-86).

872. Complaint Counsel's experts provided no expert opinion disputing the role of inflammation in the incidences of cardiovascular disease and prostate cancer. (CX1293; PX0362 (Stampfer, Dep. at 1-205); Stampfer, Tr. 689-885; CX1291; PX0361 (Sacks, Dep. at 1-273); Sacks, Tr. 1410-1625; CX1289; PX0360 (Melman, Dep. at 1-141); Melman, Tr. 1069-1197; CX1287; PX0358 (Eastham, Dep. at 1-158); Eastham, Tr. 1204-1351; CX1295; PX0357 (Stewart, Dep. at 1-194); Stewart, Tr. 3158-3242; PX0359 (Mazis, Dep. 1-242); Mazis, Tr. 2651-2761).

Response to Finding No. 872:

The proposed finding mischaracterizes the evidence. Complaint Counsel does not disagree that its experts did not explicitly dispute the role of inflammation in the incidences of cardiovascular disease and prostate cancer. However, Complaint Counsel's experts reviewed the totality of the evidence, including the studies cited above, and concluded that there is not enough reliable scientific evidence to substantiate Respondents' claims. (*See* CCFF ¶¶ 962-64, 1037, 1085-86). In particular, Complaint Counsel's experts reviewed the results of Respondents' human clinical studies in which the POM Products had no effect on biomarkers (i.e., PON 1, TBARS) for inflammation. (*See* CCFF ¶¶ 825, 884, 915, 928, 933, 949).

873. Therefore, Complaint Counsel have failed to present expert opinion on the Challenged Products' ability to lessen inflammation.

Response to Finding No. 873:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs.

D. The Antioxidants in the Challenged Products Are Bioavailable in Humans Because They Are Absorbed Into the Blood and Urine

1. Respondents Presented Overwhelming Evidence on the Bioavailability of the Antioxidants in the Challenged Products

874. The antixodiants in the Challenged Products are bioavailable in humans. (PX0073; PX0074; PX0075; PX0192, 0021, 0025; CX1352 (Heber, Dep. at 24)).

Response to Finding No. 874:
Complaint Counsel has no specific response, except to note that studies demonstrating that antioxidants are absorbed by the body do not prove that the antioxidants treats, prevents or reduces the risk of chronic diseases. RCTs are needed before drawing firm conclusions about causality. (*See* CCFF ¶¶ 1102-08). In addition, Complaint Counsel notes that the proposed finding is unsupported by PX0192_0021 and 0025.

875. A substance is said to be "bioavailable" when it has been absorbed into the body and is present in the blood, urine, or other body tissue or fluid. (PX0192-0024-0025).

Response to Finding No. 875:
The proposed finding is unsupported by the cited evidence.

876. Ellagic acid, an antioxidant in pomegranate juice, is a biomarker for bioavailability because after consuming pomegranate juice or extract, studies show that ellagic acid is absorbed into the blood of humans. (CX1352 (Heber, Dep. at 24); PX0192-0021, 0025).

Response to Finding No. 876:
Complaint Counsel does not disagree that Dr. Heber opined as such but notes that studies demonstrating that antioxidants are absorbed by the body do not prove that the antioxidants treats, prevents or reduces the risk of chronic diseases. RCTs are needed before drawing firm conclusions about causality. (*See* CCFF ¶¶ 1102-08).

877. Hydroxyl-6H-benzopyran-6-one derivatives ("urolithins"), a metabolite of punicalagin, are biomarkers for bioavailability because after consuming pomegranate juice or extract, studies show the number of urolithins in the urine of humans increases. (PX0192-0015, 0025).

Response to Finding No. 877:
The proposed finding is unsupported by the cited evidence.

878. Dimethylellagic acid glucuronide ("DMEAG"), a metabolite of punicalagin, is a biomarker for bioavailability because after consuming pomegranate juice or extract, studies show DMEAG is detected in the urine of humans. (PX0192-0025).

Response to Finding No. 878:
The proposed finding is unsupported by the cited evidence.

879. Punicalagins contain within their molecular structure ellagic acid, an antioxidant found in pomegranates, which is released and absorbed into the blood over several hours and is metabolized to an even smaller molecule called urilithin. (PX0192-0015, 0021).

Response to Finding No. 879:
Complaint Counsel does not disagree that Dr. Heber opined as such.

880. Molecules that are not absorbed into the blood in the intestine travel to the colon, where bacteria called microbiome break down some of the molecules. Urolithins are then absorbed into the blood and are biologically active. (CX1352 (Heber, Dep. at 26, 76)).

Response to Finding No. 880:

The proposed finding is incomplete in that Dr. Heber testified that he does not have data on what percentage of polyphenols consumed in food become bioavailable. (CX1352 (Heber, Dep. at 76)).

881. A great deal is known within the scientific community about the absorption and metabolism of the hydrolysable tannins in pomegranate juice. (PX0192-0024).

Response to Finding No. 881:
The proposed finding mischaracterizes Dr. Heber's expert report in that he did not state that a great deal is known "within the scientific community."

> **Seeram NP, Zhang Y, McKeever R, Henning S, Lee R, Suchard, M, Li Z, Chen S, Thames G, Zerline A, Nguyen M, Wang D, Dreher M, Heber D, "*Pomegranate juice and extracts provide similar levels of plasma and urinary ellagitannin metabolites in human subjects*" J. Medicinal Food 11(2) 2008, 390-394**

882. In 2008, in a peer-reviewed human clinical study entitled **"**Pomegranate juice and extracts provide similar levels of plasma and urinary ellagitannin metabolites in human subjects," by Seeram NP, Zhang Y, McKeever R, Henning S, Lee R, Suchard, M, Li Z, Chen S, Thames G, Zerline A, Nguyen M, Wang D, Dreher M, Heber D, J. Medicinal Food 11(2) 2008, 390-394, Dr. Heber and his colleagues examined the bioavailability of antioxidant polyphenols of pomegranate juice, POMx Pills and POMx Liquid. (PX0073-0001, 0002).

Response to Finding No. 882:
Complaint Counsel has no specific response.

883. In this study, sixteen healthy volunteers sequentially consumed, with a 1-week washout period between treatments, pomegranate juice (8 oz), POMx Liquid (5ml in 8 oz water) and POMx Pills (1,000 mg). (PX00730001, 0002).

Response to Finding No. 883:
Complaint Counsel does not disagree that the article states as such.

884. The three POM products delivered 857, 776 and 755 mg polyphenols as gallic acid equivalents ("GAE"), respectively. (PX0073-0001).

Response to Finding No. 884:
Complaint Counsel does not disagree that the article states as such.

885. Ellagic acid increased in similar levels in the plasma of all subjects following administration of the pomegranate juice or the pomegranate extract. (PX0073-0001, 0003).

Response to Finding No. 885:
Complaint Counsel does not disagree that the article states as such.

886. Urolithin-A glucuronide, a urinary metabolite of ellagic acid, was detected in similar levels in urine samples of the test subjects, reaching a maximum concentration of approximately 1,000 ng/mL and remained elevated for over 48 hours after consumption of the pomegranate juice or the pomegranate extract. (PX0073-0001, 0004).

Response to Finding No. 886:
Complaint Counsel has no specific response.

887. The pomegranate juice, POMx Pills and POMx Liquid had similar ellagitannin bioavailability. (PX0073-0001, 0004).

Response to Finding No. 887:
Complaint Counsel has no specific response.

888. This study demonstrates that the consumption of pomegranate juice, POMx Pills and POMx Liquid resulted in absorption of ellagic acid in the blood and urolithin-A glucuronide in the urine of humans. (PX0073-0001, 0004).

Response to Finding No. 888:
Complaint Counsel has no specific response, except to note that studies demonstrating that antioxidants are absorbed by the body do not prove that the antioxidants treats, prevents or reduces the risk of chronic diseases. Several antioxidant nutrients have been associated with reduced risk of prostate cancer *in vitro* and observational studies. While these nutrients worked *in vitro*, these nutrients did not have the same effect when studied in humans. Therefore, RCTs are needed before drawing firm conclusions about causality. (*See* CCFF ¶¶ 1105-06).

Seeram NP, Henning SM, Zhang, Y, Suchard, M. Li Z, Heber D, "*Pomegranate juice ellagitannin metabolites are present in human plasma and some persist in urine for up to 48 hours*" J. Nutr. 2006 6:2481-5

889. In 2006, in a peer-reviewed study entitled **"**Pomegranate juice ellagitannin metabolites are present in human plasma and some persist in urine for up to 48 hours," by Seeram NP, Henning SM, Zhang, Y, Suchard, M. Li Z, Heber D (J. Nutr. 136:2481-2485 (2006), Dr. Heber and his colleagues examined the absorption of pomegranate ellagitannins in humans. (PX0074-0001; PX0192-0024).

Response to Finding No. 889:

Complaint Counsel has no specific response.

890. In this study, 18 healthy human subjects were given 180 ml of pomegranate juice concentrate, and blood samples were obtained for 6 hours afterwards, and twenty-four hour urine collections were obtained on the day before, the day of, and the day after the study. (PX0074-0001, 0002; PX0192-0024).

Response to Finding No. 890:
Complaint Counsel does not disagree that the article states as such.

891. The most abundant bioactive polyphenol in pomegranate juice are the hydrolysable tannins called ellagitannins formed when ellagic acid binds with a carbohydrate. (PX0074-0001, 0003; PX0075-0001).

Response to Finding No. 891:
Complaint Counsel has no specific response.

892. Punicalagin, which occurs as isomers, is the predominant ellagitannin present in pomegranate juice. (PX0074-0001).

Response to Finding No. 892:
Complaint Counsel has no specific response.

893. The metabolites of punicalagin are ellagic acid, DMEAG and urolithins. (PX0074-0002).

Response to Finding No. 893:
Complaint Counsel has no specific response.

894. Ellagitannins belong to the chemical class of hydrolysable tannins, which release ellagic acid into the plasma on hydrolysis. (PX0074-0001, 0004).

Response to Finding No. 894:
Complaint Counsel has no specific response.

895. In this study, ellagic acid was detected in the plasma of all subjects post-consumption. (PX0074-0001, 0003; PX0192-0025).

Response to Finding No. 895:
Complaint Counsel has no specific response.

896. Ellagic acid metabolites, including DMEAG and urolithins, were detected in the plasma and urine of the subjects post-consumption in conjugated and free forms. (PX0074-0001, 0003; PX0192-0025).

Response to Finding No. 896:
Complaint Counsel has no specific response.

897. DMEAG was found in the urine obtained from 15 of 18 subjects on the day of the study, but was not detected on the day before or day after the study, demonstrating its potential as a biomarker of intake of pomegranate juice. (PX0074-0001, 0003; PX0192-0025).

Response to Finding No. 897:
Complaint Counsel has no specific response.

898. Urolithin A-glucuronide was found in the urine of 11 subjects on the day of the study and in the urine of 16 subjects the day after the study. (PX0074-0001, 0003; PX0192-0025).

Response to Finding No. 898:
Complaint Counsel has no specific response.

899. Urolithin B-glucuronide was found in the urine of 3 subjects on the day of the study and in the urine of 5 subjects on the day after the study. (PX0074-0001, 0003; PX0192-0025).

Response to Finding No. 899:
Complaint Counsel has no specific response.

900. Urinary ellagic acid metabolites, such as urolithins, arise from biotransformation by the intestinal microflora on ellagic acid. (PX0074-0004).

Response to Finding No. 900:
Complaint Counsel has no specific response.

901. Urolithins, formed by intestinal bacteria, contribute to the biological effects of pomegranate juice as they persist in plasma and tissues and account for some of the health benefits noted after consuming pomegranates. (PX0074-0001, 0003; PX0192-0025).

Response to Finding No. 901:
Complaint Counsel has no specific response.

902. This study demonstrates the bioavailability of the antioxidants found in pomegranate juice. (PX0074-0004; PX0192-0025).

Response to Finding No. 902:
Complaint Counsel disagrees with the conclusion drawn and notes that urolithins were not found in the urine of all study participants and the study authors concluded that "further research is warranted." (PX0074_0004 and Table 2 thereof).

Seeram NP, Lee R, Heber D, "*Bioavailability of ellagic acid in human plasma after consumption of ellagitannins from pomegranate (Punica granatum) juice*" Clinica Chimica Acta 348 (2004) 63-68

903. In 2004, in a peer-reviewed study entitled **"**Bioavailability of ellagic acid in human plasma after consumption of ellagitannins from pomegranate (Punica granatum) juice," by Seeram NP, Lee R, Heber D, Clinica Chimica Acta 348 (2004) 63-68, Dr. Heber and his colleagues examined the bioavailability ellagic acid from consumption of ellagtannins from pomegranate juice concentrate in humans. (PX0075-0001-0002).

Response to Finding No. 903:
Complaint Counsel has no specific response.

904. In this study, a human subject orally consumed 180 ml (6 oz) of pomegranate juice containing 25 mg of ellagic acid and 318 mg of ellagitannins. Blood samples were collected before and at 0.5, 1, 2, 3, 4, and 6 hours after consumption of the concentrated pomegranate juice. (PX0075-0001, 0004-0005).

Response to Finding No. 904:
Complaint Counsel has no specific response except to note that this study involved a single human subject – one of the study's authors. (PX0075-0002).

905. Ellagic acid was not detected in the subjects' blood pre-consumption. (PX0075-0005).

Response to Finding No. 905:
Complaint Counsel has no specific response.

906. Ellagic acid was detected in the blood at 0.5, 1, 2 and 3 hours post-consumption. The maximum concentration occurred after 1 hour post-consumption. (PX0075-0001, 0005).

Response to Finding No. 906:
Complaint Counsel has no specific response.

907. This was the first study to show the absorption of ellagic acid from concentrated pomegranate juice in the human body. (PX0075-0001, 0002, 0006).

Response to Finding No. 907:
Complaint Counsel has no specific response.

908. This study demonstrates that ellagic acid is a biomarker for the bioavailability of ellagitannins in humans. (PX0075-0001, 0006).

Response to Finding No. 908:
The proposed finding mischaracterizes the cited evidence. The authors of the study wrote that "EA can be considered as a biomarker for future human bioavailability studies

involving consumption of ETs from food sources . . . [h]owever, further studies should be designed." In addition, since bioavailability and pharmacokinetics vary in humans, the authors say "further clinical studies . . . should be investigated." (PX0075-0006).

909. In sum, the expert opinions and affirmative evidence presented by Respondents prove that the antioxidants in the Challenged Products are bioavailable in humans.

Response to Finding No. 909:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs.

2. Complaint Counsel Have Failed to Rebut Respondents' Evidence on the Bioavailability of the Challenged Products

910. It was not within the scope of Complaint Counsel's experts' assignment, and none opined in their report, that credible and reliable scientific evidence shows that the antioxidants in the Challenged Products are not bioavailable in humans. (CX1287; CX1289; CX1291; CX1293; CX1295).

Response to Finding No. 910:
Complaint Counsel does not disagree that its experts were not asked to explicitly opine on whether the antioxidants in the POM Products are bioavailable in humans. Nevertheless, Complaint Counsel's experts reviewed the totality of the evidence, including the studies cited above, and concluded that there is not enough reliable scientific evidence to substantiate Respondents' claims. (*See* CCFF ¶¶ 962-64, 1037, 1085-86).

911. Complaint Counsel's experts provided no expert testimony rebutting Respondents' evidence on the bioavailability of the antioxidants in the Challenged Products. (PX0362 (Stampfer, Dep. at 1-205); Stampfer, Tr. 689-885; PX0361 (Sacks, Dep. at 1-273); Sacks, Tr. 1410-1625; PX0360 (Melman, Dep. at 1-141); Melman, Tr. 1069-1197; PX0358 (Eastham, Dep. at 1-158); Eastham, Tr. 1204-1351; PX0357 (Stewart, Dep. at 1-194); Stewart, Tr. 3158-3242; PX0359 (Mazis, Dep. 1-242); Mazis, Tr. 2651-2761).

Response to Finding No. 911:
Complaint Counsel does not disagree that its experts did not explicitly opine on whether the antioxidants in the POM Products are bioavailable in humans. Nevertheless,

Complaint Counsel's experts reviewed the totality of the evidence, including the studies cited above, and concluded that there is not enough reliable scientific evidence to substantiate Respondents' claims. (*See* CCFF ¶¶ 962-64, 1037, 1085-86).

912. Complaint Counsel's expert, Dr. David Sacks, admitted that the issue of the bioequivalence of POMx to POM Juice was not within the scope of his assignment as an expert in this case. (PX0361 (Sacks, Dep. at 77); CX1291_0008-0009).

Response to Finding No. 912:
Complaint Counsel has no specific response.

913. Complaint Counsel's expert, Professor Stampfer, has no opinion on the way in which the antioxidant compounds in pomegranates are metabolized within the human body. (PX0362 (Stampfer, Dep. at 200)).

Response to Finding No. 913:
Complaint Counsel does not disagree that Dr. Stampfer testified as such.

914. Therefore, Complaint Counsel have failed to present expert opinion or affirmative evidence that the Challenged Products are not bioavailable in humans.

Response to Finding No. 914:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs.

E. POMx Is Equivalent to POM Juice in Providing Nutritional Benefits

1. Respondents Presented Overwhelming Evidence on the Equivalency of the Challenged Products

915. POMx Pills and POMx Liquid contain polyphenol antioxidants derived from pomegranates similar to those found in POM Juice. (Heber, Tr. 1993).

Response to Finding No. 915:
The proposed finding is unsupported by the cited evidence.

916. The Challenged Products contain a diverse, complex mixture of antioxidant polyphenols, including hydrolysable tannins, flavonols, anthocyanins and acids. The hydrolysable tannins include, among others, punicalagins, ellagitannins, punicalins and gallotannins. The acids include ellagic acid, gallic acid and gallagic acid. (PX0192-0016, 0024; PX0074-0002; Heber, Tr. 2001-2002).

Response to Finding No. 916:

The proposed finding mischaracterizes the evidence insofar as it suggests that POM Juice and POMx are the same. (*See* CCFF ¶¶ 125-26 (POM Juice contains 8-15% anthocyanins, sugars); CCFF ¶130 (Heber testimony that extracts contain no anthocyanins); CCFF ¶¶ 964-965 (POM Juice and POMx are not the same; Heber says that anthocyanins "undoubtedly" contribute to antioxidant capacity of POM Juice); Sacks, Tr. 1524 (noting that preliminary research suggests that anthocyanins may have effects on vascular function)).

917. The Challenged Products have a similar level of primary polyphenols, which are hydrolyzed tannins which make up over 85% of the polyphenol antioxidants in all these products. (Heber, Tr. 2001 – 2002).

Response to Finding No. 917:
The proposed finding mischaracterizes the evidence insofar as it suggests that POM Juice and POMx are the same. *See* Response to Finding 916.

918. Because 85% of the polyphenols in POMx Pills and POMx Liquid are hydrolyzable tannins, and because they play the primary role in antioxidant activity, the bioactive components of POM Juice are preserved in the POMx products. (Heber, Tr. 2001 – 2002).

Response to Finding No. 918:
The proposed finding is unsupported by the cited evidence. Dr. Heber did not say anything about "85%," or "primary role," or "bioactive." (Heber, Tr. 2001-02). Moreover, he has conceded that anthocyanins, present in POM Juice but not the extracts, "undoubtedly contribute" to the Juice's antioxidant activity. *See* Response to Finding 916.

919. The Challenged Products each deliver at least 650 mg polyphenols as gallic acid equivalent per serving. (Heber, Tr. 2186; PX0073-0001).

Response to Finding No. 919:

The proposed finding mischaracterizes the evidence insofar as it suggests that POM Juice and POMx are the same. They are different products, as set forth in Response to Finding 916.

920. Based on basic scientific studies focusing on the hydrolysable tannins family, especially punicalagins and ellagitannins, show that POMx Pills and POMx Liquid are equivalent to POM Juice in providing health benefits to humans. (Heber, Tr. 2002).

Response to Finding No. 920:
The proposed finding mischaracterizes the evidence insofar as it suggests that POM Juice and POMx are the same. *See* Response to Finding 916. Moreover, the proposed finding is irrelevant, as Respondents have failed to substantiate their advertising claims that either POM Juice or POMx prevents, reduces the risk of, or treats, heart disease, prostate cancer, or erectile dysfunction.

921. The POMx Pill and POMx Liquid have equivalent bioavailablity as POM Juice. (PX0073-0001, 0004; PX0139-0001).

Response to Finding No. 921:
Complaint Counsel objects to the proposed finding on the grounds that the term "bioavailability" is vague and ambiguous. The proposed also finding mischaracterizes the evidence. The first cited study (PX0073), sponsored by Respondent and conducted on 16 volunteers, found that consumption of the 3 products produced "similar" absorption of [ellagic acid]. (PX0073_0004). Ellagic acid, however, is only one ingredient in pomegranate juice. (CCFF ¶ 126). The cited study did not measure for absorption of other phenolic compounds, such as anthocyanins (PX0073_0004) which are present in the juice, but not in the extracts (CCFF ¶¶ 126, 130). PX0139 does not support the proposed finding in any manner.

922. Animal studies indicate that the effects of pomegranate juice and POMx Pills on prostate cancer are equivalent. (CX1352 (Heber, Dep. at 336); Heber, Tr. 2002).

Response to Finding No. 922:

The proposed finding mischaracterizes the record insofar as it suggests that the products have been shown to be the same. Dr. Heber said that in animal studies, the effects of the POM Juice and extracts were "similar." (Heber, Tr. 2002). He also said that there was no human data comparing POM Juice and POMx Pills on prostate cancer. (CX1352 (Heber, Dep. at 336)).

923. In a study entitled "*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*," Dr. Michael Carducci at John Hopkins University obtained a similar result when studying the effect of POMx on PSADT as obtained by Dr. Pantuck in his study entitled "Phase II Study of Pomegranate Juice for Men With Rising Prostate-Specific Antigen following Surgery or Radiation for Prostate Cancer," where the effectiveness of pomegranate juice on PSADT was studied. (Heber, Tr. 2002; PX0196 at 23-24; CX1341a214-0001).

Response to Finding No. 923:
Complaint Counsel does not disagree that Dr. Heber stated that the results of the two studies were "similar." However, Dr. Heber also admitted that there was no human data comparing POM Juice and POMx Pills on prostate cancer. (CX1352 (Heber, Dep. at 336)).

924. In 2009, in a study entitled "*Effects of pomegranate juice and extract polyphenols on platelt function*," Dr. Teresa Mattiello and her colleagues showed in an *in vitro* study that pomegranate juice and pomegranate extract have similar effects on inhibiting platelet aggregation, which is beneficial to cardiovascular health. (PX0192-0050; PX0017).

Response to Finding No. 924:
Complaint Counsel has no specific response, except to note that (a) the study is an *in vitro* study, conducted on human blood, (b) the number of donors is not stated, and they are described only as "healthy, drug-free volunteers," and (c) the study does not contain a direct statistical comparison of the results of tests using pomegranate juice and extract, which may explain why the results were described only as "similar." (*See* PX0192 (Heber Report at 0050)); PX0017_0001-7).

925. In laboratory studies conducted by Dr. Heber, he found no difference in the antioxidant effect between POM Juice and POMx products. (Heber, Tr. 2186-2187).

Response to Finding No. 925:
Complaint Counsel has no specific response, except to note that Dr. Heber's own research is to the contrary. In a laboratory study conducted by Dr. Heber and his colleagues, designed to compare pomegranate juice and pomegranate extract, he found that the pomegranate juice had greater antioxidant activity than the extract (CX1188_0001), which the article attributed to the fact that the juice contained more varied polyphenols, including anthocyanins. (CX1188_0006; Heber, Tr. 2187).

> **Seeram NP, Zhang Y, McKeever R, Henning S, Lee R, Suchard, M, Li Z, Chen S, Thames G, Zerline A, Nguyen M, Wang D, Dreher M, Heber D, "*Pomegranate juice and extracts provide similar levels of plasma and urinary ellagitannin metabolites in human subjects*" J. Medicinal Food 11(2) 2008, 390-394**

926. In this peer-reviewed human clinical study, POM Juice, POMx Pills and POMx Liquid were provided to test subjects in three separate interventions with a washout period. (PX0073-0001).

Response to Finding No. 926:
Complaint Counsel has no specific response except to note that the finding is unsupported by the record insofar as it asserts that the study was peer-reviewed, and to note that it involved only 16 people. (PX0073-0001-05).

927. The level of ellagic acid detected in the blood of the subjects was equivalent between the POMx Pill, POMx Liquid and pomegranate juice interventions. (PX0073-0001, 0004).

Response to Finding No. 927:
Complaint Counsel has no specific response.

928. The same level of urolithin-A glucuonide, a urinary metabolite of ellagic acid, was detected in the urine samples in all POM products and remained elevated for over 48 hours after consumption of the pomegranate polyphenols. (PX0073-0001, 0004).

Response to Finding No. 928:
Complaint Counsel has no specific response.

929. This study demonstrates that the consumption of the Challenged Products results in similar absorption of ellagic acid in the blood and urolithin-A glucuronide in the urine of humans. (PX0073-0001, 0004; CX_0022-0024).

Response to Finding No. 929:
Complaint Counsel has no specific response.

> **Heber D, Seeram N, Wyatt H, Henning S, Zhang Y, Ogden L, Dreher M, Hill J, *"Safety and antioxidant activity of a pomegranate ellagitannin-enriched polyphenol dietary supplement in overweight individuals with increased waist size"* J. Agric. Food and Chem. 2007; 55:-10050-10054**

930. In 2007, in a peer-reviewed study entitled "*Safety and antioxidant activity of a pomegranate ellagitannin-enriched polyphenol dietary supplement in overweight individuals with increased waist size*," by Heber D, Seeram N, Wyatt H, Henning S, Zhang Y, Ogden L, Dreher M, Hill J (J Agric. Food Chem. 2007; 55:-10050-10054), Dr. Heber and his colleagues examined the antioxidant activity in POMx Pills. (PX0139-0001).

Response to Finding No. 930:
Complaint Counsel does not disagree except to refer to CCFF ¶¶ 920-38 (discussion of this study).

931. In the study, 22 overweight subjects were administered two POMx Pills per day providing 1000 mg (610 mg of gallic acid equivalents) of extract versus baseline measurements. (PX0139-0001-0003).

Response to Finding No. 931:
Complaint Counsel does not disagree except to note that the finding pertains only to the single-arm, unblinded Denver study. (*See* CCFF ¶¶ 920-38).

932. Measurement of antioxidant activity as evidenced by thiobarbituric acid reactive substances ("TBARS") in plasma was taken before and after POMx Pill supplementation. (PX0139-0001, 0003).

Response to Finding No. 932:
Complaint Counsel does not disagree except to note that the finding pertains only to the single-arm, unblinded Denver study. (*See* CCFF ¶¶ 920-38). Further, other efforts to show that either POMx or POM Juice increased TBARS were unsuccessful. (*See* CCFF ¶¶ 946-49).

933. There was evidence of antioxidant activity through a significant reduction in TBARS in the test subjects between baseline and 4 weeks. (PX0139-0001, 0004).

Response to Finding No. 933:
The proposed finding mischaracterizes the evidence. (*See* CCFF ¶¶ 926-28 (describing study's findings, including that study statistician stated that the change in TBARS was of borderline significance and had not been adjusted)).

934. TBARS are an important biomarker of oxidative stress, measuring harmful products of lipid (fat) oxidation found in the blood. (PX0139-0004).

Response to Finding No. 934:
Complaint Counsel does not disagree that the published article, authored by Dr. Heber, made this assertion. TBARS is not a valid surrogate of heart disease, however. (*See* CCFF ¶ 785).

935. In regard to coronary heart disease, the amount of TBARS circulating in the blood increases, indicating elevated oxidative stress levels. (PX0139-0004; PX0037-0001).

Response to Finding No. 935:
Complaint Counsel does not disagree that the published article, authored by Dr. Heber, made this assertion. TBARS is not a valid surrogate of heart disease, however. (*See* CCFF ¶ 785).

936. In 2002, in a report entitled "Pomegranate Juice is a Major Source of Polyphenolic Flavonoids and It is Most Potent Antioxidant Against LDL Oxidation and Atherosclerosis," by Dr. Michael Aviram, the research showed that 8 ounces of pomegranate juice resulted in significant reduction of TBARS. (PX0192).

Response to Finding No. 936:
The proposed finding is unsupported by the cited evidence. PX0192 is Dr. Heber's expert report, not a study by Dr. Aviram.

937. This study demonstrates that POMx Pills, just like pomegranate juice, provide antioxidant power sufficient to reduce TBARS. (PX0139-0004).

Response to Finding No. 937:
The proposed finding is unsupported by the cited evidence. First, the cited study (PX0139-0004) does not contain any data comparing POMx Pills to POM Juice, in terms

of TBARS production. Second, *see* CCFF ¶¶ 926-28 regarding this study and its substantial limitations. Third, to the extent the proposed finding is referring to the Aviram study discussed in Finding 936, it is unsupported as that study is not in the record, in violation of the Court's Order on Post-Trial Briefs.

> **Aviram M, Volkova N, Coleman R, Dreher M, Reddy M, Ferreira D, Rosenblat M, *"Pomegranate phenolics from the peels, arils, and flowers are antiatherogenic: studies in vivo in atherosclerotic apolipoprotein e-deficient (e) mice and in vitro in cultured macrophages and lipoproteins,"* J. Agric. And Food Chem. 2008; 56:-1148-1157**

938. In 2008, in a peer-reviewed study entitled "*Pomegranate phenolics from the peels, arils, and flowers are antiatherogenic: studies in vivo in atherosclerotic apolipoprotein e-deficient (e) mice and in vitro in cultured macrophages and lipoproteins*," by Aviram M, Volkova N, Coleman R, Dreher M, Reddy M, Ferreira D, Rosenblat M, (J. Agric. And Food Chem. 2008; 56:-1148-1157), Dr. Aviram and his colleagues examined the anti-atherogenic properties and the mechanisms of action of POMx Pills, POMx Liquid and other pomegranate fruit parts as compared to pomegranate juice. (PX0008-0002).

Response to Finding No. 938:
Complaint Counsel has no specific response, except to note that the proposed finding is unsupported by the cited evidence insofar as it asserts that the study was peer-reviewed.

939. In the study, after consuming pomegranate juice, POMx Liquid and POMx Pills (200 mg of gallic acid equivalents per mouse per day) for 3 months, the atherosclerosis lesion area on the mice was significantly reduced by 44, 38 and 39% compared to the placebo treated control group, and there was no significant difference between the three POM products. (PX0008-0001, 0003).

Response to Finding No. 939:
The proposed finding mischaracterizes the evidence as there was *no* finding of "no significant difference" among the three products in terms of lesion area. Further, it mischaracterizes the evidence insofar as it is intended to support the conclusion that the three products produced identical results in all of the various tests conducted during the study. For example, the results on serum oxidative stress, PON1, MPM, MPM/PON2, LDL uptake by MPN, free radical scavenging capacity, LDL oxidation, and cellular total peroxides varied among POM Juice, POMx Pills, and POMx Liquid. (*See* PX0008-

0003). The study also attributes the antioxidant value of pomegranate juice to its pomegranate sugars. (PX0008-0003). There are no sugars in the pomegranate extracts, however. (*See* CCFF ¶ 964).

940. Consumption of the pomegranate juice, POMx Liquid and POMx Pills also reduced cellular total peroxide levels for 35-53% as compared to placebo-treated mice with no significant difference between the POM products. (PX0008-0001, 0004).

Response to Finding No. 940:
The proposed finding mischaracterizes the evidence as the study does not conclude that there was "no significant difference" among the three products. Further, it mischaracterizes the evidence insofar as it is intended to support the conclusion that the three products produced identical results in all of the various tests conducted during the study. For example, the results on serum oxidative stress, PON1, MPM, MPM/PON2, LDL uptake by MPN, free radical scavenging capacity, LDL oxidation, and cellular total peroxides varied among POM Juice, POMx Pills, and POMx Liquid. (*See* PX0008-0003). The study cites the importance of POM sugars. (*See* PX0008-0003).

941. The study found that free radical scavenging capacity of the pomegranate juice, POMx Liquid and POMx Pills was similar, with the POMx products performing better at reducing oxidated LDL-C uptake by cells than pomegranate juice. (PX0008-0001).

Response to Finding No. 941:
The proposed finding mischaracterizes the evidence insofar as it is intended to support the conclusion that the three products produced identical results in all of the various tests conducted during the study. For example, the results on serum oxidative stress, PON1, MPM, MPM/PON2, LDL uptake by MPN, free radical scavenging capacity, LDL oxidation, and cellular total peroxides varied among POM Juice, POMx Pills, and POMx Liquid. (*See* PX0008-0003). The study also cites the importance of POM sugars. (*See* PX0008-0003).

942. This study demonstrates the bioequivalence *in vitro* and *in vivo* of POMx Pills, POMx Liquid and pomegranate juice when measured at the same polyphenol levels.

Response to Finding No. 942:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Additionally, the study cited in Finding 938 does not report on "bioequivalence," and in this study, many of the test results differed, depending on the product tested. (PX0008-0001-10).

de Nigris F, et al., "*Effects of pomegranate fruit extract rich in punicalagin on oxidation-sensitive genes and enos activity at sites of perturbed shear stress and atherogenesis*" Cardiovascular Research 73 (2007) 414-423

943. In 2007, in a study entitled "*Effects of pomegranate fruit extract rich in punicalagin on oxidation-sensitive genes and enos activity at sites of perturbed shear stress and atherogenesis*," by de Nigris F, *et al. (*Cardiovascular Research 73 (2007) 414-423), Dr. de Nigris and his colleagues examined the effects of pomegranate extract on the expression of oxidation-sensitive responsive genes (such as ELK-1 and p-CREB) induced by high shear stress *in vitro* and *in vivo*. (PX0056-0001).

Response to Finding No. 943:
Complaint Counsel has no specific response.

944. The study found that the polyphenolic antioxidants contained in pomegranate juice and extract contributed similarly to the reduction in oxidative stress and atherogenesis during disturbed shear stress in the cultured human endothelial cells and in atherosclerosis-prone areas of hyperchlorestrerolemic mice used in the study. (PX0056-0001-0008).

Response to Finding No. 944:
The proposed finding mischaracterizes the evidence insofar as it is intended to support the conclusion that pomegranate juice and extract were found to have identical results in this study. The study evaluated the effects of pomegranate juice and extracts on a variety of endpoints in mouse and *in vitro* testing. On some endpoints, such as eNOS expression and lesion development, the article concluded that the extract had stronger effects (PX0056-0005-07).

945. This study demonstrates that POMx, like pomegranate juice, have comparable effects on health as they all stimulate the production of nitric oxide.

Response to Finding No. 945:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Additionally, the proposed finding mischaracterizes the record for the reasons set forth in Response to Finding 944. Further, the study found that pomegranate juice and extract did not appreciably inhibit eNOS activity at dilutions that exhibited vascular protective effects. (PX0056-0007). Finally, the study reported that positive results of various antioxidants on cardiovascular disease markers in animal and *in vitro* studies have not been successfully replicated in human trials, noting "one possible explanation of this divergence is that the models employed in experimental studies, although very useful to study pathophysiological mechanisms, may not precisely reflect the disease in humans." (PX0056-0008).

de Nigris F, et al., "*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*" 17 Nitric Oxide 50-54 (2007)

946. In 2007, in a 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*," by de Nigris F, *et al. (*17 Nitric Oxide 50-54 (2007)), Dr. de Nigris and his colleagues examined *in vivo* and *in vitro* the effect of the POMx Pill in comparison to pomegranate juice on the arterial function and biological actions of NO in rats. (PX0057-0001).

Response to Finding No. 946:
Complaint Counsel has no specific response.

947. The study found that supplementation of pomegranate extract significantly decreased the expression of vascular inflammation markers related to heart disease comparable to that of pomegranate juice. (PX0057-0001, 0003).

Response to Finding No. 947:
The proposed finding mischaracterizes the evidence. In this study, Zucker rats were divided into groups of six and treated with a high-fat diet, or high-fat diets plus pomegranate juice, extract, or seed oil, and subjected to various measures. (PX0057-0001-03). The data tables compare the effects of pomegranate juice and of pomegranate

extract to the high-fat diet alone, but in most instances the study does not attempt to draw a direct comparison between the effects of the extract and the juice. (PX0057_0003-04 (Table 1 and Figure 2)). The only point on which the effect of the extract is directly compared to the pomegranate juice is on eNOS expression; in that case, the effect of the two were described as "comparable." (PX0057_0003.)

948. The study found that supplementation of pomegranate extract significantly increased NO levels comparable to that of pomegranate juice. (PX0057-0001, 0004).

Response to Finding No. 948:
See Response to Finding 947.

949. This study demonstrates that POMx, like pomegranate juice, have comparable effects on health as they all stimulate the production of nitric oxide.

Response to Finding No. 949:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. To the extent that it is intended to refer to PX0057, the study contains no finding that POMx and POM Juice have "comparable effects on health." Rather, it concludes that "These data highlight possible clinical applications of [pomegranate extract] in metabolic syndrome." (PX0057-0001).

950. This study demonstrates that POMx and pomegranate juice are bioequivalent.

Response to Finding No. 950:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. In addition, to the extent that it is intended to refer to PX0057, the proposed finding is unsupported by that study, which contains no discussion regarding "bioequivalence." (PX0057-0001-05).

951. In sum, the expert opinions and affirmative evidence presented by Respondents prove that the Challenged Products are bioequivalent.

Response to Finding No. 951:

The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Further, it is unsupported by the studies discussed in Findings 915-950, as none of them presented findings with regard to "bioequivalence" or found that they were "bioequivalent." Complaint Counsel also objects to this finding on the basis that the terms "bioequivalence" and "bioequivalence" are vague and ambiguous. Respondents measured the effects of consumption of their products against dozens of biomarkers and health endpoints, including urinary byproducts, enzyme changes, many serum markers of antioxidant stress, many serum markers of inflammation, changes in blood flow as measured by myocardial profusion and BART, changes in CIMT, changes in prostate cancer markers in cells, animals and humans, and changes in ED related function in animals and humans. (*See, e.g.*, Respondents' Findings of Fact 866, 877-78, 882-85, 898-99, 924-25, 932, 939, 1087, 1100; *see also* CCFF ¶¶ 825, 855-56, 879-84, 914-15). Respondents have not asserted which of these biomarkers should be considered relevant in measuring "bioequivalence," much less shown that the three products have the same effect on all of these measures. Notably, a search of the trial transcript shows that none of the Respondents' experts ever used the terms "bioequivalent" or "bioequivalence" in their testimony (*See* Tr. 1-1455), although Dr. Miller stated that someone else would testify on this issue (Miller, Tr. 2214). The record shows that POM Juice is not the same as POMx Pills and POMx Liquid. (CCFF ¶¶ 129, 130, 964-65). In any event, Respondents have failed to substantiate their advertising claims that POM Juice prevents, reduces the risk of, or treats heart disease, prostate cancer, or erectile dysfunction.

2. Complaint Counsel Have Failed to Rebut Respondents' Evidence on the Bioequivalency of the Challenged Products

952. It was not within the scope of Complaint Counsel's experts' assignment, and none opined in their report, that credible and reliable scientific evidence exists that POM Juice is not bioequivalent to POMx. (CX1287; CX1289; CX1291; CX1293; CX1295).

Response to Finding No. 952:
Complaint Counsel objects to this finding on the basis that the term "bioequivalence" is vague and ambiguous, as set forth in Response to Finding 951. As noted in Response to Finding 916, the pomegranate extracts are not the same as POM Juice, and as reflected in Response to Finding 951, Respondents have shown neither efficacy of POM Juice nor "bioequivalence" of the juice and extracts. In any event, Respondents have failed to substantiate their advertising claims that POM Juice prevents, reduces the risk of, or treats heart disease, prostate cancer, or erectile dysfunction. Finally, Complaint Counsel notes that CX1295 is Dr. Stewart's expert report, and he is not a medical science expert.

953. Complaint Counsel's experts provided no testimony that credible and reliable scientific evidence shows that POM Juice is not bioequivalent to POMx. (PX0362 (Stampfer, Dep. at 1-205); Stampfer, Tr. 689-885; PX0361 (Sacks, Dep. at 1-273); Sacks, Tr. 1410-1625; PX0360 (Melman, Dep. at 1-141); Melman, Tr. 1069-1197; PX0358 (Eastham, Dep. at 1-158); Eastham, Tr. 1204-1351; PX0357 (Stewart, Dep. at 1-194); Stewart, Tr. 3158-3242; PX0359 (Mazis, Dep. 1-242); Mazis, Tr. 2651-2761).

Response to Finding No. 953:
Complaint Counsel objects to this finding on the basis that the terms "bioequivalence" and "bioequivalent" are vague and ambiguous. *See* Response to Finding 951.

954. Complaint Counsel's expert, Dr. David Sacks, admitted that the issue of the bioequivalence of POMx to POM Juice was not within the scope of his assignment as an expert in this case. (PX0361 (Sacks, Dep. at 77); CX1291_0008-0009).

Response to Finding No. 954:
Complaint Counsel objects to this finding on the basis that the term "bioequivalence" is vague and ambiguous. *See* Response to Finding 951. The proposed finding is also is unsupported by the cited evidence, insofar as Dr. Sacks was asked on the cited deposition

page whether he had opinions on the difference between POM Juice and POMx "*other than* bioequivalency," to which question he responded in the negative. (PX0361, Sacks, Dep. at 77). Indeed, the record reflects that Dr. Sacks questions the equivalence of pomegranate juice and the extracts, because pomegranate juice contains anthocyanins, and the extracts do not, explaining that *preliminary* research suggests that anthocyanins have effects on vascular functions. (PX0361 (Sacks, Dep. at 74-75; Sacks, Tr. 1524; *see also* Heber, Tr. 2164-65 (confirming that there are anthocyanins in the juice but not the extracts)).

955. Dr. Sacks admitted he has no opinion about whether POM Juice is bioequivalent to POMx Liquid. (PX0361 (Sacks, Dep. at 75)).

Response to Finding No. 955:
The proposed response mischaracterizes the evidence. *See* Response to Finding 954.

956. Dr. Sacks admitted that he has no opinion about whether there is a difference between POM Juice and POMx, or between POM Juice and the pomegranate fruit from which it is derived. (PX0361 (Sacks, Dep. at 77)).

Response to Finding No. 956:
The proposed response mischaracterizes the evidence. *See* Response to Finding 954.

957. Complaint Counsel's expert, Professor Stampfer, admitted that he has no opinion about the antioxidant effect of POM Juice relative to POMx. (PX0362 (Stampfer, Dep. at 200, 203)).

Response to Finding No. 957:
The proposed finding mischaracterizes the cited evidence. At the cited pages, Dr. Stampfer stated first that "I don't have an opinion about the antioxidant differences . . . between those two in say measures . . . in a test tube of oxidation reactions. But if you're talking about effect on human health, in my opinion, *no benefit for either* has been established." (PX0362 (Stampfer, Dep. 200) (emphasis added)).

958. Therefore, Complaint Counsel have failed to present expert opinion or affirmative evidence that POMx are not bioequivalent to POM Juice.

Response to Finding No. 958:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. In addition, Complaint Counsel objects to the proposed finding, as the term "bioequivalent" is vague and ambiguous, as set forth in Response to Finding 951. Finally, the proposed response mischaracterizes the evidence. *See* Response to Finding 954.

F. Dr. Heber Is Extremely Well Qualified To Provide the Opinions He Offered in this Case

959. Dr. Heber is a tenured Professor of Medicine and Public Health at the David Geffen School of Medicine at UCLA and the Director of the UCLA Center for Human Nutrition which he founded in 1996 within the UCLA School of Medicine. (PX0192-0005).

Response to Finding No. 959:
Complaint Counsel has no specific response.

960. As a Professor of Medicine and Public Health, Dr. Heber counsels patients at UCLA within the Risk Factor Obesity Program and medical programs of the Department of Medicine. (PX0192-0005). Dr. Heber has seen thousands of patients and has been listed as one of Best Doctors in America multiple times in the last decade. (PX0192-0005).

Response to Finding No. 960:
Complaint Counsel has no specific response.

961. Dr. Heber received his Ph.D. in Physiology from the 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).

Response to Finding No. 961:
Complaint Counsel has no specific response.

962. From 1978 to 1982, Dr. Heber served as Associate Director of the Harbor-UCLA National Institutes of Health ("NIH")-funded General Clinical Research Center. (PX0192-0005). In 1983, Dr. Heber moved to the main UCLA campus where he founded the Division of Clinical Nutrition within UCLA's Center for Health Science. (PX0192-0005).

Response to Finding No. 962:
Complaint Counsel has no specific response.

963. Dr. Heber has directed several NIH-funded research projects. From 1992 to 2007, he directed the NIH-funded Nutrition and Obesity Training Program where he supervised

the training of 22 M.D. or Ph.D. postdoctoral fellows and from 1999 to 2006, he directed the NIH-funded UCLA Center for Dietary Supplements Research: Botanicals. (PX0192-0006). From 1991 to 2006, Dr. Heber was also the Director of the National Cancer Institute-funded UCLA Clinical Nutrition Research Unit. (PX0192-0006).

Response to Finding No. 963:
Complaint Counsel has no specific response.

964. Dr. Heber is a member of many prestigious organizations. He has been a member of the American Society for Nutrition since and was elected as the first Chair of its Nutrition Council. (PX0192-0005-0006). Dr. Heber is a Fellow of the American College of Physicians and the American College of Nutrition. (PX0192-0005). In 2009, Dr. Heber became a member of the Certification Board for Nutrition Specialists. (PX0192-0006).

Response to Finding No. 964:
Complaint Counsel has no specific response.

965. Dr. Heber has been a member of multiple National Institute of Health Study Sections which review research grant applications including the Metabolic Pathology Study Section from 1987 to 1992 and Special Study Sections which review large program projects as well as programs within the National Institutes of Health. (PX0192-0006).

Response to Finding No. 965:
Complaint Counsel has no specific response.

966. Dr. Heber has served on a number of government nutrition advisory committees including the National Cancer Institute Nutrition Implementation Committee in 1985. (PX0192-0006).

Response to Finding No. 966:
Complaint Counsel has no specific response.

967. Dr. Heber's personal laboratory and clinical research has been on the effects of pomegranate juice phytonutrients on prostate cancer prevention. Dr. Heber has conducted basis research on the mechanisms of the immune system effects on pomegranate phytonutrients, and on the bioavailability and antioxidant activity of pomegranate phytonutrients in humans. (PX0192-0015).

Response to Finding No. 967:
Complaint Counsel has no specific response.

968. Dr. Heber is an expert in basic biology, clinical research, endocrinology, the interface of nutrition and prostate cancer, research on prostate treatment, including hormonal results of prostate cancer treatment, the basic mechanisms underlying erectile function and their interface with nutrition, and the basic mechanisms underlying cardiovascular disease and their interface with nutrition. (Heber, Tr. 2034-2035; PX0353, (Heber, Dep. at 10-12)).

Response to Finding No. 968:
The proposed finding mischaracterizes the evidence. Respondents specifically offered Dr. Heber as an "expert in the relationship between the nutrition and various diseases, including coronary heart disease and prostate cancer, other diseases as well, but *those* are the things he's going to talk about." (Tr. 1940) Additionally, Dr. Heber disclaimed expertise in a number of areas, including CVD, CVD treatment, blood pressure, prostate cancer treatment, and erectile function treatment. (*See* CCFF ¶ 728).

969. Based his research on congestive heart failure and cholesterol-lowering substances and is counseling of patients with heart disease, Dr. Heber is an expert in the biology and mechanisms around heart disease. (Heber, Tr. 2037).

Response to Finding No. 969:
See Response to Finding 968. In fact, Dr. Heber specifically testified that he is not an expert in cardiovascular disease or cardiovascular disease treatment. (Heber, Tr. 2041).

970. Dr. Heber is an expert on the basic mechanisms of action of pomegranate phytochemicals as antioxidants, the potency of pomegranate phytochemicals, and how phytochemicals act in the body. (PX0353, Heber, Dep. at 9)).

Response to Finding No. 970:
Complaint Counsel has no specific response except to refer to Response to Finding 968.

971. Dr. Heber is an expert on the basic mechanisms related to erectile dysfunction, especially as related to the role of nitric oxide in erectile health. (Heber, Tr. 2039).

Response to Finding No. 971:
Complaint Counsel has no specific response except to refer to Response to Finding 968 and to note that, at his deposition, Dr. Heber testified that he was not an expert in erectile dysfunction treatment. (PX0353 (Heber, Dep. at 11)).

972. Dr. Heber's nutritional research experience spans the gamut from basic molecular, cellular, and animal model studies to human clinical trials. (PX0192-0008).

Response to Finding No. 972:
Complaint Counsel has no specific response.

973. Basic molecular, cellular, and animal model studies are important in understanding the benefits of fruits and vegetables. (PX0192-0008).

Response to Finding No. 973:
Complaint Counsel has no specific response.

974. Dr. Heber maintains an active research career, including Dr. Heber's areas of research interest encompass clinical nutrition, inflammation, phytonutrients, obesity, and cancer. (PX0192-0006). Dr. Heber has conducted numerous clinical research projects with implications for public health, including on the potential health benefits of a number of different phytonutrients found in fruits and vegetables. (PX0192-0005-007).

Response to Finding No. 974:
Complaint Counsel has no specific response.

975. Dr. Heber is familiar with epidemiological research as it can inform placebo-controlled nutritional intervention trials in large numbers of subjects. (PX0192-0005).

Response to Finding No. 975:
Complaint Counsel has no specific response.

976. Dr. Heber directs core laboratory services in Nutritional Biomarkers including measures of oxidant stress, analytical phytochemistry, gene-nutrient interaction, immune modulation by nutrients, and has interacted extensively with the biostatisticians at UCLA over the last 27 years in the design and analysis of clinical studies. (PX0192-0006).

Response to Finding No. 976:
Complaint Counsel has no specific response.

977. Dr. Heber was Co-Investigator of the UCLA Clinical Site of the Women's Health Initiative, the largest women's health study in history, which examined the impact of low fat diet, calcium, and vitamin D on cardiovascular disease and cancer. (PX0192-0005).

Response to Finding No. 977:
Complaint Counsel has no specific response.

978. Dr. Heber has directed the UCLA Risk Factor Obesity Program since 2001 which is a comprehensive multidisciplinary obesity treatment program which currently has over 100 active patients. (PX0192-0006).

Response to Finding No. 978:
Complaint Counsel has no specific response.

979. In 2005, Dr. Heber chaired the NIH Special Study Section for Clinical Nutrition Research Units. (PX0192-0006) In 2003, Dr. Heber was the organizing chair of the NIH/NCCAM Center Director's Meeting. (PX0192-0006). In 2006, Dr. Heber gave testimony to the President's Cancer Panel on "Diet, Obesity, Inflammation, and Cancer." (PX0192-0006).

Response to Finding No. 979:
Complaint Counsel has no specific response.

980. Dr. Heber has published extensively in peer-reviewed journals, including many articles relating to nutrition. (PX0192-0006). Dr. Heber also originated the concept of color groups linked to phytonutrient content. (PX0192-0007). In that regard, Dr. Heber authored the book "What Color Is Your Diet?" (Harper Collins, 2001), which was a national best seller and is available in eleven languages. (PX0192-0007).

Response to Finding No. 980:
Complaint Counsel has no specific response.

981. Dr. Heber was editor-in-chief of Nutritional Oncology 2nd Edition (Academic Press, 2006), a professional text containing 50 chapters written by national and international experts in nutrition and cancer summarizing the synthesis of information from population studies, basic animal and cell culture studies, and the limited information available from human clinical studies. (PX0192-0006-0007).

Response to Finding No. 981:
Complaint Counsel has no specific response.

982. Dr. Heber has written a number of scientific reviews, including Heber D, Bowerman S., "Applying science to changing dietary patterns," J Nutr. 2001; 131:3078S-81S, linked to the concept of color groups linked to phytonutrient from which he is generally recognized by the nutrition science community. (PX0192-0007).

Response to Finding No. 982:
Complaint Counsel has no specific response.

983. Dr. Heber is a physician scientist expert in nutrition translational research. (PX0192-0008-0009).

Response to Finding No. 983:
Complaint Counsel has no specific response.

984. Translational nutritional science examines the best available evidence, including *in vitro*, animal, population and limited clinical intervention studies in humans, as a totality, rather than just one type of clinical study. (PX0192-0013; (PX0353 (Heber, Dep. at 13-14)). Translational science includes the practice of translating bench science to bedside clinical practice or dissemination to population-based community interventions. (PX0192-0008-0009).

Response to Finding No. 984:
Complaint Counsel has no specific response except to refer to Response to Finding 971.

985. Dr. Heber has extensive experience in translational research on pomegranate phytonutrients extrapolating from cell culture and animal studies to humans. Dr. Heber's intimate knowledge of translational research on pomegranate phytonutrients extrapolating from cell culture and animal studies to humans enables him to communicate a firsthand understanding of scientific basis for an understanding of the health benefits of

pomegranate juice within the overall context of what is known about the role of colorful fruits and vegetables in the diet through effects on oxidant stress, inflammation, and the multiple processes underlying common age-related chronic diseases. (PX0192-0007).

Response to Finding No. 985:
Complaint Counsel has no specific response.

986. The NIH is funding several Clinical Translation Science Centers, including one at UCLA which will replace the former General Clinical Research Centers. (PX0192-0013).

Response to Finding No. 986:
Complaint Counsel has no specific response.

987. Dr. Heber counsels patients with prostate cancer on nutritional matters. (Heber, Tr. 2035; CX1352 (Heber, Dep. at 239)).

Response to Finding No. 987:
Complaint Counsel has no specific response.

988. Because his obese patients who have heart disease want to be fully informed, Dr. Heber counsels them about the research on pomegranates. (CX1352 (Heber, Dep. at 239)).

Response to Finding No. 988:
Complaint Counsel has no specific response.

989. Dr. Heber received no compensation for his work in this case. (PX0192-0008).

Response to Finding No. 989:
The proposed finding mischaracterizes the record. (*See* CCFF ¶724 (noting that Dr. Heber is on "retainer" for Respondents and that Respondents have paid UCLA over $2.7 million in gifts and contract awards for Dr. Heber's work)).

990. Therefore, Dr. Heber is extremely well qualified to provide the expert opinions he offered in this case.

Response to Finding No. 990:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs.

XIII. THE CHALLENGED PRODUCTS ARE SAFE FOR HUMAN CONSUMPTION

A. Respondents Presented Overwhelming Evidence on Safety

991. Pomegranate juice is a traditional source of human nutrition. (PX0192-0018).

Response to Finding No. 991:
Complaint Counsel has no specific response, except to note that Dr. Heber (whose report is cited for this proposition) conceded that he did not live thousands of years ago and does not know why people consumed pomegranates at that time, or in what form. (Heber, Tr. 2162).

992. Pomegranates have been safely consumed as nutritious food by humans for thousands of years. (PX0192-0013, 0018).

Response to Finding No. 992:
The proposed finding is irrelevant, given that pomegranate juice and pomegranate extract are not the same as whole pomegranates. (*See* CCFF ¶¶ 124-34 regarding the processing involved in the production of pomegranate juice and the extracts). *See* Response to Finding 991, with regard to Dr. Heber's knowledge. *See also* Responses to Findings 129, 201, and 217, with regard to safety.

993. Pomegranate juice has been safely consumed by humans for centuries. (PX0192-0042).

Response to Finding No. 993:
The proposed finding mischaracterizes the record. *See* Response to Finding 991, with regard to Dr. Heber's knowledge. *See also* Responses to Findings 129, 201, and 217, with regard to safety.

994. Pomegranate juice and pomegranate extract have a "high degree of safety." (PX0192-0013).

Response to Finding No. 994:
Complaint Counsel does not disagree that Dr. Heber made this assertion. Nonetheless, the proposed finding mischaracterizes the record. *See* Responses to Findings 129, 201, and 217, with regard to safety.

995. Pomegranate juice is safe for human consumption if consumed within the nutritional range. (PX0192-0018; PX0353 (Heber, Dep. at 129-131)).

Response to Finding No. 995:

Complaint Counsel does not disagree that Dr. Heber made this assertion. Nonetheless, the proposed finding mischaracterizes the record. First, Dr. Heber never explained what he meant by "the nutritional range." Moreover, Dr. Heber himself has recommended that consumers strictly limit or avoid fruit juices, noting that "it takes two oranges to make a glass of orange juice" and he would prefer consumers eat the whole orange. (Heber, Tr. 2163). Dr. Ornish has provided similar advice. In his book, *The Spectrum*, he recommends choosing foods that have no more than six to eight grams of sugar per serving, "unless it is a treat." (Ornish, Tr. 2461-62). Pomegranate juice, however, has 31 grams of sugar per serving. (Ornish, Tr. 2461). *See also* Responses to Findings 129, 201, and 217, with regard to safety.

996. POMx is safe for human consumption if consumed within the nutritional range. (PX0192-0018).

Response to Finding No. 996:
Complaint Counsel does not disagree that Dr. Heber made this assertion. Nonetheless, the proposed finding mischaracterizes the record. *See* Responses to Findings 129, 201, and 217, with regard to safety.

997. All fruits are assumed safe for human consumption if consumed within the nutritional range. (PX0353 (Heber, Dep. at 129)).

Response to Finding No. 997:
Complaint Counsel does not disagree that Dr. Heber made this assertion. However, as noted in Response to Finding 992, pomegranate juice and the extracts are not the same as whole pomegranates; further, Dr. Heber did not explain what he meant by "the nutritional range." *See also* Responses to Findings 129, 201, and 217, with regard to safety.

998. One reason fruits are safe for human consumption is because they induce their own metabolism rapidly in the body. (PX0353 (Heber, Dep. at 129)).

Response to Finding No. 998:

Complaint Counsel does not disagree that Dr. Heber made this assertion. However, as noted in Response to Finding 992, pomegranate juice and the extracts are not the same as whole pomegranates. *See also* Responses to Findings 129, 201, and 217, with regard to safety.

999. Unlike some drugs, pomegranate juice has no adverse side effects. (PX0192-0042).

Response to Finding No. 999:
Complaint Counsel does not disagree that Dr. Heber made this assertion, but contend that the proposed finding mischaracterizes the record. *See also* Responses to Findings 129, 201, and 217, with regard to safety.

1000. The FDA maintains a list of substances that are identified by the FDA as generally regarded as safe ("GRAS"). (Heber, Tr. 2008-2009).

Response to Finding No. 1000:
Complaint Counsel agrees.

1001. Before a substance can be GRAS identified, the FDA reviews the scientific literature and the traditional intake of the substance. (Heber, Tr. 2009).

Response to Finding No. 1001:
Complaint Counsel has no specific response.

1002. Both pomegranate juice and pomegranate extract are GRAS identified. (Heber, Tr. 2009; 32; 21 C.F.R. § 182.20).

Response to Finding No. 1002:
Complaint Counsel has no specific response, except to note that a GRAS identification does not prove that a product is safe. (*See* Sacks, Tr. 1525-26).

1003. There have been no reported cases of persons being harmed by eating a pomegranate or drinking pomegranate juice. (Heber, Tr. 1947-1948).

Response to Finding No. 1003:
Complaint Counsel has no specific response, except to refer to Responses to Findings 129, 201, and 217.

1004. There have been no reported cases of toxicity where pomegranates or pomegranate juice have been consumed in nutritional amounts. (Heber, Tr. 1948).

Response to Finding No. 1004:
Complaint Counsel has no specific response, except to refer to Responses to Findings Nos. 129, 201, and 217.

1005. In all the studies that have been conducted on pomegranate juice and pomegranate extract, there has never been any reports of any material harm caused to the subjects by consuming the products. (Heber, Tr. 2007-2008; PX0353 (Heber, Dep. at 115)).

Response to Finding No. 1005:
Complaint Counsel has no specific response, except to refer to Responses to Findings 129, 201, and 217.

1006. None of the clinical studies conducted on pomegranate juice and pomegranate extract found any serious risk to human health from consuming the products. (PX0192-0018).

Response to Finding No. 1006:
Complaint Counsel has no specific response, except to refer to Responses to Findings Nos. 129, 201, and 217.

1007. No serious adverse events occurred and no subjects discontinued use due to adverse events during Dr. Padma-Nathan's study entitled "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," International J. of Impotence Research (2007), 1-4. (CX0908_0003).

Response to Finding No. 1007:
Complaint Counsel has no specific response except to note that the finding refers to a 53-person study. (CCFF ¶ 1064).

1008. Pomegranate juice is a food. (PX0192-0011).

Response to Finding No. 1008:
The proposed finding is incomplete and mischaracterizes the evidence. *See* Response to Finding 495.

1009. Pomegranate extract is a food-based dietary supplement which has substances found in pomegranate juice at levels within the nutritional range. (PX0192-0011).

Response to Finding No. 1009:
Complaint Counsel does not agree that Dr. Heber made this assertion; however, Dr. Heber nowhere stated what he meant by "the nutritional range." (*See* PX0192-0011).

1010. Pomegranate juice is a natural fruit and documented for over 5,000 years, and as a result, urologist would not require RCTs to determine its safety. (Goldstein, Tr. 2600, 2620).

Response to Finding No. 1010:
Complaint Counsel has no specific response.

1011. The IND approvals that the FDA issued for the POMx Pill and POMx Liquid found that the proposed studies regarding POMx were reasonably safe. (PX0192-0018).

Response to Finding No. 1011:
Complaint Counsel objects to the proposed finding. Dr. Heber is not authorized to speak for FDA and does not identify the specific IND upon which he relies. Additionally, the proposed finding is incomplete and mischaracterizes the evidence.

(CX1169_0019, *in camera*). [redacted]

[redacted] (CX1169_0019-20, *in camera*). [redacted]

(CX1169_0019-20, *in camera*). [redacted]

(CX1169_0005, *in camera* (emphasis added)).

1012. There were no changes in blood levels of the routine things you check for regarding drug safety and the liver tests of the subjects were normal in the study entitled "Safety and Antioxidant Activity of a Pomegranate Ellagitannin-Enriched Polyphenol Dietary Supplement in Overweight Individuals with Increased Waist Size." (Heber, Tr. 2008).

Response to Finding No. 1012:
Complaint Counsel does not disagree that Dr. Heber made this assertion. However, the proposed finding mischaracterizes the evidence insofar as it suggests that POMx has been shown to be safe. *See* Response to Finding 1011.

1013. Pomegranate juice is no more unsafe for diabetics than any other fruit juice. (Heber, Tr. 2011).

Response to Finding No. 1013:
Complaint Counsel does not disagree that Dr. Heber made this assertion. However, it should be noted that according to Respondents' own Medical Research Portfolio Review, 4 ounces of 100% juice is defined as a "single serving" by the American Diabetes Association and Smart Choices Labeling Program. (CX1029_0006). Respondents' advertising recommends daily consumption of 8 ounces of their juice. (*See, e.g.,* CCFF ¶¶ 332, 336).

1014. 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. (Heber, Tr. 2010).

Response to Finding No. 1014:
Complaint Counsel does not disagree that Dr. Heber made this assertion. However, it should be noted that according to Respondents' own Medical Research Portfolio Review, "POM Juice has the highest Glycemic Index among 100% juices, a potential concern for diabetics & their dieticians." (CX 1029_0006.)

1015. A particular food is not unsafe simply because it has a high glycemic index. (Heber, Tr. 2011).

Response to Finding No. 1015:
Complaint Counsel does not disagree that Dr. Heber made this assertion. *See also* Response to Finding 1014.

1016. The glycemic index of pomegranate juice is 50, which is a midlevel glycemic index. (Heber, Tr. 2011).

Response to Finding No. 1016:
Complaint Counsel does not disagree that Dr. Heber made this assertion; however, Respondents' own document stated that POM Juice has the highest glycemic index among 100% juices and that according to the American Dietetic Association, a serving of juice should contain only 4 ounces. (*See* CX1029_0006).

1017. Based on conversations with Dr. David Heber and a human study finding POM Juice did not cause drug interaction, Stewart Resnick believed that pomegranate juice did not trigger drug interactions in humans. (S Resnick, Tr. 1774-1775).

Response to Finding No. 1017:
The proposed finding, as to Mr. Resnick's asserted belief, is not relevant. Further, Respondent's Medical Research Portfolio Review stated that additional studies should be conducted to address concerns about drug interactions, particularly with regard to anti-coagulants. (CX1029_0020 (citing *in vitro* evidence about pomegranate juice inhibition of CYP3A inhibiting activity, and animal evidence that pomegranate juice triggers drug interaction in rat models)). *See also* Response to Finding 1011 for [redacted]

1018. Despite the occurrence of mild diarrhea in 7.7% of the patients in Dr. Michael Carducci's prostate-related study of POMx, it is not known whether the consumption of the POMx caused the mild diarrhea in the human subjects. (Heber, Tr. 2007-2008; PX0192-0028).

Response to Finding No. 1018:
The proposed finding is unsupported by the cited evidence insofar as it reports that "it is not known" whether consumption of POMx was the cause. *See also* Response to Finding

1011, citing CX1169_0019*, in camera,* regarding

1019. Mild diarrhea is a common side effect in studies in general. (Heber, Tr. 2007).

Response to Finding No. 1019:
The proposed finding mischaracterizes the evidence insofar as it is designed to suggest that pomegranate polyphenols do not cause diarrhea. *See* Response to Finding 1011, citing CX1169_0019*, in camera,* regarding

1020. Complaint Counsel's expert, Professor Meir Stampfer, believes it is better to err on the side of giving the information to the public as opposed to withholding the information and, thus is an advocate of giving information to the public where the risk of harm of a product is slight and a potential benefit of the product exists. (Stampfer, Tr. 827-828).

Response to Finding No. 1020:
Complaint Counsel has no specific response, except to note that Dr. Stampfer did not state or suggest that he was in favor of providing misleading information to the public.

Pomegranate Juice Does Not Impair Clearance of Oral or Intravenous Midazolam, a Probe for Cytochrome P450-3A Activity: *Comparison With grapefruit juice*, by Farkas D, Oleson L, Zhao Y, Harmatz, J, Zinny M, Court M, Greenblatt D, J Clin. Pharmocol 2007; 47:286-294

1021. In 2007, in a peer reviewed study entitled "Pomegranate juice does not impair clearance of oral or intravenous midazolam, a probe for cytochrome P450-3a activity: comparison with grapefruit juice," by Farkas D, Oleson L, Zhao Y, Harmatz, J, Zinny M, Court M, Greenblatt D (J Clin. Pharmocol 2007; 47:286-294), Dr. Greenblatt and his colleagues examined the effect of POM Juice and grapefruit juice on inhibiting enteric cytocrhome P450-3A activity in healthy human volunteers. (PX0136-0001).

Response to Finding No. 1021:
Complaint Counsel has no specific response.

1022. When a substance produces inhibition of enteric cytochrome P450-3A enzymes, it causes pharmacokinetic interactions with certain drugs. (PX0136-0001-0002).

Response to Finding No. 1022:
Complaint Counsel has no specific response.

1023. POM Juice was shown to not cause drug interaction humans. (PX0136-0008).

Response to Finding No. 1023:

Complaint Counsel agrees that this 2007 report concludes that, in a study of 13 healthy male nonsmokers who were free of disease and taking no medications, results did not show that pomegranate juice caused a statistically significant inhibition of CYP3A in humans who took midazolam as a test medication. (PX0136-0008). Nonetheless, two years later, in their Medical Research Portfolio Review, Respondents stated that it was important to publish another human clinical study on drug interaction, for example with regard to anti-coagulants. (CX1029_0020). [redacted] (CX1169_0020, *in camera*). Thus, it does not appear that the cited study, PX0136, is dispositive on the issue of potential drug interactions.

***Safety and antioxidant activity of a pomegranate ellagitannin-enriched polyphenol dietary supplement in overweight individuals with increased waist size,* by Heber D, Seeram N, Wyatt H, Henning S, Zhang Y, Ogden L, Dreher M, Hill J, J Agric. Food Chem. 2007; 55:-10050-10054**

1024. In 2007, in a peer reviewed study entitled **"**Safety and antioxidant activity of a pomegranate ellagitannin-enriched polyphenol dietary supplement in overweight individuals with increased waist size," by Heber D, Seeram N, Wyatt H, Henning S, Zhang Y, Ogden L, Dreher M, Hill J (J Agric. Food Chem. 2007; 55:-10050-10054), Dr. Heber and his colleagues examined the safety in humans of consuming POMx Pills. (PX0139-0001).

Response to Finding No. 1024:
Complaint Counsel has no specific response except to refer to CCFF ¶¶ 920-43, which contain a complete discussion of the two studies on overweight individuals sponsored by

Respondents, and which explain how Dr. Heber chose to report only a portion of the results in the published report.

1025. In the study, 64 overweight individuals with increased waist size consumed either one or two POMx Pills per day for 4 week providing 710 mg and 1420 mg of extract containing 435 and 870 mg of gallic acid equivalents, respectively. (PX0139-0001, 0002).

Response to Finding No. 1025:
The proposed finding is incomplete. This finding reports only on the San Diego/Accelovance arm of this study, which (contrary to the description of the study in PX0139) was designed to look at the effect of taking POMx on markers of antioxidation and inflammation. (*See* CCFF ¶¶ 929-37). The article cited in Response to Finding 1024 did not provide the results of the anti-oxidant and inflammatory markers, which were null. (*See* CCFF ¶¶ 933-37).

1026. To maintain blinding, subjects in the 710 mg arm received one bottle of placebo and one bottle of POMx Pills. Subjects in the 1420 arm received two bottles of POMx Pills. In addition, 7 of the 64 subjects received only a placebo. (PX0139-0002, 0003).

Response to Finding No. 1026:
The proposed finding is incomplete. *See* Response to Finding 1025.

1027. No adverse events related to the POMx Pill consumption or changes in blood count, serum chemistry, or urinalysis was observed in the subjects. (PX0139-0001, 0004).

Response to Finding No. 1027:
Complaint Counsel does not disagree that the cited study contained this statement.

1028. Although there were 11 minor adverse events reported by 9 of the 64 subjects, none of these minor adverse effects were deemed to be related to POMx Pills. (PX0139-0003).

Response to Finding No. 1028:
Complaint Counsel has no specific response.

1029. The study demonstrates the safety of POMx Pills in humans. (PX0139-0001, 0004).

Response to Finding No. 1029:
The proposed finding is mischaracterizes the evidence. The cited article carefully qualified its findings, noting that "this study demonstrates in preliminary fashion" the

safety of POMx. (PX0139-0004).

***POM oil: subchronic toxicity study (90 day dietary study in rats)* by Merkel D**

1030. In 2007, in an unpublished study entitled "POM Oil: subchronic toxicity study (90-day dietary study in rates)," by Merkel D, Dr. Merkel examined the potential subchronic toxicity of POMx Oil in male and female rats likely to arise from continuous exposure to POMx oil over a 90-day test period. (PX0138-0008).

Response to Finding No. 1030:
Complaint Counsel has no specific response except to note that this case does not involve

POM Oil.

1031. There were no test substance-related mortalities. There were no ophthalmological, clinical observations, organ weight changes, gross finding clinical or histopathologic alterations that were considered to be of toxicological significance as result of the POMx Oil. (PX0138-0008, 0016, 0021).

Response to Finding No. 1031:
Complaint Counsel has no specific response except to note that this case does not involve

POM Oil.

1032. The study concluded that there were no safety or toxicology issues with POMx Oil in rats. (PX0138-0008).

Response to Finding No. 1032:
Complaint Counsel has no specific response except to note that this case does not involve

POM Oil.

B. Complaint Counsel Experts Failed To Rebut Respondents' Evidence on the Safety of the Challenged Products

1033. It was not within the scope of Complaint Counsel's experts' assignment, and none opined in their report, on the safety of the Challenged Products or the safety of pomegranate juice and extracts in general. (CX1287; CX1289; CX1291; CX1293; CX1295).

Response to Finding No. 1033:
The proposed finding is unsupported by the record as a whole. Dr. Sacks testified that,

for scientific purposes, the burden is on the proponent to show safety. (Sacks, Tr. 1539).

He noted that there are signals of potential safety problems in some of the study results, including transient increases in blood glucose, triglycerides, lipoprotein A, and gamma GT, as well as the weight gain seen in Dr. Davidson's CIMT study. (Sacks, Tr. 1525; *see also*, PX0361 (Sacks, Dep. at 0073-74) (stating that there had not been enough RCTs on the juice or the pills to satisfactorily evaluate safety and that there were safety "signals" in some of the small studies that need to be evaluated in larger studies)). Dr. Stampfer, too, testified that there was evidence in the materials he reviewed of an increase in triglyceride levels, which could be expected with higher carbohydrate load; he stated that juices with a high sugar content, such as pomegranate juice, are associated with higher risk of diabetes and weight gain. (PX0362 (Stampfer, Dep. at 195-96); *see also* CCFF ¶ 1021 (regarding accelerated prostate cancer in the Carducci study)). Thus, pomegranate juice and the pomegranate extracts have not been proven to be safe. (Sacks, Tr. 1525).

[redacted] as set forth in CX1169, *in camera*, and described in Response to Finding 1011.

1034. Complaint Counsel's experts did not provide any testimony refuting Respondents' evidence on the safety of the Challenged Products. (PX0362 (Stampfer, Dep. at 1-205); Stampfer, Tr. 689-885; PX0361 (Sacks, Dep. at 1-273); Sacks, Tr. 1410-1625; PX0360 (Melman, Dep. at 1-141); Melman, Tr. 1069-1197; PX0358 (Eastham, Dep. at 1-158); Eastham, Tr. 1204-1351; PX0357 (Stewart, Dep. at 1-194); Stewart, Tr. 3158-3242; PX0359 (Mazis, Dep. 1-242); Mazis, Tr. 2651-2761).

Response to Finding No. 1034:
See Response to Finding 1033.

1035. Complaint Counsel's expert, Professor Meir Stampfer, admitted that there are no safety concerns with consuming pomegranate juice apart from "the usual harm that comes with fruit juice, sugary beverages… but that is not specific to pomegranate juice." (PX0362 (Stampfer, Dep. at 195-196)).

Response to Finding No. 1035:
The proposed finding is mischaracterizes the evidence. *See* Response to Finding 1033.

1036. Complaint Counsel's expert, Professor Meir Stampfer, admitted he has no opinion about whether there are safety concerns regarding POMx Pills or POMx Liquid relative to the pomegranate fruit that both are derived from. (PX0362 (Stampfer, Dep. at 201)).

Response to Finding No. 1036:
The proposed finding is mischaracterizes the evidence. *See* Response to Finding 1033.

1037. Complaint Counsel's expert, Dr. David Sacks, admitted that the issue of the safety of the Challenged Products was not within the scope of his assignment as in this case, that his expert report contains no opinions on the safety of the Challenged Products, and that he has "no opinion about whether [the Challenged Products are] safe or not." (PX0361 (Sacks, Dep. at 74, 76); CX1291_0008-0009).

Response to Finding No. 1037:
The proposed finding is mischaracterizes the evidence. *See* Response to Finding 1033.

1038. Complaint Counsel's expert, Dr. David Sacks, is unaware of any adverse side effects associated with consuming pomegranate juice. (PX0361 (Sacks, Dep. at 119)).

Response to Finding No. 1038:
The proposed finding is mischaracterizes the evidence. *See* Response to Finding 1033.

1039. Complaint Counsel's expert, Dr. Gerald Melman, is unaware of any adverse side effects associated with consuming pomegranate juice. (PX0360 (Melman, Dep. at 59)).

Response to Finding No. 1039:
The proposed finding is mischaracterizes the evidence. *See* Response to Finding 1033.

XIV. RESPONDENTS' HEART HEALTH CLAIMS ARE SUBSTANTIATED BY COMPETENT AND RELIABLE SCIENTIFIC EVIDENCE.

A. Complaint Counsel's Allegations Regarding Respondents' Heart Health Claims

1040. Complaint Counsel allege that Respondents have falsely represented, expressly or by implication, that clinical studies, research, and/or trials prove that:

A. 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 (1) decreasing arterial plaque, (2) lowering blood pressure, and/or (3) improving blood flow to the heart; and

B. Drinking eight ounces of POM Juice, or taking one POMx Pill or one teaspoon of POMx Liquid, daily, treats heart disease, including by (1) decreasing arterial plaque, (2) lowering blood pressure, and/or (3) improving blood flow to the heart.

(CX 1426_0017-0018).

Response to Finding No. 1040:
Complaint Counsel agrees.

1041. Complaint Counsel also allege that, in the area of heart health, there was no:

> significant difference between consumption of pomegranate juice and a control beverage in carotid intima-media thickness progression rates after 18 months; two smaller studies funded by POM Wonderful or its agents showed no significant difference between consumption of pomegranate juice and a control beverage on measures of cardiovascular function; and multiple studies funded by POM Wonderful or its agents did not show that POM Wonderful products reduce blood pressure.

(CX 1426_0018).

Response to Finding No. 1041:
Complaint Counsel agrees, except to note that the proposed finding is incomplete.

Preceding the block quote in the proposed finding, the Complaint alleges that in truth and in fact, clinical studies, research and trials do not prove that POM Juice, POMx Pill, and POM x Liquid treats, prevents, or reduces the risk of heart disease. "Among other things, the Davidson Study showed no significant difference between . . . ." (CX1426_00018).

1042. Complaint Counsel also allege that:

[R]espondents have represented, expressly or by implication, that:

A. 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 (1) decreasing arterial plaque, (2) lowering blood pressure, and/or (3) improving blood flow to the heart;

B. Drinking eight ounces of POM Juice, or taking one POMx Pill or one teaspoon of POMx Liquid, daily, treats heart disease, including by (1) decreasing arterial plaque, (2) lowering blood pressure, and/or (3) improving blood flow to the heart.

(CX 1426_0019).

Response to Finding No. 1042:
Complaint Counsel agrees.

B. Respondents Deny Complaint Counsel's Allegations that Their Advertisements Are False and Misleading

1043. Respondents deny Complaint Counsel's allegations that their advertising and promotional materials make the claim that 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 reduces the risk; or treats heart disease, including by (1) decreasing arterial plaque, (2) lowering blood pressure, and/or (3) improving blood flow to the heart. (Answer, ¶ 12).

Response to Finding No. 1043:
Complaint Counsel has no specific response.

1044. Respondents dispute Complaint Counsel's allegations or characterizations regarding Respondents' science and aver there is substantial scientific research indicating the health benefits of their products and substantiating their advertising and promotional materials. (Answer, ¶ 13).

Response to Finding No. 1044:
Complaint Counsel has no specific response.

1045. Respondents deny Complaint Counsel's allegations that their advertising and promotional materials make the claim that drinking eight ounces of POM Juice, or taking one POMx Pill or one teaspoon of POMx Liquid, daily, prevents or reduces the risk; or treats heart disease, including by (1) decreasing arterial plaque, (2) lowering blood pressure, and/or (3) improving blood flow to the heart. (Answer, ¶ 19).

Response to Finding No. 1045:
Complaint Counsel has no specific response.

C. Overview of Cardiovascular Disease

1046. A heart attack occurs when there is a sudden rupture of an inflamed plaque which covers about 50 percent of the lumen of a coronary vessel. (Heber, Tr. 1959).

Response to Finding No. 1046:
Complaint Counsel agrees that Dr. Heber testified as such, however, Dr. Heber does not hold himself out as an expert in cardiovascular disease (CCFF ¶ 728) and was not asked to opine on whether the heart benefit claims challenged in the complaint were true or substantiated (CCFF ¶¶ 730-31).

1047. Plaque is the end result of decades of damage to the blood vessel, which begins with oxidation. (Heber, Tr. 1959).

Response to Finding No. 1047:
Complaint Counsel agrees that Dr. Heber testified as such, however, Dr. Heber does not hold himself out as an expert in cardiovascular disease (CCFF ¶ 728) and was not asked to opine on whether the heart benefit claims challenged in the complaint were true or substantiated (CCFF ¶¶ 730-31).

1048. The process begins when a protein called low-density lipoprotein ("LDL") or so-called "bad cholesterol," which circulates through the blood, becomes oxidized. (Heber, Tr. 1959).

Response to Finding No. 1048:
Complaint Counsel agrees that Dr. Heber testified as such, however, Dr. Heber does not hold himself out as an expert in cardiovascular disease (CCFF ¶ 728) and was not asked to opine on whether the heart benefit claims challenged in the complaint were true or substantiated (CCFF ¶¶ 730-31).

1049. When the LDL cholesterol gets oxidized, the chemical nature of the protein changes, causing the protein to reside and deposit in the wall of the blood vessel, where it accumulates. (Heber, Tr. 1959; CX1348 (Aviram, Dep. at 5)).

Response to Finding No. 1049:
Complaint Counsel has no specific response.

1050. It is not only the quantity of cholesterol in the blood which determines the risk for heart attack and stroke, but also the quality. (CX1348 (Aviram, Dep. at 5)).

Response to Finding No. 1050:
The proposed finding is incomplete. Dr. Aviram's testimony described in the proposed finding is only a "theory." (CX1358 (Aviram, Dep. at 5)); *see also* CCFF ¶ 1105; CX1293 (Stamper, Report at 0010 ("free radical damage to . . . (LDL) cholesterol is ***hypothesized*** to be an initial step in the formation of atherosclerotic plaque") (emphasis added)).

1051. Regular cholesterol passes in and out of the arteries, but the oxidized cholesterol remains there. (Heber, Tr. 1959-60).

Response to Finding No. 1051:

Complaint Counsel agrees that Dr. Heber testified as such, however, Dr. Heber does not hold himself out as an expert in cardiovascular disease (CCFF ¶ 728) and was not asked to opine on whether the heart benefit claims challenged in the complaint were true or substantiated (CCFF ¶¶ 730-31).

1052. Macrophages (white blood cells that respond to inflammation by digesting cellular debris), come in and they eat up this oxidized cholesterol. (Heber, Tr. 1960).

Response to Finding No. 1052:
Complaint Counsel has no specific response.

1053. Macrophages have ravenous appetites which do not stop, and they continue to accumulate until they become what are called foam cells, which are full of cholesterol and actually burst into the area, bringing in more cells and more inflammation. (Heber, Tr. 1960).

Response to Finding No. 1053:
Complaint Counsel has no specific response.

1054. Basically, oxidation is followed by inflammation, which is followed by damage to the interior of the blood vessel. (Heber, Tr. 1960).

Response to Finding No. 1054:
Complaint Counsel has no specific response.

1055. This damage is detected as yellow streaks in the coronary arteries. (Heber, Tr. 1960).

Response to Finding No. 1055:
Complaint Counsel has no specific response.

1056. As this process progresses, plaque forms and begins to fill those lumen. (Heber, Tr. 1960).

Response to Finding No. 1056:
Complaint Counsel has no specific response.

1057. Plaque can have different characteristics; it can be stable or unstable. (Heber, Tr. 1960).

Response to Finding No. 1057:
Complaint Counsel has no specific response.

1058. Unstable plaque is full of oxidized cholesterol and macrophages, rift with inflammation. (Heber, Tr. 1960).

Response to Finding No. 1058:
Complaint Counsel has no specific response.

1059. By blocking that inflammation and oxidation, it is possible to stabilize the plaque. (Heber, Tr. 1960; PX0192-0033).

Response to Finding No. 1059:
Complaint Counsel has no specific response.

1060. Inhibitors of the oxidation process are called antioxidants. (CX1348 (Aviram, Dep. at 5)).

Response to Finding No. 1060:
The proposed finding incomplete. Dr. Aviram testified that this proposed finding is only a "theory." (CX1358 (Aviram, Dep. at 5)); *see also* CCFF ¶ 1103-05).

1061. Several studies have indicated that pomegranate juice has antioxidant and anti-atherosclerotic properties due to the presence of multiple polyphenols such as tannins, flavonols, anthocyanins and ellagic acid. (PX0025-0008).

Response to Finding No. 1061:
Complaint Counsel has no specific response.

1062. Punicalagin, an ellagitannin, is the most abundant polyphenol that accounts for more than 50% of the antioxidant activity. (PX0025-0008).

Response to Finding No. 1062:
Complaint Counsel has no specific response.

1063. The evidence suggests that pomegranate juice may be effective in reducing heart disease risk factors, including LDL oxidation, macrophage oxidative status, and foam cell formation, all of which are steps in atherosclerosis and cardiovascular disease. (PX0025-0008).

Response to Finding No. 1063:
Complaint Counsel agrees that this is Dr. Ornish' opinion, but disagrees with the broader conclusion drawn. (*See* CCFF ¶¶ 950-65).

D. Respondents' Scientific Research on Cardiovascular Health Demonstrates Beneficial Effects on Arterial Plaque, Blood Pressure, and Blood Flow

1. Basic Science and Animal Studies

1064. 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).

Response to Finding No. 1064:
Complaint Counsel objects to PX0002 and PX0009 cited in the proposed finding because the documents were not produced in compliance with discovery; the documents' probative value is outweighed by unfair prejudice; and the documents have not been authenticated.

1065. The earliest heart studies on pomegranate juice were carried out by Dr. Aviram at the Technion Institute in Israel. (Heber, Tr. 1957).

Response to Finding No. 1065:
Complaint Counsel has no specific response.

1066. Dr. Aviram is a Professor at the Technion Faculty of Medicine, Rappaport Institute for Research in the Medical Sciences and Rambam Medical Center, in Haifa, Israel, which is a highly regarded institution where several Nobel prizes have been awarded. (Heber, Tr. 1957-58).

Response to Finding No. 1066:
Complaint Counsel has no specific response.

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. (Heber, Tr. 1957-58).

Response to Finding No. 1067:
Complaint Counsel agrees that Dr. Heber testified as such, but notes that the proposed finding is uncorroborated by any cited evidence to either Dr. Aviram's studies or testimony.

1068. 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. (Sacks, Tr. 1571).

Response to Finding No. 1068:
Complaint Counsel agrees.

1069. For the last 30 years, Dr. Aviram's major research focus has been on dietary antioxidants and antioxidants in general, especially their role in cardiovascular disease. (CX1348 (Aviram, Dep. at 5)).

Response to Finding No. 1069:
Complaint Counsel has no specific response.

1070. Before studying pomegranates, Dr. Aviram examined a number of antioxidants from plants, including lycopene from tomatoes, green tea, citrus fruits, and then red wine. (Heber, Tr. 1958).

Response to Finding No. 1070:
Complaint Counsel agrees that Dr. Heber testified as such, but notes that the proposed finding is uncorroborated by any cited evidence to either Dr. Aviram's studies or testimony.

1071. Dr. Aviram published a red-wine study, which explained partially the "French paradox," that people in France, even though they eat fatty foods like the Finnish, they do not get heart attacks in France compared to Finland. It was shown epidemiologically that it has to do with drinking red wine, because red wine contains antioxidants from the skin of the grape. (CX1348 (Aviram, Dep. at 5)).

Response to Finding No. 1071:
Complaint Counsel has no specific response.

1072. Dr. Aviram was approached by POM and Les Dornfeld, who wanted him to do the same type of study that he did for red wine, and other fruits and vegetables, but now for pomegranates. (CX1348 (Aviram, Dep at 6)).

Response to Finding No. 1072:
Complaint Counsel agrees.

1073. After a year of studying in 1998 or 1999, Dr. Aviram concluded that pomegranate juice had greater antioxidant potencies than red wine. (CX1348 (Aviram, Dep. at 6)).

Response to Finding No. 1073:
Complaint Counsel has no specific response except to note that Respondents' sponsored RCTs repeatedly showed no improvement in markers of oxidative stress. (CCFF ¶¶ 825, 884, 915, 933, 949).

1074. Dr. Aviram knew that pomegranate could inhibit the oxidation of cholesterol from very basic test tube studies, but he also noticed that pomegranate juice could inhibit the uptake of that oxidized cholesterol into the macrophages. (Heber, Tr. 1960-61).

Response to Finding No. 1074:

Complaint Counsel agrees that Dr. Heber testified as such, but notes that the proposed finding is uncorroborated by any cited evidence to either Dr. Aviram's studies or testimony.

1075. 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).

Response to Finding No. 1075:
Complaint Counsel has no specific response.

1076. Dr. Aviram found that pomegranate juice benefits the activity of paraoxonase or PON1 by increasing its binding to HDL cholesterol. (Heber, Tr. 1961).

Response to Finding No. 1076:
Complaint Counsel agrees that Dr. Heber testified as such, but notes that the proposed finding is uncorroborated by any cited evidence to either Dr. Aviram's studies or testimony and that Respondents' sponsored RCTs repeatedly showed no improvement in markers of oxidative stress such as PON. (CCFF ¶¶ 825, 884, 915, 933, 949)

1077. Beginning in 2000 and continuing as recently as 2010, Dr. Aviram and others observed that pomegranate juice and/or POMx has beneficial effects on cardiovascular health in their cellular and animal research by resulting in, among other things, the following:

- reduction in 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;
- inhibition of macrophage cholesterol biosynthesis;
- decrease in macrophage oxidative stress;
- protection against cellular lipid peroxidation;
- reduction of serum lipids and glucose levels;
- improvement of PON1; and
- lessening of platelet aggregation.

(PX0002, PX0007, PX0008, PX0009, PX0010, PX0015, CX0543, PX0017, PX0022, and CX0053).

Response to Finding No. 1077:
Complaint Counsel has no specific response, except that Complaint Counsel disagrees with the conclusions drawn. (*See* CCFF ¶¶ 763-64, 962-65, 1103-08, 1119). Complaint Counsel objects to PX0002 and PX0009 cited in the proposed finding because the documents were not produced in compliance with discovery; the documents' probative value is outweighed by unfair prejudice; and the documents have not been authenticated.

1078. 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).

Response to Finding No. 1078:
Complaint Counsel does not disagree.

1079. 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).

Response to Finding No. 1079:
The proposed finding is incomplete. Dr. Sacks testified that changes in macrophage levels are not a reliable surrogate marker of heart health. (Sacks, Tr. 1622).

1080. 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).

Response to Finding No. 1080:
The proposed finding mischaracterizes Dr. Sacks' testimony. Rather, Dr. Sacks agreed that these studies showed favorable effects on the *mechanisms* involved in cardiovascular disease, which is not confirmed in humans. (Sacks, Tr. 1578; (emphasis added); CCFF ¶¶ 764, 1103-08; CX1291 (Sacks, Report at 0015-16) ("studies on animals do not provide reliable scientific support for claims that POM Juice, POMx Pills, or POMx Liquid is

effective at preventing, reducing the risk of, or treating cardiovascular disease in humans")).

1081. Respondents have also sponsored significant research in the area of nitric oxide and understanding its role in cardiovascular health. (PX0055, PX0056, PX0057, PX0058, PX0059).

Response to Finding No. 1081:
Complaint Counsel has no specific response.

1082. Nitric oxide is produced by the cells lining the heart blood vessels and by the cells lining the blood vessels of many organs around the body. (Heber, Tr. 1966).

Response to Finding No. 1082:
Complaint Counsel has no specific response.

1083. Nitric oxide is beneficial in that it improves blood flow to almost every organ in the body that is dependent upon blood flow. (Heber, Tr. 1969-70).

Response to Finding No. 1083:
Complaint Counsel has no specific response.

1084. Nitric oxide opens up tiny blood vessels and helps, among other things, preserve blood flow to the heart. (Heber, Tr. 1968).

Response to Finding No. No. 1084:
Complaint Counsel has no specific response.

1085. Pomegranate juice contains an extraordinary ability to enhance the effect of nitric oxide and inhibit oxidative stress. (Heber, Tr. 1967-68).

Response to Finding No. 1085:
The proposed finding is unsupported by the cited evidence.

1086. To this end, Respondents have sponsored research by Dr. deNigris, Dr. Napoli, and, most notably, Dr. Louis Ignarro, winner of the 1998 Nobel Prize and Professor of Pharmacology at UCLA School of Medicine, to conduct basic research on the effects of pomegranate juice on nitric oxide in the human body. (PX0055, PX0056, PX0057, PX0058, PX0059).

Response to Finding No. 1086:
Complaint Counsel has no specific response except to refer to CCFF ¶¶ 763-64 (summarizing purposes of *in vitro* and animal studies).

1087. In their studies, Dr. deNigris, Dr. Napoli, Dr. Ignarro, and others found that pomegranate juice and/or POMx demonstrated, among other things, the following beneficial effects:

- 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; and
- 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.

(PX0055, PX0056, PX0057, PX0058, PX0059).

Response to Finding No. 1087:
Complaint Counsel has no specific response except to refer to CCFF ¶¶ 763-64 (summarizing purposes of *in vitro* and animal studies) and Response to Finding 1100.

1088. In short, Respondents' basic and animal science constitutes competent and reliable scientific evidence that pomegranate juice and/or its extract are beneficial toward cardiovascular health by, among other things, reducing the oxidation of LDL cholesterol and its uptake, diminishing the size and scope of atherosclerotic legions, macrophages, and foam cells, lessening platelet aggregation, and enhancing the presence of nitric oxide. (PX0002, PX0007, PX0008, PX0009, PX0010, PX0015, CX0543, PX0017, PX0022, CX0053, PX0055, PX0056, PX0057, PX0058, PX0059).

Response to Finding No. 1088:
Complaint Counsel disagrees with the conclusions drawn. Complaint Counsel's experts found that the animal and *in vitro* studies relied upon by Respondents are not reliable scientific evidence to show 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. (CX1291 (Sacks, Report at 0015-16); Stampfer, Tr. 736-40, 725-26, 773; CX1293 (Stampfer, Report at 0016-17); *see also* CCFF ¶¶ 763-64,

962-65, 1103-08, 1119)). Complaint Counsel objects to PX0002 and PX0009 cited in the proposed finding because the documents were not produced in compliance with discovery; the documents' probative value is outweighed by unfair prejudice; and the documents have not been authenticated.

2. Respondents' Clinical Trials

1089. 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).

Response to Finding No. 1089:
Complaint Counsel does not disagree that Respondents published 10 studies on humans, except to note that only two published human studies were designed as RCTs – the Davidson CIMT Study and the Ornish MP Study. (CCFF ¶¶ 824-54, 879-911). Respondents also conducted additional human studies on POM Juice and POMx Pills related to cardiovascular health, including the Davidson BART/FMD Study (CCFF ¶¶ 912-919), the Ornish CIMT Study (CCFF ¶¶ 855-74), the "cardiac arm" of the Ornish MP Study (CCFF ¶¶ 824-25), and the Denver and the San Diego Studies (CCFF ¶¶ 920-43).

1090. In addition to enlisting the assistance of Dr. Aviram, Respondents also worked with two of the most pre-eminent research scientists in the field of cardiovascular health to better understand the potential benefits of pomegranate juice and/or its derivatives in humans: Dr. Dean Ornish and Dr. Michael Davidson. (PX0014, PX0023).

Response to Finding No. 1090:
Complaint Counsel has no specific response.

1091. Dr. Dean Ornish is the Founder and President of the non-profit Preventive Medicine Research Institute in Sausalito, California and Clinical Professor of Medicine at the University of California, San Francisco. (PX0025-0001).

Response to Finding No. 1091:
Complaint Counsel agrees.

1092. Dr. Ornish is considered a pioneer in cardiovascular health and human wellness and one of the most influential people in the world in this regard. (Heber, Tr. 1970).

Response to Finding No. 1092:
Complaint Counsel agrees that Dr. Heber testified as such.

1093. Dr. Ornish, who conducted a landmark study showing that the effects of lifestyle on heart health, is widely published and continues to do research. (Heber, Tr. 1970).

Response to Finding No. 1093:
Complaint Counsel agrees that Dr. Heber testified as such.

1094. Dr. Davidson is the Clinical Professor of Medicine and Director of Preventive Cardiology at the University of Chicago Medical Center, Medical Director of Radiant Research, Chicago, and a practicing physician who typically treats patients with cholesterol abnormalities, coronary artery disease, or clinical atherosclerosis. (JX3; CX1134_0001; CX 1336 (Davidson, Dep. at 218-220)).

Response to Finding No. 1094:
Complaint Counsel agrees.

1095. Dr. Davidson has been involved, in some manner, in over 700 clinical studies over the past 25 years. (JX 3; CX1336 (Davidson, Dep. at 220-221)).

Response to Finding No. 1095:
Complaint Counsel agrees.

1096. Dr. Davidson is a nationally recognized expert on statins, novel lipid-lowering drugs and the reduction of coronary artery disease risk through diet and exercise. (http://www.uchospitals.edu/physicians/michael-davidson.html)

Response to Finding No. 1096:
The proposed finding is irrelevant; it is also unsupported because the evidence cited is not

in the record, in violation of the Court's Order on Post-Trial Briefs.

1097. Dr. Frank Sacks regards Dr. Davidson as one of the foremost clinical researchers in the cardiovascular field with a superb reputation for top-quality clinical trial research in cardiovascular disease. (Sacks, Tr. 1490).

Response to Finding No. 1097:
Complaint Counsel agrees.

1098. In their studies, Dr. Aviram, Dr. Ornish, Dr. Davidson and others found that pomegranate juice and/or POMx had, among other things, the following beneficial effects in humans:

- 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 intima-media thickness of the coronary artery ("CIMT"); and
- increase blood flow or myocardial perfusion.

(PX0004, PX0005, CX0611, PX0014, PX0020, PX0021, PX0023, PX0038, PX0127, CX0934).

Response to Finding No. 1098:

Complaint Counsel disagrees with the conclusions drawn. (CCFF ¶¶ 950-65). *With regard to heart-related biomarkers*, Respondents' studies were unsupportive of the proposition that POM products benefit heart health. Davidson Bart/FMD study showed no significant benefit in BART/FMD, blood pressure, cholesterol, PON, triglycerides, ACE, PON, and two TBARs. (CCFF ¶¶ 950-65). The Ornish MP Study did not show a benefit in cholesterol, LDL, HDL, or triglycerides. (CCFF ¶¶ 829-54). The Davidson CIMT Study showed no significant benefit from pomegranate juice on PON1. (CCFF ¶¶ 882-911). The Davidson BART/FMD Study showed no significant benefit in ACE and PON, among other things. (CCFF ¶¶ 914-19). *With regard to decreased arterial plaque*, the Davidson CIMT Study and the Ornish CIMT Study both showed no benefit in CIMT from consuming POM Juice. (CCFF ¶¶ 882, 855-68). The Aviram CIMT/BP Study (2004) was small, unblinded, and uncontrolled, and therefore, unreliable to confirm beneficial effects on CIMT results from consuming pomegranate juice. (CCFF ¶¶ 814-16). *With regard to blood flow*, the results of the Ornish MP Study should be interpreted as no effect on any measure of cardiac health given the significant problems with the

study and that myocardial perfusion is not a recognized surrogate marker. (CCFF ¶¶ 844-54). *With regard to lowering blood pressure*, both Aviram ACE/BP Study (2001) and Aviram CIMT/BP Study (2004) were small, unblinded, and uncontrolled, therefore unreliable to confirm lowering blood pressure. (CCFF ¶¶ 955-58). In addition, five subsequent RCTs showed no benefit to blood pressure. (CCFF ¶ 956).

1099. In conclusion, 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)).

Response to Finding No. 1099:
Complaint Counsel disagrees with the conclusions drawn. *See* Responses to Findings 1077, 1087, 1088, 1098.

1100. The following chart summarizes Respondents' basic, animal, and human science demonstrating the benefits of pomegranate juice and/or POMx on cardiovascular health:

RESPONDENTS' PUBLISHED CARDIOVASCULAR HEALTH STUDIES				
Respondents' Basic Science and Animal Studies				
Year	**Publication/Researcher**	**Product Tested**	**Method**	**Findings**
2001	Kaplan, *et al*., Pomegranate juice supplementation to atherosclerotic mice reduces macrophage lipid peroxidation, cellular cholesterol accumulation and development of atherosclerosis, 131 *J. Nutr.* 2082-89 (2001). Researcher/Affiliation Dr. Aviram The Lipid Research Laboratory, Technion Faculty of Medicine,	POM Wonderful 100% pomegranate juice	Apo E-deficient mice	Pomegranate juice supplementation to Apo E mice with advanced atherosclerosis reduced the lesion size by 17% compared to placebo mice. This supplementation reduced macrophage oxidative stress.

RESPONDENTS' PUBLISHED CARDIOVASCULAR HEALTH STUDIES				
Respondents' Basic Science and Animal Studies				
Year	**Publication/Researcher**	**Product Tested**	**Method**	**Findings**
	Rambam Medical Center (CX0543)			
2005	Fuhrman, *et al*., Pomegranate juice inhibits oxidized LDL uptake and cholesterol biosynthesis in macrophages, 16 *J. Nutr. Biochemistry* 570-6 (2005). Researcher/Affiliation Dr. Aviram The Lipid Research Laboratory, Technion Faculty of Medicine, Rambam Medical Center (PX0015)	POM Wonderful 100% pomegranate juice	*In vitro*	Pre-incubation of macrophages with juice resulted in a significant reduction in ox-LDL degradation by 40%. Macrophage cholesterol biosynthesis was inhibited by 50% after cell incubation with juice.
2005	de Nigris, *et.al*., Beneficial effects of pomegranate juice on oxidation-sensitive genes and eNOS activity at sites of perturbed shear stress, 102(13) *Proceedings of the National Academy of Sciences* 4896-4901 (2005). Researcher/Affiliation Drs. Napoli and Ignarro University of Naples and UCLA (PX0059)	POM Wonderful 100% pomegranate juice	*In vitro* and *in vivo*	Pomegranate juice significantly increased levels of nitric oxide in cell culture, as well as decreased the expression genes that are associated with stress and progression of atherosclerosis. These results were also seen in mice both when juice was used as a preventative and a therapeutic treatment. Furthermore, LDL oxidation, the size of the atherosclerotic plaques, and formation of foam cells were significantly decreased in mice.
2006	Rosenblat, *et al*., Pomegranate byproduct administration to apolipoprotein e-deficient mice attenuates atherosclerosis development as a result of	POMx	*In vitro* and Apo E-deficient mice	Consumption of POMx by atherosclerotic mice E-deficient mice resulted in a significant reduction in the mouse macrophage oxidative stress and in the atherogenic oxidized LDL

RESPONDENTS' PUBLISHED CARDIOVASCULAR HEALTH STUDIES				
Respondents' Basic Science and Animal Studies				
Year	**Publication/Researcher**	**Product Tested**	**Method**	**Findings**
	decreased macrophage oxidative stress and reduced cellular uptake of oxidized low-density lipoprotein, J *Agric Food Chem*. 2006 Mar 8;54(5):1928-35 Researcher/Affiliation Dr. Aviram The Lipid Research Laboratory, Technion Faculty of Medicine, Rambam Medical Center (CX0053)			uptake by the cells, and these effects were associated with a significant attenuation atherosclerotic lesion development. Thus, the results showed that POMx significantly attenuates atherosclerosis development by its antioxidant properties in vitro and in E-deficient mice.
2006	Ignarro, *et al*., Pomegranate juice protects nitric oxide against destruction and enhances the biological actions of nitric oxide, 15 *Nitric Oxide* 93-102. Researcher/Affiliation Dr. Ignarro UCLA (PX0058)	POM Wonderful 100% pomegranate juice	*In vitro*	Pomegranate juice is more potent in preserving nitric oxide than red wine, concord grape and blueberry juice. Pomegranate polyphenols retard vascular smooth muscle growth.
2006	de Nigris, *et al*., Pomegranate juice reduces oxidized low-density lipoprotein down regulation of endothelial nitric oxide synthase in human coronary endothelial cells, 15 *Nitric Oxide* 259-263 (2006). Researcher/Affiliation Drs. Napoli & Ignarro	POM Wonderful 100% pomegranate juice	*In vitro*	Pomegranate juice can revert the potent down regulation of the expression of endothelial nitric oxide synthase induced by oxidized LDL cholesterol in human endothelial cells via a significant dose dependent pathway.

RESPONDENTS' PUBLISHED CARDIOVASCULAR HEALTH STUDIES				
Respondents' Basic Science and Animal Studies				
Year	**Publication/Researcher**	**Product Tested**	**Method**	**Findings**
	University of Naples & UCLA (PX0055)			
2006	Rozenberg, et al., Pomegranate juice sugar fraction reduces macrophage oxidative state whereas grape juice fraction increases it, 188 *Atherosclerosis* 68-76. <u>Researcher/Affiliation</u> Dr. Aviram The Lipid Research Laboratory, Technion Faculty of Medicine, Rambam Medical Center (PX0022)	POM Wonderful 100% pomegranate juice	Male balb/C mice	PJ sugar fraction decreases macrophage oxidative stress by up to 72% whereas white grape juice increases oxidative stress by up to 37% vs. control group.
2007	deNigris, *et al*., 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, *Nitric Oxide* 17 (2007) 50–54 <u>Researcher/Affiliation</u> Dr. Napoli University of Naples (PX0057)	POM Juice, POMx Pills, and POM seed oil	Zucker rats	POM Juice and POMx Pills significantly reduce the expression of vascular inflammatory markers as well as significantly increasing nitric oxide levels.
2007	de Nigris, *et al*., Effects of a Pomegranate Fruit Extract rich in punicalagin on oxidation-sensitive genes and eNOS activity at sites of perturbed shear stress and atherogenesis, *Cardiovascular Research*	POM Wonderful 100% pomegranate juice and POMx Liquid	*In vitro*	Results showed that proartherogenic effects induced by perturbed sheer stress is reduced by POMx and POM Juice.

RESPONDENTS' PUBLISHED CARDIOVASCULAR HEALTH STUDIES				
Respondents' Basic Science and Animal Studies				
Year	**Publication/Researcher**	**Product Tested**	**Method**	**Findings**
	73 (2007) 414–423 Researcher/Affiliation Dr. Napoli University of Naples (PX0056)			
2007	Shiner, *et al*., Macrophage paraoxonase 2 expression is up-regulated by pomegranate juice phenolic antioxidants via PPARy and AP-1 pathway activation, 195 *Atherosclerosis* 313-321. Researcher/Affiliation Dr. Aviram The Lipid Research Laboratory, Technion Faculty of Medicine, Rambam Medical Center (PX0007)	POM Wonderful 100% pomegranate juice	*In vitro*	Pomegranate juice up-regulates arterial macrophage PON2 expression and protects against cellular lipid peroxidation.
2008	Aviram, *et al*., Pomegranate Phenolics from the Peels, Arils, and Flowers Are Antiatherogenic: Studies in Vivo and in Atherosclerotic Apolipoprotein Edeficient (E) Mice and in Vitro in Cultured Macrophages and Lipoproteins, *J. Agric. Food Chem*. (2008), 56, 1148-1157 Researcher/Affiliation Dr. Aviram The Lipid Research Laboratory, Technion Faculty of Medicine,	POM Wonderful 100% pomegranate juice, POMx Liquid, POMx Pills, POM oil, POM seeds, POM flowers, POM arils	*In vitro* and *in vivo*	All POM extracts possess antioxidant activity in vitro. After consumption of PJ, POMxl, POMxp, POMf, or POM arils by Apo E mice, the atherosclerotic lesion area was significantly decreased by 44, 38, 39, 6 or 70%, respectively as compared to placebo, while POMo had no effect and POMf reduced serum lipids and glucose levels by 18-25%.

RESPONDENTS' PUBLISHED CARDIOVASCULAR HEALTH STUDIES				
Respondents' Basic Science and Animal Studies				
Year	**Publication/Researcher**	**Product Tested**	**Method**	**Findings**
	Rambam Medical Center (PX0008)			
2009	Mattiello, *et al*., Effects of Pomegranate Juice and Extract Polyphenols on Platelet Function, *J. Medicinal Foods* 12 (2) (2009) <u>Researcher/Affiliation</u> Dr. Mattielo Sapienza University of Rome (PX0017)	POM Wonderful 100% pomegranate juice and POMx Pills	*In vitro*	POM Juice and POMx reduce all platelet responses studied. Results demonstrated that cardiovascular health benefits of pomegranate may in part be related to the ability of polyphenols to inhibit platelet function.
2010	Fuhrman, *et al*., Pomegranate juice polyphenols increase recombinant paraoxonase-1 binding to high-density lipoprotein: studies in vitro and in diabetic patients, *Nutrition*. 2010 Apr; 26(4):359-66 <u>Researcher/Affiliation</u> Drs. Avirom and Fuhrman The Lipid Research Laboratory, Technion Faculty of Medicine, Rambam Medical Center (PX0009, unpub. manuscript)	POM Wonderful 100% pomegranate juice	*In vitro*	Oxidative stress impairs binding of PON1 to HDL. POM Juice polyphenols increase the binding beyond their anti-oxidative effect. These effects could be related to a POM Juice-mediated reduction in oxidative stress and to a direct effect of POM Juice polyphenols on the HDL-PON1 association.
2010	Khateeb, *et al*., Paraoxonase 1 (PON1) expression in hepatocytes is upregulated by pomegranate polyphenols: a role for PPAR-gamma	POM Wonderful 100% pomegranate juice	*In vitro*	The anti-atherogenic characteristics of POM Juice polyphenols are modulated, at least in part, via PON1 upregulation and its subsequent release to

RESPONDENTS' PUBLISHED CARDIOVASCULAR HEALTH STUDIES				
Respondents' Basic Science and Animal Studies				
Year	**Publication/Researcher**	**Product Tested**	**Method**	**Findings**
	pathway, *Atherosclerosis*. 2010 Jan; 208(1):119-25 Researcher/Affiliation Dr. Aviram The Lipid Research Laboratory Technion Faculty of Medicine Rambam Medical Center (PX0002, unpub. manuscript)			the medium.
2011	Rosenblat, *et al*., Pomegranate Juice Protects Macrophages from Triglyceride Accumulation: Inhibitory Effect on DGAT1 Activity and on Triglyceride Biosynthesis, Ann. Nutr. Metab. (2011), 58:1-9 Researcher/Affiliation Dr. Aviram The Lipid Research Laboratory Technion Faculty of Medicine Rambam Medical Center (PX0010)	POM Wonderful 100% pomegranate juice	*In vitro*	When macrophages were treated with pomegranate juice or punicalagin, the content and formation of triglycerides were reduced by at least 30%. The accumulation of lipids, to include triglycerides, within macrophages has been linked to the formation of atherosclerotic plaques. The authors concluded that the ability of POM Juice polyphenols to protect against macrophage triglyceride accumulation is an important contributor to the anti-artherogenic properties of pomegranate.

Respondents' Human Clinical Trials				
Year	**Publication/Researcher**	**Product Tested**	**Method**	**Findings**
2000	Researcher/Affiliation Aviram, *et al*., Pomegranate juice consumption reduces oxidative stress, atherogenic modifications to LDL, and platelet	POM Wonderful 100% pomegranate juice	Humans (and Apo E-deficient mice)	This study demonstrates that antioxidant activity in the blood of 13 healthy male volunteers who drank POM Wonderful pomegranate juice for 2 weeks increased by 9%,

Respondents' Human Clinical Trials				
Year	**Publication/Researcher**	**Product Tested**	**Method**	**Findings**
	aggregation: studies in humans and in atherosclerotic apolipoprotein E-deficient mice, 71(5) *Am. J. Clinical Nutrition* 1062-76 (2000) Researcher/Affiliation Dr. Aviram The Lipid Research Laboratory, Technion Faculty of Medicine, Rambam Medical Center (PX0004)			and the amount of LDL cholesterol oxidation decreased by 20%. The study also measured similar effects on mice with abnormal fatty deposits in their arteries. It was found that plaque build-up was 44% less than these mice than in the mice who did not receive pomegranate juice.
2001	Aviram, *et al*., Pomegranate juice consumption inhibits serum angiotensin converting enzyme activity and reduces systolic blood pressure, 158 *Atherosclerosis* 195-98 (2001). Researcher/Affiliation Dr. Aviram The Lipid Research Laboratory, Technion Faculty of Medicine, Rambam Medical Center (PX0005)	POM Wonderful 100% pomegranate juice	Humans	Ten patients, ranging in age from 62 to 77, with an average blood pressure of over 155/83 drank 8 oz 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 to lower blood pressure was also reduced by 36%.
2004	Aviram, *et al*., Pomegranate juice consumption for 3 years by patients with carotid artery stenosis reduces common carotid intima-media thickness, blood pressure and LDL oxidation, 23 *Clinical Nutrition* 423-33 (2004).	POM Wonderful 100% pomegranate juice	Humans	Ten patients consumed 8 oz a day of POM Wonderful pomegranate juice for 1 year. Nine patients did not consume pomegranate juice (controls). The intima-media thickness (IMT) of the carotid artery wall was measured at 3 month

Respondents' Human Clinical Trials				
Year	**Publication/Researcher**	**Product Tested**	**Method**	**Findings**
	Researcher/Affiliation Dr. Aviram The Lipid Research Laboratory, Technion Faculty of Medicine, Rambam Medical Center (CX0611)			intervals. 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, those consuming juice had a significant reduction in systolic blood pressure and a reduction of LDL oxidation by 90%. Benefits were maintained in 5 patients that continued to drink juice for 2 additional years.
2004	Esmaillzadeh, *et al*., Concentrated pomegranate juice improves lipid profiles in diabetic patients with hyperlipidemia, 7 *J. Med. Food* 3 (2004) Researcher/Affiliation Dr. Esmaillzadeh Shaheed Beheshti University of Medical Sciences Tehran, Iran (PX0038)	POMx Liquid	Humans	The authors concluded that concentrated pomegranate juice consumption may modify heart disease risk factors in hyperlipidemic patients, and its inclusion therefore in their diets may be beneficial.
2005	Sumner, *et al*., Effects of pomegranate juice consumption on myocardial perfusion in patients with coronary heart disease, 96 *Am. J. Cardiol.* 810-14 (2005). Researcher/Affiliation Dr. Ornish The Preventive Medicine Research Institute in	POM Wonderful 100% pomegranate juice	Humans	After 3 months, the extent of stress-induced ischemia decreased in the pomegranate juice group but increased in the control group for a significant change.

Respondents' Human Clinical Trials				
Year	**Publication/Researcher**	**Product Tested**	**Method**	**Findings**
	Sausalito, California (PX0023)			
2006	Rosenblat, *et al*., Anti-oxidant effects of pomegranate juice consumption by diabetic patients on serum and on macrophages, 187 *Atherosclerosis* 363-371. <u>Researcher/Affiliation</u> Dr. Aviram The Lipid Research Laboratory, Technion Faculty of Medicine, Rambam Medical Center (PX0020)	POM Wonderful 100% pomegranate juice	Humans	Pomegranate juice resulted in significant reduction in serum peroxides, TBAR levels by 56% and 28%, and cellular peroxides by 71% and increased glutathione levels by 141% in patients with diabetes. Juice resulted in significant antioxidant benefit for people with diabetes.
2007	Heber, *et al*., Safety and antioxidant activity of pomegranate ellagitannin-enriched polyphenol dietary supplement in overweight individuals with increased waist size, *J. Agric. Food Chem*. 2007, 55, 10050–10054 <u>Researcher/Affiliation</u> Drs. Heber and Hill UCLA & University of Colorado (PX00139)	POMx Pills	Humans	No adverse events related to POMx were observed. After one month, a significant 13% percent reduction in plasma TBARS compared to baseline was observed.
2008	Rock, *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	POM Wonderful 100% pomegranate juice and POM Liquid	Humans	After 4 weeks, there was a significant 30% improvement in HDL paraoxonase 1 (PON1) and an overall lowering of oxidative stress associated with reduced atherosclerosis risk. POM Juice and POMx had

Respondents' Human Clinical Trials				
Year	**Publication/Researcher**	**Product Tested**	**Method**	**Findings**
	J. Agric. Food Chem. (2008) Researcher/Affiliation Dr. Aviram The Lipid Research Laboratory, Technion Faculty of Medicine, Rambam Medical Center (PX0127)			similar efficacy. The beneficial effects of pomegranate juice consumption on serum PON1 stability and activity could lead to retardation of atherosclerosis development in diabetic patients.
2009	Davidson, *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) Researcher/Affiliation Dr. Davidson Radiant Research University of Chicago (PX0014)	POM Wonderful 100% pomegranate juice	Humans	A randomized, placebo-controlled, double-blind clinical trial followed 289 subjects at moderate risk for coronary heart disease. These subjects consumed 8 ounces per day of either Wonderful variety 100% pomegranate juice or a placebo beverage. After 18 months, there was no reduction in the progression of intima-media thickness of the carotid artery (CIMT) in the 100% pomegranate juice group as a whole. However, further analysis revealed that the rate of CIMT progression slowed in nearly one third of 100% pomegranate juice subjects, those with elevated cardiovascular disease risk factors.
2010	Rosenblat, *et al*., Consumption of polyphenolic-rich beverages (mostly pomegranate and black currant juices) by healthy subjects for a short term	POM Wonderful 100% pomegranate juice		100% pomegranate juice and 100% black currant juice demonstrated the highest total polyphenol content and antioxidant potency in a comparative study of 35 U.S. beverages

Respondents' Human Clinical Trials				
Year	**Publication/Researcher**	**Product Tested**	**Method**	**Findings**
	increased serum antioxidant status, and the serum's ability to attenuate macrophage cholesterol accumulation, Food Funct. 2010, 1, 99-109. Researcher/Affiliation Dr. Aviram The Lipid Research Laboratory Technion Faculty of Medicine Rambam Medical Center (PX0021)			including red wine, green tea, and several deeply colored fruit juices. In addition, the blood serum of healthy subjects who drank 100% Wonderful-variety pomegranate juice and 100% black currant juice for one week exhibited several measures of increased antioxidant activity.

Response to Finding No. 1100:

With regard to Respondents' Basic and Animal Studies, Complaint Counsel's responses are set forth below after each study. *See* Responses to Findings 1077, 1088. (*See also* CCFF ¶¶ 763-64, 1103-05).

RESPONDENTS' PUBLISHED CARDIOVASCULAR HEALTH STUDIES				
Respondents' Basic Science and Animal Studies				
Year	**Publication/Researcher**	**Product Tested**	**Method**	**Findings**
2001	Kaplan, *et al*., Pomegranate juice supplementation to atherosclerotic mice reduces macrophage lipid peroxidation, cellular cholesterol accumulation and development of atherosclerosis, 131 *J. Nutr.* 2082-89 (2001). Researcher/Affiliation Dr. Aviram The Lipid Research Laboratory, Technion Faculty of Medicine,	POM Wonderful 100% pomegranate juice	Apo E-deficient mice	Pomegranate juice supplementation to Apo E mice with advanced atherosclerosis reduced the lesion size by 17% compared to placebo mice. This supplementation reduced macrophage oxidative stress.

RESPONDENTS' PUBLISHED CARDIOVASCULAR HEALTH STUDIES				
Respondents' Basic Science and Animal Studies				
Year	**Publication/Researcher**	**Product Tested**	**Method**	**Findings**
	Rambam Medical Center (CX0543)			
	Complaint Counsel has no specific response, but notes that Respondents did not provide any expert testimony to explain this study. Respondents' subsequent human RCTs showed that PJ did not change oxidative stress or inflammatory markers. (CCFF ¶¶ 825, 884, 915, 933, 949). Human metabolism and disease processes are very complicated and cannot be replicated in a petri dish, and therefore *in vitro* studies produce results that cannot be replicated in humans. (CCFF ¶ 763).			
2005	Fuhrman, *et al*., Pomegranate juice inhibits oxidized LDL uptake and cholesterol biosynthesis in macrophages, 16 *J. Nutr. Biochemistry* 570-6 (2005). Researcher/Affiliation Dr. Aviram The Lipid Research Laboratory, Technion Faculty of Medicine, Rambam Medical Center (PX0015)	POM Wonderful 100% pomegranate juice	*In vitro*	Pre-incubation of macrophages with juice resulted in a significant reduction in ox-LDL degradation by 40%. Macrophage cholesterol biosynthesis was inhibited by 50% after cell incubation with juice.
	See Response to Finding above.			
2005	de Nigris, *et.al*., Beneficial effects of pomegranate juice on oxidation-sensitive genes and eNOS activity at sites of perturbed shear stress, 102(13) *Proceedings of the National Academy of Sciences* 4896-4901 (2005).	POM Wonderful 100% pomegranate juice	*In vitro* and *in vivo*	Pomegranate juice significantly increased levels of nitric oxide in cell culture, as well as decreased the expression genes that are associated with stress and progression of atherosclerosis. These results were also seen in mice both when juice was used as a preventative and

RESPONDENTS' PUBLISHED CARDIOVASCULAR HEALTH STUDIES				
Respondents' Basic Science and Animal Studies				
Year	**Publication/Researcher**	**Product Tested**	**Method**	**Findings**
	Researcher/Affiliation Drs. Napoli and Ignarro University of Naples and UCLA (PX0059)			a therapeutic treatment. Furthermore, LDL oxidation, the size of the atherosclerotic plaques, and formation of foam cells were significantly decreased in mice.
	Complaint Counsel disagrees with the conclusion drawn. This study examined the effect of POM Juice *in vitro* and in mice, and found that it *appeared* to decrease LDL oxidation and the size of plaques. (CX1293 (Stampfer, Report at 0016); s*ee also* CCFF ¶¶ 763-64, 1103-05)).			
2006	Rosenblat, *et al*., Pomegranate byproduct administration to apolipoprotein e-deficient mice attenuates atherosclerosis development as a result of decreased macrophage oxidative stress and reduced cellular uptake of oxidized low-density lipoprotein, J *Agric Food Chem*. 2006 Mar 8;54(5):1928-35 Researcher/Affiliation Dr. Aviram The Lipid Research Laboratory, Technion Faculty of Medicine, Rambam Medical Center (CX0053)	POMx	*In vitro* and Apo E-deficient mice	Consumption of POMx by atherosclerotic mice E-deficient mice resulted in a significant reduction in the mouse macrophage oxidative stress and in the atherogenic oxidized LDL uptake by the cells, and these effects were associated with a significant attenuation atherosclerotic lesion development. Thus, the results showed that POMx significantly attenuates atherosclerosis development by its antioxidant properties in vitro and in E-deficient mice.
	The proposed finding mischaracterizes the cited evidence. The proposed finding states this study was conducted on POMx, however, the article reports the study was conducted on an			

RESPONDENTS' PUBLISHED CARDIOVASCULAR HEALTH STUDIES Respondents' Basic Science and Animal Studies				
Year	**Publication/Researcher**	**Product Tested**	**Method**	**Findings**
	unidentified extract byproduct containing anthocyanins. (CX0053). *See also* Response to Finding 2498. Respondents did not provide any expert testimony to explain or support this study. Human metabolism and disease processes are very complicated and cannot be replicated in a petri dish, and therefore *in vitro* studies produce results that cannot be replicated in humans. (CCFF ¶ 763).			
2006	Ignarro, *et al*., Pomegranate juice protects nitric oxide against destruction and enhances the biological actions of nitric oxide, 15 *Nitric Oxide* 93-102. Researcher/Affiliation Dr. Ignarro UCLA (PX0058)	POM Wonderful 100% pomegranate juice	*In vitro*	Pomegranate juice is more potent in preserving nitric oxide than red wine, concord grape and blueberry juice. Pomegranate polyphenols retard vascular smooth muscle growth.
	The proposed finding is incomplete. The authors also found that "PJ did not influence either eNOS protein expression or catalytic activity. Similarly, PJ failed to stimulate eNOS promoter activity under the defined experimental conditions." (PX0058-0008). This result appears to be inconsistent with another study, PX0057, which found eNOS changes. *See also* Responses to Findings 152, 785, 835, 839, 2088. Human metabolism and disease processes are very complicated and cannot be replicated in a petri dish, and therefore *in vitro* studies produce results that cannot be replicated in humans. (CCFF ¶ 763).			
2006	de Nigris, *et al*., Pomegranate juice reduces oxidized low-density lipoprotein down regulation of endothelial nitric oxide synthase in	POM Wonderful 100% pomegranate juice	*In vitro*	Pomegranate juice can revert the potent down regulation of the expression of endothelial nitric oxide synthase induced by oxidized LDL

RESPONDENTS' PUBLISHED CARDIOVASCULAR HEALTH STUDIES				
Respondents' Basic Science and Animal Studies				
Year	**Publication/Researcher**	**Product Tested**	**Method**	**Findings**
	human coronary endothelial cells, 15 *Nitric Oxide* 259-263 (2006). Researcher/Affiliation Drs. Napoli & Ignarro University of Naples & UCLA (PX0055)			cholesterol in human endothelial cells via a significant dose dependent pathway.
	The proposed finding is incomplete, as the study acknowledges that "cell-culture studies may indeed bear only partial relevance to pathophysiological mechanisms activated in humans." (PX0055-0004). None of Respondents' witnesses specifically discussed it in their expert reports or testimony. Complaint Counsel's expert Dr. Melman did, and stated that the study did not show efficacy in humans. (Melman, Tr. 1132). *See also* Responses to Findings 831-833. Human metabolism and disease processes are very complicated and cannot be replicated in a petri dish, and therefore *in vitro* studies produce results that cannot be replicated in humans. (CCFF ¶ 763).			
2006	Rozenberg, et al., Pomegranate juice sugar fraction reduces macrophage oxidative state whereas grape juice fraction increases it, 188 *Atherosclerosis* 68-76. Researcher/Affiliation Dr. Aviram The Lipid Research Laboratory, Technion Faculty of Medicine, Rambam Medical Center (PX0022)	POM Wonderful 100% pomegranate juice	Male balb/C mice	PJ sugar fraction decreases macrophage oxidative stress by up to 72% whereas white grape juice increases oxidative stress by up to 37% vs. control group.

RESPONDENTS' PUBLISHED CARDIOVASCULAR HEALTH STUDIES				
Respondents' Basic Science and Animal Studies				
Year	**Publication/Researcher**	**Product Tested**	**Method**	**Findings**
	The proposed finding is incomplete. This *in vitro* and animal study was designed to examine whether POM Juice (PJ) simple or complex sugars contribute to the antioxidative properties in PJ in comparison to white grape juice. (PX0022-001). The study found that increasing concentrations of the PJ sugar fraction resulted in a dose-dependent decrement in the macrophage peroxide level of up to 72%. Human metabolism and disease processes are very complicated and cannot be replicated in a petri dish, and therefore *in vitro* studies produce results that cannot be replicated in humans. (CCFF ¶ 763). Animal studies must be confirmed by RCTs since agents that work in mice often do not work the same way in humans. (CCFF ¶ 764). Animal studies alone are not sufficient to show that a tested product will prevent or treat human disease. (CCFF ¶ 764). Respondents did not provide any expert testimony to explain or support this study.			
2007	deNigris, *et al*., 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, *Nitric Oxide* 17 (2007) 50–54 <u>Researcher/Affiliation</u> Dr. Napoli University of Naples (PX0057)	POM Juice, POMx Pills, and POM seed oil	Zucker rats	POM Juice and POMx Pills significantly reduce the expression of vascular inflammatory markers as well as significantly increasing nitric oxide levels.
	The proposed finding is incomplete and mischaracterizes the evidence. This study did not examine the effects of POMx Pills. The purpose of this study was to evaluate the effect of pomegranate fruit extract (PFE) in comparison to pomegranate juice (PJ) and seed oil on the			

RESPONDENTS' PUBLISHED CARDIOVASCULAR HEALTH STUDIES Respondents' Basic Science and Animal Studies				
Year	**Publication/Researcher**	**Product Tested**	**Method**	**Findings**
	biological actions of nitric oxide and the arterial function of obese Zucker rats. (PX0057-0001). Respondents' subsequent human RCTs showed that PJ did not change inflammatory markers. (CCFF ¶¶ 884, 933, 949). Human metabolism and disease processes are very complicated and cannot be replicated in a petri dish, and therefore *in vitro* studies produce results that cannot be replicated in humans. (CCFF ¶ 763). Respondents did not provide any expert testimony to explain or support this study.			
2007	de Nigris, *et al*., Effects of a Pomegranate Fruit Extract rich in punicalagin on oxidation-sensitive genes and eNOS activity at sites of perturbed shear stress and atherogenesis, *Cardiovascular Research* 73 (2007) 414–423 <u>Researcher/Affiliation</u> Dr. Napoli University of Naples (PX0056)	POM Wonderful 100% pomegranate juice and POMx Liquid	*In vitro*	Results showed that proartherogenic effects induced by perturbed sheer stress is reduced by POMx and POM Juice.
	Complaint Counsel does not disagree, but notes that human metabolism and disease processes are very complicated and cannot be replicated in a petri dish, and therefore *in vitro* studies produce results that cannot be replicated in humans. (CCFF ¶ 763). Respondents did not provide any expert testimony to explain or support this study.			
2007	Shiner, *et al*., Macrophage paraoxonase 2 expression is up-regulated by pomegranate juice phenolic antioxidants via PPARy and AP-1 pathway activation, 195	POM Wonderful 100% pomegranate juice	*In vitro*	Pomegranate juice up-regulates arterial macrophage PON2 expression and protects against cellular lipid peroxidation.

RESPONDENTS' PUBLISHED CARDIOVASCULAR HEALTH STUDIES				
Respondents' Basic Science and Animal Studies				
Year	**Publication/Researcher**	**Product Tested**	**Method**	**Findings**
	Atherosclerosis 313-321. Researcher/Affiliation Dr. Aviram The Lipid Research Laboratory, Technion Faculty of Medicine, Rambam Medical Center (PX0007)			
	The proposed finding mischaracterizes the findings of the study. The authors of the study conclude that "although the physiological role of PON2 is not known yet," the "results demonstrate that the ability of PJ and its polyphenols to reduce cellular oxidative stress was attenuated upon inhibition of PAPRy or of JNK, *suggesting* that anti-oxidative effect of PJ is maintained by up-regulation of PON2 expression . . . [which] *may* protect against lipid peroxidation[.]" (PX0007-0008) (emphasis added). Human metabolism and disease processes are very complicated and cannot be replicated in a petri dish, and therefore *in vitro* studies produce results that cannot be replicated in humans. (CCFF ¶ 763). Respondents did not provide any expert testimony to explain or support this study.			
2008	Aviram, *et al*., Pomegranate Phenolics from the Peels, Arils, and Flowers Are Antiatherogenic: Studies in Vivo and in Atherosclerotic Apolipoprotein Edeficient (E) Mice and in Vitro in Cultured Macrophages and Lipoproteins, *J. Agric. Food Chem*. (2008), 56, 1148-1157 Researcher/Affiliation	POM Wonderful 100% pomegranate juice, POMx Liquid, POMx Pills, POM oil, POM seeds, POM flowers, POM arils	*In vitro* and *in vivo*	All POM extracts possess antioxidant activity in vitro. After consumption of PJ, POMxl, POMxp, POMf, or POM arils by Apo E mice, the atherosclerotic lesion area was significantly decreased by 44, 38, 39, 6 or 70%, respectively as compared to placebo, while POMo had no effect and POMf reduced serum lipids and glucose levels by 18-25%.

RESPONDENTS' PUBLISHED CARDIOVASCULAR HEALTH STUDIES				
Respondents' Basic Science and Animal Studies				
Year	**Publication/Researcher**	**Product Tested**	**Method**	**Findings**
	Dr. Aviram The Lipid Research Laboratory, Technion Faculty of Medicine, Rambam Medical Center (PX0008)			
	Complaint Counsel does not disagree, but notes that human metabolism and disease processes are very complicated and cannot be replicated in a petri dish, and therefore *in vitro* studies produce results that cannot be replicated in humans. (CCFF ¶ 763). Animal studies must be confirmed by RCTs since agents that work in mice often do not work the same way in humans. (CCFF ¶ 764). Respondents did not provide any expert testimony to explain or support this study.			
2009	Mattiello, *et al*., Effects of Pomegranate Juice and Extract Polyphenols on Platelet Function, *J. Medicinal Foods* 12 (2) (2009) <u>Researcher/Affiliation</u> Dr. Mattielo Sapienza University of Rome (PX0017)	POM Wonderful 100% pomegranate juice and POMx Pills	*In vitro*	POM Juice and POMx reduce all platelet responses studied. Results demonstrated that cardiovascular health benefits of pomegranate may in part be related to the ability of polyphenols to inhibit platelet function.
	See Response to Finding above. This study was published after Respondents made claims that POM Products can treat, prevent, or reduce the risk of heart disease. (*See* CCFF Sections V.D and E; *see also* CCFF ¶ 953).			
2010	Fuhrman, *et al*., Pomegranate juice polyphenols increase recombinant paraoxonase-1 binding to high-density	POM Wonderful 100% pomegranate juice	*In vitro*	Oxidative stress impairs binding of PON1 to HDL. POM Juice polyphenols increase the binding beyond their anti-oxidative

RESPONDENTS' PUBLISHED CARDIOVASCULAR HEALTH STUDIES				
Respondents' Basic Science and Animal Studies				
Year	**Publication/Researcher**	**Product Tested**	**Method**	**Findings**
	lipoprotein: studies in vitro and in diabetic patients, *Nutrition*. 2010 Apr; 26(4):359-66 Researcher/Affiliation Drs. Avirom and Fuhrman The Lipid Research Laboratory, Technion Faculty of Medicine, Rambam Medical Center (PX0009, unpub. manuscript)			effect. These effects could be related to a POM Juice-mediated reduction in oxidative stress and to a direct effect of POM Juice polyphenols on the HDL-PON1 association.
	Complaint Counsel objects to PX0009 cited in the proposed finding because the document was not produced in compliance with discovery; the document's probative value is outweighed by unfair prejudice; and the documents have not been authenticated.			
2010	Khateeb, *et al*., Paraoxonase 1 (PON1) expression in hepatocytes is upregulated by pomegranate polyphenols: a role for PPAR-gamma pathway, *Atherosclerosis*. 2010 Jan; 208(1):119-25 Researcher/Affiliation Dr. Aviram The Lipid Research Laboratory Technion Faculty of Medicine Rambam Medical Center (PX0002, unpub. manuscript)	POM Wonderful 100% pomegranate juice	*In vitro*	The anti-atherogenic characteristics of POM Juice polyphenols are modulated, at least in part, via PON1 upregulation and its subsequent release to the medium.
	Complaint Counsel objects to PX0002 cited in the proposed finding because the document			

RESPONDENTS' PUBLISHED CARDIOVASCULAR HEALTH STUDIES				
Respondents' Basic Science and Animal Studies				
Year	**Publication/Researcher**	**Product Tested**	**Method**	**Findings**
	was not produced in compliance with discovery; the document's probative value is outweighed by unfair prejudice; and the documents have not been authenticated.			
2011	Rosenblat, *et al*., Pomegranate Juice Protects Macrophages from Triglyceride Accumulation: Inhibitory Effect on DGAT1 Activity and on Triglyceride Biosynthesis, Ann. Nutr. Metab. (2011), 58:1-9 <u>Researcher/Affiliation</u> Dr. Aviram The Lipid Research Laboratory Technion Faculty of Medicine Rambam Medical Center (PX0010)	POM Wonderful 100% pomegranate juice	*In vitro*	When macrophages were treated with pomegranate juice or punicalagin, the content and formation of triglycerides were reduced by at least 30%. The accumulation of lipids, to include triglycerides, within macrophages has been linked to the formation of atherosclerotic plaques. The authors concluded that the ability of POM Juice polyphenols to protect against macrophage triglyceride accumulation is an important contributor to the anti-artherogenic properties of pomegranate.
	Complaint Counsel does not disagree, but notes that human metabolism and disease processes are very complicated and cannot be replicated in a petri dish, and therefore *in vitro* studies produce results that cannot be replicated in humans. (CCFF ¶ 763). Respondents did not provide any expert testimony to explain or support this study. This study was published after Respondents made claims that POM Products can treat, prevent, or reduce the risk of heart disease. (*See* CCFF Sections V.D and E; *see also* CCFF ¶ 953).			

With regard to Respondents' summary of Human Clinical Trials, Complaint Counsel's responses are set forth below after each study. (*See* CCFF ¶¶ 950-65).

Respondents' Human Clinical Trials

Year	Publication/Researcher	Product Tested	Method	Findings
2000	Researcher/Affiliation Aviram, *et al*., Pomegranate juice consumption reduces oxidative stress, atherogenic modifications to LDL, and platelet aggregation: studies in humans and in atherosclerotic apolipoprotein E-deficient mice, 71(5) *Am. J. Clinical Nutrition* 1062-76 (2000) Researcher/Affiliation Dr. Aviram The Lipid Research Laboratory, Technion Faculty of Medicine, Rambam Medical Center (PX0004)	POM Wonderful 100% pomegranate juice	Humans (and Apo E-deficient mice)	This study demonstrates that antioxidant activity in the blood of 13 healthy male volunteers who drank POM Wonderful pomegranate juice for 2 weeks increased by 9%, and the amount of LDL cholesterol oxidation decreased by 20%. The study also measured similar effects on mice with abnormal fatty deposits in their arteries. It was found that plaque build-up was 44% less than these mice than in the mice who did not receive pomegranate juice.
	The proposed finding is incomplete. With regard to the results on animal research, animal studies must be confirmed by RCTs since agents that work in mice often do not work the same way in humans. (CCFF ¶ 764). Animal studies alone are not sufficient to show that a tested product will prevent or treat human disease. (CCFF ¶ 764). With regard to results reported on humans, this is a one-arm, unblinded, and uncontrolled study, which was not confirmed by the subsequent results of the Davidson CIMT Study. (CCFF ¶¶ 882-83). This study does not provide competent and reliable scientific evidence to support claims that POM Products are effective in treating, preventing, or reducing the risk of cardiovascular disease in humans. (CX1291 (Sacks, Report at 0015-16)).			
2001	Aviram, *et al*., Pomegranate juice	POM Wonderful	Humans	Ten patients, ranging in age from 62 to 77, with an average blood pressure

Respondents' Human Clinical Trials				
Year	**Publication/Researcher**	**Product Tested**	**Method**	**Findings**
	consumption inhibits serum angiotensin converting enzyme activity and reduces systolic blood pressure, 158 *Atherosclerosis* 195-98 (2001). Researcher/Affiliation Dr. Aviram The Lipid Research Laboratory, Technion Faculty of Medicine, Rambam Medical Center (PX0005)	100% pomegranate juice		of over 155/83 drank 8 oz 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 to lower blood pressure was also reduced by 36%.
	Complaint Counsel does not disagree, but notes that this study was unblinded, not placebo-controlled, and only consisted of 10 elderly, hypertensive patients. (*See* CCFF ¶¶ 796-801). Thus study does not provide competent and reliable evidence to support a heart benefit claim. (CCFF ¶¶ 803-04). When Respondents attempted to replicate these results in subsequent double-blinded RCTs, there was no significant change in ACE, as shown in the Davidson BART/FMD Study, or in blood pressure, as shown in both the Davidson CIMT and Davidson BART/FMD studies. (CCFF ¶¶ 883, 917, 960-61).			
2004	Aviram, *et al*., Pomegranate juice consumption for 3 years by patients with carotid artery stenosis reduces common carotid intima-media thickness, blood pressure and LDL oxidation, 23 *Clinical Nutrition* 423-33 (2004).	POM Wonderful 100% pomegranate juice	Humans	Ten patients consumed 8 oz a day of POM Wonderful pomegranate juice for 1 year. Nine patients did not consume pomegranate juice (controls). The intima-media thickness (IMT) of the carotid artery wall was measured at 3 month intervals. 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%.

Respondents' Human Clinical Trials				
Year	**Publication/Researcher**	**Product Tested**	**Method**	**Findings**
	Researcher/Affiliation Dr. Aviram The Lipid Research Laboratory, Technion Faculty of Medicine, Rambam Medical Center (CX0611)			Furthermore, those consuming juice had a significant reduction in systolic blood pressure and a reduction of LDL oxidation by 90%. Benefits were maintained in 5 patients that continued to drink juice for 2 additional years.
	The proposed finding is incomplete and mischaracterizes the evidence. There were a total of nineteen patients in the Aviram CIMT/BP Study (2004) who had severe carotid artery stenosis. (CCFF ¶ 805). Ten patients in the first group consumed 50 ml of concentrated pomegranate juice daily for one year and five of them continued for up to three years. (CCFF ¶805). The second group, who did not consume pomegranate juice, consisted of nine patients and received dissimilar treatments from the juice group. (CCFF ¶¶ 806, 808). This study was unblinded (CCFF ¶ 807) and not placebo-controlled (CCFF ¶¶ 806-07). The article reports that no additional improvements in CIMT were seen in the five patients who continued drinking the juice for two additional years. (CCFF ¶ 809). The article concludes that further clinical trials are needed to prove the beneficial effect of dietary antioxidants in patients in general and in patients with cardiovascular disease. (CCFF ¶ 821). (*See also* CCFF ¶¶ 814-21). When Respondents attempted to replicate the results in an RCT, the results showed no change in CIMT progression. (CX1065; CCFF ¶¶ 951, 883).			
2004	Esmaillzadeh, *et al*., Concentrated pomegranate juice improves lipid profiles in diabetic patients with hyperlipidemia, 7 *J. Med. Food* 3 (2004)	POMx Liquid	Humans	The authors concluded that concentrated pomegranate juice consumption may modify heart disease risk factors in hyperlipidemic patients, and its inclusion therefore in their diets may be beneficial.

Respondents' Human Clinical Trials				
Year	**Publication/Researcher**	**Product Tested**	**Method**	**Findings**
	Researcher/Affiliation Dr. Esmaillzadeh Shaheed Beheshti University of Medical Sciences Tehran, Iran (PX0038)			

The proposed finding is mischaracterizes the cited evidence and is incomplete. The product tested in the study was concentrated pomegranate juice, not POMx Liquid. (PX0038-0001). This study was an unblinded, unrandomized, uncontrolled 22-person study. (PX0038-0002; CX1291 (Sacks, Report at 0036)). The article states that "it seems that a high plasma cholesterol level is a requisite for the hypocholesterolemic effect of flavonoid-rich foods." (PX0038-0003). The authors of the study found that there was no significant effect on HDL or triagylgycerol. (PX0038-0001, Table 3). The authors concluded that "[o]ur results should not be interpreted to imply that consumption of large quantities of [pomegranate juice] should be recommended by hypercholesterolemic individuals . . . Thus, cardioprotective nutrients in amounts equivalent to those in 40 g of [pomegranate juice] should be provided from a combination of different foods." (PX0038-0004). This study was not an RCT and therefore, the reported results are unreliable. (CX1291 (Sacks, Report at 0037)). A qualified scientist cannot conclude whether any of the changes in measured parameters resulted from pomegranate juice consumption, or from some other factor, such as the placebo effect. (CX1291 (Sacks, Report at 0037)). The study was too small, and of too limited of a duration, to prove that consumption of pomegranate juice is safe for consumption by diabetics. (CX1291 (Sacks, Report at 0037)). Therefore, this study does not provide reliable scientific evidence to support claims that POM Products prevents, reduces the risk of, or treats heart

Respondents' Human Clinical Trials				
Year	**Publication/Researcher**	**Product Tested**	**Method**	**Findings**
	disease. (CX1291 (Sacks, Report at 0037)). Respondents did not provide any expert testimony to explain or support this study.			
2005	Sumner, *et al*., Effects of pomegranate juice consumption on myocardial perfusion in patients with coronary heart disease, 96 *Am. J. Cardiol.* 810-14 (2005). Researcher/Affiliation Dr. Ornish The Preventive Medicine Research Institute in Sausalito, California (PX0023)	POM Wonderful 100% pomegranate juice	Humans	After 3 months, the extent of stress-induced ischemia decreased in the pomegranate juice group but increased in the control group for a significant change.
	The proposed finding is incomplete. The Ornish MP Study (2005) was based on testing to evaluate whether the daily consumption of pomegranate juice for 12 months would affect myocardial perfusion (blood flow) to the heart in patients with CHD and myocardial ischemia. (CCFF ¶¶ 826-27). However, the myocardial perfusion data was published in the study was based on measures at baseline and *three months* (rather than twelve months) for myocardial perfusion measures on SSS, SRS, and SDS. (CCFF ¶ 827). The Ornish MP Study (2005) reported that a significant improvement at $p = .05$ was shown in SDS but not SSS or SRS. (CCFF ¶ 827). In addition, the article reported no significant changes in blood pressure, cholesterol, LDL, HDL, or triglycerides. (CCFF ¶ 829). The authors of the study concluded that "statistically significant improvements in myocardial perfusion observed in the experimental group over a rather short period *suggest* that daily consumption of pomegranate			

Respondents' Human Clinical Trials				
Year	**Publication/Researcher**	**Product Tested**	**Method**	**Findings**
	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." (CCFF ¶ 828). With regard to the "carotid" group, the results CIMT results showed that POM Juice did not provide a benefit. (CCFF ¶ 829). (*See also* CCFF ¶¶ 843-54). The results should be interpreted as having no effect on any measure of cardiac health given the significant problems with the study and furthermore, myocardial perfusion is not a recognized surrogate marker. (CCFF ¶¶ 844-54).			
2006	Rosenblat, *et al*., Anti-oxidant effects of pomegranate juice consumption by diabetic patients on serum and on macrophages, 187 *Atherosclerosis* 363-371. <u>Researcher/Affiliation</u> Dr. Aviram The Lipid Research Laboratory, Technion Faculty of Medicine, Rambam Medical Center (PX0020)	POM Wonderful 100% pomegranate juice	Humans	Pomegranate juice resulted in significant reduction in serum peroxides, TBAR levels by 56% and 28%, and cellular peroxides by 71% and increased glutathione levels by 141% in patients with diabetes. Juice resulted in significant antioxidant benefit for people with diabetes.
	The proposed finding is incomplete. The study consisted of only 20 male patients (10 of which were non-insulin dependent diabetics) who consumed POM Juice for three months. (PX0020-0001). The results of the study show that POM Juice consumption did not affect cholesterol, LDL, or HDL. (PX0020-0003; CX1291 (Sacks, Report at 0037)). The authors concluded that consumption of POM Juice by "diabetic patients did not worsen the diabetic			

Respondents' Human Clinical Trials				
Year	**Publication/Researcher**	**Product Tested**	**Method**	**Findings**
	parameters, but rather resulted in anti-oxidative effects on serum and macrophages, which *could* contribute to attenuation of atherosclerosis development in these patients." (PX0020-0001 (emphasis added)). When Respondents attempted to replicate the results in an RCT, the results showed no change in TBARS in diabetics (CCFF ¶ 949) and no change in antioxidant markers (CCFF ¶ 884). This study was not an RCT and therefore, the reported results are unreliable. (CX1291 (Sacks, Report at 0037)). A qualified scientist cannot conclude whether any of the changes in measured parameters resulted from POM Juice consumption, or from some other factor, such as the placebo effect. (CX1291 (Sacks, Report at 0037)). The study was too small, and of too limited of a duration, to prove that consumption of POM Juice is safe for consumption by diabetics. (CX1291 (Sacks, Report at 0037)). Therefore, this study does not provide reliable scientific evidence to support claims that POM Products prevents, reduces the risk of, or treats heart disease. (CX1291 (Sacks, Report at 0037)). Respondents did not provide any expert testimony to explain or support this study.			
2007	Heber, *et al*., Safety and antioxidant activity of pomegranate ellagitannin-enriched polyphenol dietary supplement in overweight individuals with increased waist size, *J. Agric. Food Chem*. 2007, 55, 10050–10054 <u>Researcher/Affiliation</u> Drs. Heber and Hill UCLA & University of Colorado	POMx Pills	Humans	No adverse events related to POMx were observed. After one month, a significant 13% percent reduction in plasma TBARS compared to baseline was observed.

Respondents' Human Clinical Trials				
Year	**Publication/Researcher**	**Product Tested**	**Method**	**Findings**
	(PX00139)			
	The proposed finding is incomplete and mischaracterizes the evidence. This article describes the single-arm Denver Study and two-arm San Diego Study. (CCFF ¶¶ 935-36). With regard to the "13% [sic] reduction in plasma TBARS," according to the article this was only "preliminary evidence of a reduction in TBARS [ ] seen in the subjects of who were studied at the Denver site." (PX00139-0004; CCFF ¶ 936). The authors conclude that "these pilot studies demonstrate both 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." (CCFF ¶ 936). The article makes no reference to the biomarkers of antioxidant stress or inflammation measured in Dr. Heber's San Diego Study, however, the evidence shows that there were no changes in these markers or other markers. (CCFF ¶¶ 933, 937).			
2008	Rock, *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) <u>Researcher/Affiliation</u> Dr. Aviram The Lipid Research Laboratory, Technion Faculty of Medicine, Rambam Medical Center	POM Wonderful 100% pomegranate juice and POM Liquid	Humans	After 4 weeks, there was a significant 30% improvement in HDL paraoxonase 1 (PON1) and an overall lowering of oxidative stress associated with reduced atherosclerosis risk. POM Juice and POMx had similar efficacy. The beneficial effects of pomegranate juice consumption on serum PON1 stability and activity could lead to retardation of atherosclerosis development in diabetic patients.

Respondents' Human Clinical Trials				
Year	**Publication/Researcher**	**Product Tested**	**Method**	**Findings**
	(PX0127)			
	The proposed finding is incomplete. This study looked at the relationship of PON1 and HDL cholesterol activity in 30 diabetic patients consuming POM Juice and POMx Liquid for four to six weeks. (PX0127-0001; CCFF ¶ 944). The authors concluded that POM Juice consumption by diabetic males and females and POM Liquid extract by diabetic males did not worsen their diabetic parameters but resulted in an increased PON1 association with HDL. (PX0127-0009). The cited evidence does not support the proposed finding that there was "an overall lowering of oxidative stress associated with reduced atherosclerosis risk." This study was unblinded, unrandomized, and uncontrolled. (CCFF ¶ 945). Therefore, a qualified scientist cannot conclude whether any changes in measured parameters resulted from pomegranate juice or pomegranate extract consumption, or from some other factor. (CCFF ¶ 945).			
2009	Davidson, *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) <u>Researcher/Affiliation</u> Dr. Davidson Radiant Research University of Chicago (PX0014)	POM Wonderful 100% pomegranate juice	Humans	A randomized, placebo-controlled, double-blind clinical trial followed 289 subjects at moderate risk for coronary heart disease. These subjects consumed 8 ounces per day of either Wonderful variety 100% pomegranate juice or a placebo beverage. After 18 months, there was no reduction in the progression of intima-media thickness of the carotid artery (CIMT) in the 100% pomegranate juice group as a whole. However, further analysis revealed that the rate of CIMT progression slowed in nearly one third of 100% pomegranate juice subjects, those with elevated cardiovascular disease risk factors.

Respondents' Human Clinical Trials				
Year	**Publication/Researcher**	**Product Tested**	**Method**	**Findings**
	Complaint Counsel does not disagree that the Davidson CIMT Study showed no significant influence of 18 months of pomegranate juice consumption on CIMT progress in the overall study sample. (CCFF ¶ 882). The proposed finding is incomplete with regard to omitting that the study also reported no statistically significant changes in blood pressure (a validated surrogate marker for heart disease) inflammation or oxidative stress including high sensitivity C-reactive protein, PON1, and two measures of TBARS. (CCFF ¶¶ 883-84). The proposed finding that "the rate of CIMT progression slowed in nearly one third of 100% pomegranate juice subjects" is unsupported and mischaracterizes the evidence. Rather, the authors state that "the results of the 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[.]" (PX0014-0006; CCFF ¶ 887). The authors further state that "Because the decrease in CIMT progression in these subgroups was based on analyses that were not preplanned and had no correction for multiple comparisons . . . these findings will need to be confirmed in future investigations." (PX0014-0006; CCFF ¶ 887). Despite the Davidson CIMT Study results, Respondents continued to advertise the results of the Aviram CIMT Study results (*i.e.,* "30% reduction in arterial plaque"). (CCFF ¶ 935).			
2010	Rosenblat, *et al*., Consumption of polyphenolic-rich beverages (mostly pomegranate and black currant juices) by healthy subjects for a short term increased serum antioxidant status,	POM Wonderful 100% pomegranate juice		100% pomegranate juice and 100% black currant juice demonstrated the highest total polyphenol content and antioxidant potency in a comparative study of 35 U.S. beverages including red wine, green tea, and several deeply colored fruit juices. In addition, the blood serum of healthy subjects who drank 100% Wonderful-

Respondents' Human Clinical Trials				
Year	**Publication/Researcher**	**Product Tested**	**Method**	**Findings**
	and the serum's ability to attenuate macrophage cholesterol accumulation, Food Funct. 2010, 1, 99-109. Researcher/Affiliation Dr. Aviram The Lipid Research Laboratory Technion Faculty of Medicine Rambam Medical Center (PX0021)			variety pomegranate juice and 100% black currant juice for one week exhibited several measures of increased antioxidant activity.
	The proposed finding is incomplete. This study analyzed the antioxidative effects of various beverages (*in vitro*), and also the effect of short term consumption of beverages richest in polyphenols by six healthy subjects, who consumed the beverages for up to 1 week. (PX0021-0001, 03). High levels of antioxidants in *in vitro* studies may not translate to increased antioxidant levels in the human body. (CCFF ¶¶ 1103-04). The human part of the study was unblinded and uncontrolled. (PX0021-0003). Respondents' efforts to show changes in antioxidant markers in RCTs failed in the Ornish MP Study, Davidson CIMT Study, Davidson BART/FMD Study, and the San Diego Study. (CCFF ¶¶ 825, 882, 915, 933). Respondents did not provide any expert testimony to explain or support this study. This study was published after Respondents made claims that POM Products can treat, prevent, or reduce the risk of heart disease. (*See* CCFF Sections V.D and E; *see also* CCFF ¶ 953).			

In addition, the proposed finding is incomplete with regard to Respondents' human clinical trials. Respondents' chart omits human studies with results that do not show benefits on heart related biomarkers from consuming POM Products, including the Ornish CIMT Study, the "carotid" arm of the Ornish MP Study, the Davidson BART/FMD Study, and full results of the Denver Study, and San Diego Study. (*See* CCFF ¶¶ 825, 855-78, 912-43).

3. Selected Cardiovascular Studies Sponsored by Respondents

(a) **Aviram, et al.,** ***Pomegranate juice consumption reduces oxidative stress, atherogenic modifications to LDL, and platelet aggregation: studies in humans and in atherosclerotic apolipoprotein E-deficient mice,*** **Am. J. Clin. Nutr. 2000: 71;1062-76. (PX0004).**

1101. In 2000, in a 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" by Aviram M, Dornfeld L, Rosenblat M, Volkova N, Kaplan M, Coleman R, Hayek T, Presser D, and Fuhrman B (Am. J. Clin. Nutr. 2000: 71;1062-76), Dr. Aviram and his colleagues examined the effect of pomegranate juice consumption on the atherogensis process (the development of fatty plaques in the walls of arteries) in humans, animal models, and cells. (PX0004).

Response to Finding No. 1101:
Complaint Counsel has no specific response.

1102. In this study, 13 human subjects consumed pomegranate juice daily for two weeks with three subjects receiving increased doses for 10 weeks. A polipoprotein E-deficient mice also received pomegranate juice supplementation for a period of 11 weeks. (PX0004).

Response to Finding No. 1102:
Complaint Counsel has no specific response, except that study consisted of two human studies; one involving 13 subjects and the other involving 3 subjects undergoing different treatments. (PX0004-0002).

1103. In humans, Dr. Aviram found that pomegranate juice consumption decreased, by 20%, LDL susceptibility to aggregation and retention and increased, by 18%, the activity of PON1. (PX0004).

Response to Finding No. 1103:
Complaint Counsel does not disagree, except to note that the study reported that "[a]dministration of PJ [pomegranate juice] to 13 healthy men for 2 wk had no significant effect on the plasma lipid profile, including total cholesterol, LDL-cholesterol, VLDL-cholesterol, HDL-cholesterol, and triacylglycerol concentrations . . . . There was also no significant effect of increasing PJ doses on blood chemistry and plasma lipid and lipoprotein patterns in 3 studied subjects, except that plasma-glucose, cholesterol, and triacylglycerol concentrations were 10-15% higher after 1 wk of supplementation with the highest PJ dose . . . . Similarly, no significant effect of PJ consumption on plasma lipid concentrations was shown in E^0 mice [ ]." (PX0004-0005; CX1358 (Aviram, Dep. at 19-20)). In addition, the proposed finding is incomplete. The 20% decrease in LDL susceptibility was only found in 3 subjects. (PX0004-0005).

1104. In mice, pomegranate consumption reduced the oxidation of LDL by up to 90%, the uptake of oxidized and native LDL by macrophage foam cells (white blood cells that respond to inflammation by digesting cellular debris) by 20%, and the size of atherosclerotic lesions and foam cells by 44%. (PX0004).

Response to Finding No. 1104:
Complaint Counsel has no specific response.

1105. The authors concluded that the study "showed the antiatherogenic capabilities of PJ [pomegranate juice] in 3 related components of atherosclerosis, plasma lipoproteins, arterial macrophages, and blood platelets. The potent antioxidative capacity of PJ against lipid peroxidation may be the central link for the antiatherogenic effects of PJ on lipoproteins, macrophages, and platelets" (PX0004-0014).

Response to Finding No. 1105:
Complaint Counsel has no specific response. (*See also* CCFF ¶¶ 764, 1102-08, 950-65).

1106. Dr. Aviram's study constitutes competent and reliable evidence that the consumption of pomegranate juice is beneficial to cardiovascular health by, among other things, decreasing the LDL oxidation process and increasing PON1 in humans. (PX0004).

Response to Finding No. 1106:

Complaint Counsel disagrees. This study is not competent and reliable evidence to support a heart benefit claim. (*See* CCFF ¶¶ 764, 1102-08, 950-65).

(b) **Aviram*, et al., Pomegranate juice consumption inhibits serum angiotensin converting enzyme activity and reduces systolic blood pressure,* Atherosclerosis 158 (2001) 195-198 (CX0005).**

1107. In 2001, in a study entitled "Pomegranate juice consumption inhibits serum angiotensin converting enzyme activity and reduces systolic blood pressure" by Aviram M and Dornfled L, (Atherosclerosis 158 (2001) 195-198), Dr. Aviram and his co-workers also demonstrated the effects of pomegranate juice on blood pressure via an action on ACE. (CX0005).

Response to Finding No. 1107:
Complaint Counsel does not disagree with the purpose of the study, but notes that this study was unblinded, not placebo-controlled, and only consisted of 10 elderly, hypertensive patients. (*See* CCFF ¶¶ 796-804).

1108. In humans, after two weeks of pomegranate juice consumption, the study observed a 36% reduction in serum ACE activity and a 5% decrease in systolic blood pressure. A 31% decrease of was observed also *in vitro*, thus confirming the effect of pomegranate juice. (CX0005; CX1348 (Aviram, Dep. at 22-23)).

Response to Finding No. 1108:
See Response to Finding 1107.

1109. 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." (CX0005_0003).

Response to Finding No. 1109:
Complaint Counsel does not disagree that this is what the study states, but notes that Dr. Aviram stated that this was his "thinking" and "opinion." (CCFF ¶ 800).

1110. Dr. Aviram's study constitutes competent and reliable evidence that the consumption of POM Juice is beneficial to cardiovascular health by, among other things, lowering blood pressure. (CX0005).

Response to Finding No. 1110:

Complaint Counsel disagrees. This study does not constitute competent and reliable evidence that the consumption of POM Juice is beneficial to cardiovascular health by, among other things, lowering blood pressure. (*See* CCFF ¶¶ 802-04, 950-65).

(c) **Aviram, et al., *Pomegranate juice consumption for 3 years by patients with carotid artery stenosis reduces common carotid intima-media thickness, blood pressure and LDL oxidation,* Clin Nutr. 2004;23:423-33. (CX0611).**

1111. In 2004, in a study entitled "Pomegranate juice consumption for 3 years by patients with carotid artery stenosis reduces common carotid intima-media thickness, blood pressure and LDL oxidation" by Aviram M, Rosenblat M, Gaitini D, Nitecki S, Hoffman A, Dornfeld L, Volkova N, Presser D, Attias J, Liker H, Hayek T., Clin Nutr. 2004; 23:423-33, Dr. Aviram and his co-workers investigated, among other things, the effects of pomegranate juice consumption by patients with carotid artery stenosis. (CX0611).

Response to Finding No. 1111:
Complaint Counsel has no specific response.

1112. The carotid arteries are located on each side of the neck which provide the main blood supply to the brain. (JX3).

Response to Finding No. 1112:
Complaint Counsel agrees.

1113. Carotid artery stenosis ("CAS") is a narrowing of constriction of the inner surface (lumen) of the carotid artery, usually caused by atherosclerosis. (JX3).

Response to Finding No. 1113:
Complaint Counsel agrees.

1114. Stenosis occurs when a person has more than a 50 percent blockage in one of his or her carotid arteries. (Heber, Tr. 1963).

Response to Finding No. 1114:
Complaint Counsel agrees that Dr. Heber testified as such, however, Dr. Heber does not hold himself out as an expert in cardiovascular disease (CCFF ¶ 728), and was not asked to opine on whether the heart benefit claims challenged in the complaint were true or substantiated. (CCFF ¶¶ 730-31).

1115. To remove a blockage in the carotid artery, a person undergoes an operation called an endarterectomy, where the buildup is removed and a graft is placed in the artery. (Heber, Tr. 1963).

Response to Finding No. 1115:
Complaint Counsel agrees that Dr. Heber testified as such, however, Dr. Heber does not hold himself out as an expert in cardiovascular disease (CCFF ¶ 728), and was not asked to opine on whether the heart benefit claims challenged in the complaint were true or substantiated. (CCFF ¶¶ 730-31).

1116. Although originally believed these carotid lesions in the carotid arteries were a risk factor for stroke, carotid stenosis is actually a risk for heart disease. (Heber, Tr. 1963).

Response to Finding No. 1116:
Complaint Counsel agrees that Dr. Heber testified as such, however, Dr. Heber does not hold himself out as an expert in cardiovascular disease (CCFF ¶ 728), and was not asked to opine on whether the heart benefit claims challenged in the complaint were true or substantiated. (CCFF ¶¶ 730-31).

1117. In this study, 10 patients received pomegranate juice for one year and five of them continued for up to 3 years. (CX0611).

Response to Finding No. 1117:
Complaint Counsel agrees.

1118. In the control group that did not consume pomegranate juice, the patients' carotid intima-media thickness ("CIMT" or thickness of the carotid artery) increased by 9% during one year, whereas, pomegranate juice consumption resulted in a significant CIMT reduction, by up to 30%, after one year. (CX0611).

Response to Finding No. 1118:
Complaint Counsel does not disagree that the study states such, but notes that this study was small, not randomized, unblinded, and not placebo-controlled. The patients in the active and so-called "control" group received a different treatment. (*See* CCFF ¶¶ 808-09, 814-15).

1119. There was a 39 percent comparative improvement comparing the pomegranate juice group to the placebo group. (Heber, Tr. 1964).

Response to Finding No. 1119:
Complaint Counsel agrees that Dr. Heber testified as such, however, any implication that there was a between-group analysis provided in the study is incorrect. The CIMT and blood pressure changes were all within-group analysis. (CCFF ¶¶ 811, 818).

1120. Systolic blood pressure was reduced after one year of pomegranate juice consumption by 12%.

Response to Finding No. 1120:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. (*See* CCFF ¶ 810 (blood pressure results as reported in study).

1121. In the study, Dr. Aviram was able to remove and examine portions of certain patients' carotid arteries and by doing so, found less oxidized LDL cholesterol in their plaque and importantly confirmed the effects of pomegranate juice on humans that he had previously shown in cellular studies. (Heber, Tr. 1963-64).

Response to Finding No. 1121:
The proposed finding is incomplete. Dr. Heber testified that Dr. Aviram "found that there were less oxidized LDL cholesterol in that plaque that he analyzed, demonstrating *some* of the antioxidant effects of pomegranate juice that he had shown in cellular studies. . . ." (Heber, Tr. 1963-64) (emphasis added)). In addition, the study concludes that further clinical trials are needed to confirm the benefits of antioxidants in patients with cardiovascular diseases. (*See* CCFF ¶ 812).

1122. Although this was a relatively small study, sometimes small studies can be more informative than large studies. (Heber, Tr. 1963).

Response to Finding No. 1122:
Complaint Counsel agrees that Dr. Heber testified as such but notes that Dr. Heber also stated in his report that this study was a start leading to a "much larger, controlled trial and also triggered basic mechanistic investigations to provide scientific substantiation." (CCFF ¶ 816).

1123. Dr. Aviram sent his material to an independent institution in the United States, to verify his results. (Heber, Tr. 1964).

Response to Finding No. 1123:
Complaint Counsel has no specific response.

1124. The results of this study concluded that pomegranate juice consumption by patients with CAS decreased CIMT which were related to the potent antioxidant characteristics of pomegranate juice polyphenols. (CX0611).

Response to Finding No. 1124:
The proposed finding is incomplete. The study reports that the "results of the present study thus *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. (CX0611_0002) (emphasis added)). In addition, the study concludes that further clinical trials are needed to confirm the benefits of antioxidants in patients with cardiovascular diseases. (*See* CCFF ¶ 812).

1125. Specifically, the authors wrote: "Complaint Counsel 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).

Response to Finding No. 1125:
Complaint Counsel has no specific response, except to note that the authors of the study made the conclusion in the proposed finding, not "Complaint Counsel."

1126. 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).

Response to Finding No. 1126:
Complaint Counsel disagrees. This study does not constitute 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. (*See* CCFF ¶¶ 814-21, 950-65). Dr. Heber did not testify as such. Dr. Heber does not hold himself out

as an expert in cardiovascular disease (CCFF ¶ 728), and was not asked to opine on whether the heart benefit claims challenged in the complaint were true or substantiated. (CCFF ¶¶ 730-31).

(d) **Sumner, et al., *Effects of pomegranate juice consumption on myocardial perfusion in patients with coronary heart disease,* 96 Am. J. Cardiology 810 (2005) (PX0023).**

1127. In 2005, Dr. Dean Ornish and colleagues investigated whether the daily consumption of pomegranate juice for three months would affect myocardial perfusion (or blood flow) in 45 patients who had coronary heart disease and myocardial ischemia (narrowing of the arteries) in a randomized, placebo-controlled, double-blind study. (PX0023).

Response to Finding No. 1127:
Complaint Counsel has no specific response, except to note that this study was designed to be a 12 month study (not a 3 month study), which was not disclosed in the published report. (*See* CCFF ¶¶ 834, 853).

1128. Dr. Ornish's randomized, double blinded, placebo controlled study measured the effect of pomegranate juice consumption on a patient's blood flow (or myocardial perfusion) at rest and under stress. (PX0023; Ornish, Tr. 2336; Heber, Tr. 1970-71).

Response to Finding No. 1128:
Complaint Counsel agrees that data on measures at baseline and three months were taken for myocardial perfusion include the summed rest score, summed stress, score and summed difference scores. (*See* CCFF ¶ 827).

1129. In this study, patients were randomly assigned into one or two groups: a pomegranate juice group (240 ml/day) or a placebo group that drank a beverage of similar caloric content, amount, flavor, and color. (PX0023).

Response to Finding No. 1129:
Complaint Counsel agrees.

1130. 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. (PX0023; Ornish, Tr. 2337; Heber, Tr. 1970-71).

Response to Finding No. 1130:

Complaint Counsel disagrees. The study reports that after three months, there was a 17% improvement in the SDS score in the POM Juice group (but no significant improvement in SSS or SRS scores), as compared to an average worsening of 18% in the control group. (PX0023-0003-04; CCFF ¶¶ 827, 845-51).

1131. The comparative benefit of the pomegranate juice group to the placebo group was about 35 percent. (PX0023; Ornish, Tr. 2337-38; Heber, Tr. 1972).

Response to Finding No. 1131:
Complaint Counsel has no specific response.

1132. Those differences were statistically significant and the results were published in the American Journal of Cardiology. (PX0023; Ornish, Tr. 2337-39); Heber, Tr. 1971-72).

Response to Finding No. 1132:
Complaint Counsel has no specific response, except given the problems with the design and conduct of the study, the interpretation of this study 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. (CCFF ¶¶ 843-54)

1133. 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. (Ornish, Tr. 2338).

Response to Finding No. 1133:
See Response to Finding 1132.

1134. 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 SOS." (PX0023-0004).

Response to Finding No. 1134:
The proposed finding is incomplete. Dr. Ornish also concluded that "[f]urther 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." (CCFF ¶ 828).

1135. 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. (Ornish, Tr. 233).

Response to Finding No. 1135:
The proposed finding is unsupported by the cited evidence.

1136. 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. (Ornish, Tr. 2338).

Response to Finding No. 1136:
Complaint Counsel has no specific response.

1137. Dr. Ornish drinks POM Juice and takes POMx. (PX0355 (Ornish, Dep. at 72)).

Response to Finding No. 1137:
The proposed finding is irrelevant.

1138. Dr. Ornish's myocardial perfusion study constitutes competent and reliable scientific evidence showing that pomegranate juice lessens the risk of cardiovascular problems by improving blood flow in people who already have heart disease and is likely to work even better in helping prevent them in the first place. (Ornish, Tr. 2354-55).

Response to Finding No. 1138:
Complaint Counsel disagrees. This study does not constitute competent and reliable evidence showing that pomegranate juice lessens the risk of cardiovascular problems by improving blood flow in people who already have heart disease and is likely to work even better in helping prevent them in the first place. (CCFF ¶¶ 843-54, 950-65).

(e) **Davidson, et al., *Effects of consumption of pomegranate juice on carotid intima-media thickness in men and women at moderate risk for coronary heart disease,* Am J Cardiol. 2009; 104:936-42. (PX0014).**

1139. In 2009, Dr. Davidson published the findings of his randomized, double-blinded, and placebo-controlled study on the effects of consuming pomegranate juice on CIMT thickness on patients at moderate risk for coronary heart disease. (PX0014).

Response to Finding No. 1139:
Complaint Counsel agrees.

1140. Dr. Davidson's study examined 289 participants who consumed pomegranate juice and placebos for 12 and 18 months. (PX0014).

Response to Finding No. 1140:
Complaint Counsel agrees.

1141. At 12 months, data 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. (PX0014; CX 1336 (Davidson, Dep. at 55)).

Response to Finding No. 1141:
Complaint Counsel disagrees. With regard to the 12 month data, showing that absolute CIMT measurements were smaller in the pomegranate juice group than those of the placebo group, 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 CIMT progression, as the published report did for the primary and secondary endpoints at 18 moths. Therefore the unpublished change rate in CIMT data at 12 months was not significant although it trended positive. (CCFF ¶¶ 885-86, 906).

1142. In a post-hoc exploratory analysis of subjects with the highest risk factors of coronary heart disease, however, Dr. Davidson noted that those in the pomegranate juice group had significantly less anterior wall and/or composite CIMT progression versus control subjects. (PX0014).

Response to Finding No. 1142:
Complaint Counsel does not disagree that the study states as such, except to note that the post-hoc analysis is hypothesis-generating for future research, and had not been corrected for multiple comparisons. Therefore, a qualified scientist could not rely on the post-hoc analysis of the subgroup populations as reliable scientific evidence that POM Juice or POMx prevents, reduces the risk of, or treats heart disease in these subpopulations. (CCFF ¶¶ 887, 891, 908-11).

1143. 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)).

Response to Finding No. 1143:

The proposed finding mischaracterizes the cited evidence. The study states that the "composite measurement of CIMT showed a significantly smaller value at 12 months in the pomegranate juice group compared to the control group . . . However, this difference was no longer significant at the end of the treatment period[.]" (PX0014-0005). Dr. Davidson testified that in the post hoc analysis, "a subgroup of patients that had increased progression of their carotid IMT, there was benefit for the pomegranate juice versus the control."

1144. Dr. Davidson, who has a very low HDL and high triglyceride levels and fits the subgroup population, has been consuming the POMx extract since his study came out. (CX1336 (Davidson, Dep. at 226)).

Response to Finding No. 1144:
The proposed finding is irrelevant. However, the POMx extract Dr. Davidson consumes is provided by POM. (CX1336 (Davidson, Dep. at 236)).

1145. Dr. Davidson recommends pomegranate juice to his patients who appear to fit the profile in the post hoc analysis. (CX1336 (Davidson, Dep. at 226)).

Response to Finding No. 1145:
Complaint Counsel has no specific response.

1146. 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. (PX0014; Heber Tr. 1979-86).

Response to Finding No. 1146:
Complaint Counsel disagrees. The Davidson CIMT Study (2009) provides competent and reliable scientific evidence that consumption of pomegranate juice *did not improve* CIMT in subjects with one or more cardiovascular risk factors at the end of the study. (CCFF ¶¶ 903-06; 951-54).

E. Respondents' Experts Confirm That Respondents' Scientific Research Constitutes Competent and Reliable Scientific Evidence of the Effect of Pomegranate Juice and/or Its Extracts on Arterial Plaque, Blood Pressure, and Blood Flow

1. Qualifications of Respondents' Experts on Cardiovascular Health and Nutrition and Cardiovascular Health

(a) Dr. Dean Ornish

1147. Dr. Dean Ornish is the Founder and President of the non-profit Preventive Medicine Research Institute in Sausalito, California. (PX0025-0001).

Response to Finding No. 1147:
Complaint Counsel agrees.

1148. He is also a medical doctor and also serves as a Clinical Professor of Medicine at the University of California, San Francisco. (PX0025-0001; Ornish, Tr. 2314 2321).

Response to Finding No. 1148:
Complaint Counsel has no specific response.

1149. In 1975, Dr. Ornish received a Bachelor of Arts (B.A.) degree in Humanities summa cum laude from the University of Texas in Austin, where he gave the baccalaureate address. (PX0025-0001; Ornish, Tr. 2314-15).

Response to Finding No. 1149:
Complaint Counsel has no specific response.

1150. In 1980, Dr. Ornish received a Doctor of Medicine (M.D.) degree from the Baylor College of Medicine in Houston, where he studied bypass surgery with Dr. Michael DeBakey, who developed open heart surgery. (PX0025-0001; Ornish, Tr. 2315).

Response to Finding No. 1150:
Complaint Counsel has no specific response.

1151. From 1981-1984, Dr. Ornish was a Clinical Fellow in Medicine at Harvard Medical School and an Intern, Junior Assistant Resident in Medicine, and Senior Resident in Medicine at the Massachusetts General Hospital in Boston. (PX0025-0001; Ornish, Tr. 2315-16).

Response to Finding No. 1151:
Complaint Counsel has no specific response.

1152. For over 34 years, Dr. Ornish has directed clinical research on the relationship between diet and lifestyle and coronary heart disease demonstrating, for the first time, the landmark study that comprehensive lifestyle changes may begin to reverse even severe coronary heart disease, without drugs or surgery. (PX0025-0001; Ornish, Tr. 2316-17).

Response to Finding No. 1152:
Complaint Counsel has no specific response.

1153. Dr. Sacks credits Dr. Ornish for having proven that his overall lifestyle program, including diet, could reverse coronary artery disease and publishing his "landmark" study in the Lancet. (Sacks, Tr. 1480-81).

Response to Finding No. 1153:
Complaint Counsel has no specific response.

1154. Many of his studies have been on the subject of cardiovascular disease which has been the principal area of his research for over 35 years. (Ornish, Tr. 2319).

Response to Finding No. 1154:
Complaint Counsel does not disagree Dr. Ornish testified as such, except to note that Dr. Ornish's research focuses on the proposition that *comprehensive, intensive* dietary and lifestyle changes can improve medical risk factor changes in people with disease, including coronary heart disease. (*See* CCFF ¶ 734).

1155. In August 2010, Medicare agreed to provide coverage for his Program for Reversing Heart Disease, the first time that Medicare has covered a program of comprehensive lifestyle changes for reversing coronary heart disease. (PX0025-0001; Ornish, Tr. 2319).

Response to Finding No. 1155:
Complaint Counsel has no specific response.

1156. U.S. News and World Report rated his diet as number one for heart health, among all such diets. (Ornish, Tr. 2320-21).

Response to Finding No. 1156:
Complaint Counsel has no specific response.

1157. Dr. Ornish directed the first randomized controlled trial demonstrating that comprehensive lifestyle changes may affect the progression of early-stage prostate cancer, which was done in collaboration with the Chair of Urology at UCSF and the then-Chair of Urology and Urologic Oncology at Memorial Sloan-Kettering Cancer Center. (PX0025-0001; Ornish, Tr. 2318).

Response to Finding No. 1157:
Complaint Counsel has no specific response.

1158. Dr. Ornish's current research showed that these comprehensive lifestyle changes affect gene expression, "turning on" disease-preventing genes and "turning off" genes that promote prostate cancer, breast cancer and heart disease, as well as increasing

telomerase, an enzyme that lengthens telomeres, the ends of our chromosomes which control aging (in collaboration with Dr. Elizabeth Blackburn, who was awarded the Nobel Prize in Medicine in 2009). (PX0025-0001).

Response to Finding No. 1158:
Complaint Counsel has no specific response.

1159. The research that Dr. Ornish and his colleagues conducted has been published in the Journal of the American Medical Association, The Lancet, Proceedings of the National Academy of Sciences, Circulation, the American Journal of Cardiology, The Lancet Oncology, The New England Journal of Medicine, and elsewhere. (PX0025-0001; Ornish, Tr. 2318-19).

Response to Finding No. 1159:
Complaint Counsel has no specific response.

1160. Dr. Ornish has written numerous articles for peer-reviewed journals, as well as a chapter on the management of coronary heart disease in Harrison Principles of Internal Medicine and the companion to the Braunwald Cardiology textbooks. (Ornish, Tr. 2319).

Response to Finding No. 1160:
Complaint Counsel has no specific response.

1161. Dr. Ornish has been a reviewer of scientific and medical articles for several of the leading peer-reviewed journals. (PX0025-0003).

Response to Finding No. 1161:
Complaint Counsel has no specific response.

1162. A one-hour documentary of Dr. Ornish's work was broadcast on NOVA, the PBS science series, and was featured on Bill Moyers' PBS series, Healing & The Mind. Dr. Ornish's work has been featured in all major media, including cover stories in Newsweek, Time, and U.S. News & World Report. (PX0025-0003).

Response to Finding No. 1162:
Complaint Counsel has no specific response.

1163. Dr. Ornish has written a monthly column for Newsweek and Reader's Digest magazines and is currently Medical Editor of The Huffington Post. (PX0025-0003).

Response to Finding No. 1163:
Complaint Counsel has no specific response.

1164. Dr. Ornish is a member of the boards of directors of the non-profit San Francisco Food Bank and the nonprofit J. Craig Venter Institute and previously served on the board of directors of the United Nations High Commission on Refugees. (PX0025-0003).

Response to Finding No. 1164:

Complaint Counsel has no specific response.

1165. Dr. Ornish was appointed by President Clinton to the White House Commission on Complementary and Alternative Medicine Policy and elected to the California Academy of Medicine. He has consulted with food companies to make more healthful foods. Dr. Ornish also chaired the Google Health Advisory Council 2007-2009. (PX0025-0003).

Response to Finding No. 1165:
Complaint Counsel has no specific response.

1166. Dr. Ornish has written six published books on the subject of the effect of diet and lifestyle on heart disease and other diseases, including Dr. Dean Ornish's Program for Reversing Heart Disease; Eat More, Weigh Less; Love & Survival; and The Spectrum, and chapters in standard medicine and cardiology books by other people. (PX0025-0003; Ornish, Tr. 2318).

Response to Finding No. 1166:
Complaint Counsel does not disagree.

1167. Dr. Ornish has received several awards, including the 1994 Outstanding Young Alumnus Award from the University of Texas, Austin, the University of California, Berkeley, "National Public Health Hero" award, the Jan J. Kellermann Memorial Award for distinguished contribution in the field of cardiovascular disease prevention from the International Academy of Cardiology, a Presidential Citation from the American Psychological Association, the Beckmann Medal from the German Society for Prevention and Rehabilitation of Cardiovascular Diseases, the "Pioneer in Integrative Medicine" award from California Pacific Medical Center, the Golden Plate Award from the American Academy of Achievement, the Linus Pauling Award from the Institute for Functional Medicine, the Glenn Foundation Award for Research, the Bravewell Collaborative Pioneer of Integrative Medicine award, and the Sheila Kar Health Foundation Humanitarian Award from Cedars-Sinai Medical Center (Los Angeles). (PX0025-0003-0004; Ornish, Tr. 2320).

Response to Finding No. 1167:
Complaint Counsel has no specific response.

1168. Dr. Ornish was selected as one of the "TIME 100" in integrative medicine, honored as "one of the 125 most extraordinary University of Texas alumni in the past 125 years," chosen by LIFE magazine as "one of the fifty most influential members of his generation" and by Forbes magazine as "one of the seven most powerful teachers in the world." (PX0025-0004; Ornish, Tr. 2320).

Response to Finding No. 1168:
Complaint Counsel has no specific response.

1169. Dr. Ornish has received many awards, including: the Kellerman Award for Distinguished Contribution to the Field of Cardiovascular Disease Prevention awarded by International

Academy of Cardiology; recognized by the University of Texas as one of the most extraordinary alumni in the past 125 years; listed by Life Magazine as one of the 50 most influential people of his generation; recognized by Forbes as one of the most powerful teachers in the world. (Ornish, Tr. 2320).

Response to Finding No. 1169:
Complaint Counsel has no specific response.

1170. Dr. Ornish has been a physician consultant to President Clinton since 1993 and to several bipartisan members of the U.S. Congress, and has consulted with the chefs at The White House, Camp David, and Air Force One to cook more healthfully (1993-2000). (PX0025-0004).

Response to Finding No. 1170:
Complaint Counsel has no specific response.

1171. Dr. Ornish has served or is serving as principal investigator in several federally-funded studies relating to nutrition and coronary heart disease, including support from the National Heart, Lung, and Blood Institute of the National Institutes of Health and from the Department of Defense. (PX0025-0004; Ornish, Tr. 2317-18).

Response to Finding No. 1171:
Complaint Counsel has no specific response.

1172. Dr. Ornish is frequently invited to lecture on the role of nutrition and lifestyle in preventing and reversing coronary heart disease and other chronic illnesses, including recent lectures at Medical Grand Rounds at the Mayo Clinic, The Cleveland Clinic, UCSF, and the M.D. Anderson Cancer Center, and keynote presentations at the American College of Preventive Medicine and American College of Lifestyle Medicine annual meetings. (PX0025-0004; Ornish, Tr. 2321).

Response to Finding No. 1172:
Complaint Counsel has no specific response.

1173. Dr. Ornish has lectured on several occasions at the World Economic Forum in Davos and at the TED conferences and has given invited presentations at the annual scientific meetings of the American Heart Association, the American Dietetic Association, and the American College of Cardiology. (PX0025-0004).

Response to Finding No. 1173:
Complaint Counsel has no specific response.

1174. In 2009, Dr. Ornish was invited to give a keynote speech reviewing the science of integrative medicine at the Institute of Medicine's Summit on Integrative Medicine at the National Academy of Sciences. (PX0025-0004).

Response to Finding No. 1174:
Complaint Counsel has no specific response.

1175. Dr. Ornish is on reasonably good terms with the Resnicks even though they cut funding midway through one of his studies because he apparently was not recruiting patients as fast as initially projected. (Ornish, Tr. 2322-23).

Response to Finding No. 1175:
Complaint Counsel has no specific response.

1176. The Resnicks are not presently sponsoring any of Dr. Ornish's current research. (Ornish, Tr. 2323).

Response to Finding No. 1176:
Complaint Counsel has no specific response.

1177. As an expert witness, Dr. Ornish is only being compensated one dollar an hour. (Ornish, Tr. 2323-24).

Response to Finding No. 1177:
Complaint Counsel has no specific response.

1178. Although he has been asked to serve as an expert witness all of the time, Dr. Ornish has never done so. (Ornish, Tr. 2374).

Response to Finding No. 1178:
The proposed finding is not supported by the cited evidence.

1179. Dr. Ornish is serving as expert witness in this case because he believes this is a historic case and that liberties of the American public are at stake. (Ornish, Tr. 2324).

Response to Finding No. 1179:
The proposed finding is irrelevant.

1180. Dr. Ornish testified that keeping valuable information from the American people could make a difference in the quality of their lives and possibly even be life-saving to them. (Ornish, Tr. 2324).

Response to Finding No. 1180:
The proposed finding is irrelevant.

1181. Based upon his professional training, knowledge, and experience, Dr. Ornish is qualified as 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; Ornish, Tr. 2321-22).

Response to Finding No. 1181:
Complaint Counsel does not disagree. (*See* CCFF ¶ 736).

1182. In arriving at his expert opinions, Dr. Ornish relied upon and reviewed, among other things, the Expert Report of Dr. Sacks and supporting materials, Respondents' sponsored

cardiovascular studies, and also relied upon peer-reviewed published literature in the field including human studies as well as basic animal and *in vitro* evidence of health benefits of pomegranate juice. (PX0025-0004-0007).

Response to Finding No. 1182:
The proposed finding is incomplete. Dr. Ornish did not consider his own CIMT study. (*See* CCFF ¶ 738).

(b) Dr. David Heber

1183. Based upon his professional training, knowledge, and experience, Dr. Heber is qualified as an expert on the role of nutrition and cardiovascular health. (*See* RFF 959-990).

Response to Finding No. 1183:
Complaint Counsel has no specific response, except to note that Dr. Heber admits that he is not an expert in cardiovascular disease (CCFF ¶ 728), and he was not asked to opine on whether the heart benefit claims challenged in the complaint were true or substantiated. (CCFF ¶¶ 730-31; s*ee also* Responses to Findings 959-990).

2. Standard for Evaluating Cardiovascular Research

1184. In evaluating whether a food, is beneficial in maintaining cardiovascular health and in lessening the risk of cardiovascular disease, the totality and preponderance of the evidence should be examined, given that: (1) pomegranate juice and its extract are safe; and (2) no one suggests that pomegranate juice or extract should be offered in lieu of conventional medical treatment or surgery studies. (PX0025-0007).

Response to Finding No. 1184:
The proposed finding is a legal conclusion, which is unsupported by the citation to the record. According to experts in the fields of nutrition and cardiovascular disease, claims that a food or supplement treats, prevents, or reduces the risk of heart disease must be supported by data from well-designed, well-conducted, randomized, placebo-controlled, and double-blinded human clinical trials. (CCFF ¶¶ 1102-08). Data from RCTs provide the best evidence of a causal relationship between a nutrient and a disease outcome in humans. (CCFF ¶ 771; *see also* ¶¶ 763-64).

1185. It is a rather extreme position to state that only evidence from RCTs should be considered in evaluating the therapeutic efficacy. (PX0025-0007).

Response to Finding No. 1185:
Complaint Counsel does not disagree that this is Dr. Ornish's opinion.

1186. 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. (PX0025-0007).

Response to Finding No. 1186:
The proposed finding mischaracterizes Dr. Sacks' report. Dr. Sacks did not say that epidemiological and observational evidence was not relevant as a clinical or scientific matter. Rather, Dr. Sacks explains that the type of evidence required to substantiate a claim that a product can treat, prevent or reduce the risk of a disease are RCTs. (CX1291 (Sacks, Report at 0010)).

1187. Much of what physicians provide patients in their clinical practices has not been proven to be beneficial in RCTs. (PX0025-0007).

Response to Finding No. 1187:
The proposed finding is irrelevant.

1188. 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. (PX0025-0007).

Response to Finding No. 1188:
Complaint Counsel has no specific response, except that *in vitro* and animal studies are not sufficient to show that a tested product will prevent or treat a human disease. (CCFF ¶¶ 763-64; 1103-08).

1189. 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. (PX0025-0007).

Response to Finding No. 1189:
Complaint Counsel agrees that this is Dr. Ornish's opinion, except to note that the value of *in vitro* studies is to identify potential biological mechanisms and generate hypotheses

for studies in humans. (CCFF ¶ 763). Similarly, animal studies are tools for identifying potential treatments, mechanisms, and side effects. (CCFF ¶ 764).

1190. RCTs, even when conducted perfectly, do not control for all sources of bias and may inject new ones unique to RCTs. (PX0025-0008).

Response to Finding No. 1190:
Complaint Counsel agrees that this is Dr. Ornish's opinion.

1191. 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).

Response to Finding No. 1191:
Complaint Counsel agrees that this is Dr. Ornish's opinion.

1192. 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. (PX0025-0008).

Response to Finding No. 1192:
Complaint Counsel agrees that this is Dr. Ornish's opinion, however, Complaint Counsel disagrees with this conclusion if the therapeutic efficacy of the fruit juice or extract is to treat, prevent, or reduce the risk of a disease. (CCFF ¶ 1102).

1193. The benefits of pomegranates have been described since Biblical times over thousands of years. (PX0025-0008).

Response to Finding No. 1193:
The proposed finding is irrelevant. The products at issue are not whole pomegranates but rather POM Juice, POMx Pills, and POMx Liquid, which are processed. POM Juice consists of concentrate and 85.4% water and does not contain fiber or vitamin C. (CCFF ¶¶ 125-26). POMx, a dietary supplement, is derived from fruit mash that remains after the first juice pressing. (CCFF ¶ 130).

1194. Dr. Ornish is not aware of any studies showing any harmful effects of consuming pomegranates or pomegranate juice. (PX0025-0008).

Response to Finding No. 1194:
Complaint Counsel has no specific response.

1195. 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. (PX0025-0008).

Response to Finding No. 1195:
Complaint Counsel agrees that this is Dr. Ornish's opinion, but the level of evidence required depends on the claim being made; for drug-like claims that a product can treat, prevent, or reduce the risk of a disease, RCTs are "the best study design that permits a causal inference concerning the relationship between an administered agent (whether a drug or nutrient) and any specific outcome." (CX1293 (Stampfer, Report at 30); Stampfer, Tr. 830-31 ("If the claim implies that a causal link has been established, then you have to have evidence to back it up."); CCFF ¶¶ 1102-08).

1196. A new drug needs to be held to a higher standard than a juice that has been around for thousands of years. (Ornish, Tr. 2340).

Response to Finding No. 1196:
Complaint Counsel has no specific response, except to note that POM Juice has been available for sale since 2002. (CCFF ¶ 139).

1197. 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. (PX0025-0008).

Response to Finding No. 1197:
Complaint Counsel agrees that this is Dr. Ornish's opinion.

1198. 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. (PX0025-0008).

Response to Finding No. 1198:
Complaint Counsel agrees that this is Dr. Ornish's opinion.

1199. 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. (Ornish, Tr. 2324-25).

Response to Finding No. 1199:

Complaint Counsel disagrees. POM Juice has been available for sale since 2002. (CCFF ¶ 139).

1200. Pfizer got four drugs approved in the last 10 years at an average cost of one to four billion dollars each. (Ornish, Tr. 2325).

Response to Finding No. 1200:
Complaint Counsel agrees Dr. Ornish testified as such, but notes that the proposed finding is uncorroborated by any cited evidence concerning Pfizer's drug approvals in the last 10 years.

1201. 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. (Ornish, Tr. 2325).

Response to Finding No. 1201:
Complaint Counsel has no specific response.

1202. 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. (Ornish, Tr. 2326).

Response to Finding No. 1202:
Complaint Counsel agrees Dr. Ornish testified as such, but notes that Respondents are not making "simple health claims" but rather making claims that the POM Products treat, prevent, and reduce the risk of heart disease, prostate cancer, and erectile dysfunction. (*See* CCFF Section V).

1203. 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. (Ornish, Tr. 2326-27).

Response to Finding No. 1203:

Complaint Counsel agrees Dr. Ornish testified as such, but notes that POM Products are not whole foods or whole food products. RCTs are required for the specific disease benefit claims at issue. (*See* CCFF ¶¶ 124-26, 130-32, 134; CCFF Section VII).

1204. 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. (PX0025-0008).

Response to Finding No. 1204:
Complaint Counsel does not disagree that this is Dr. Ornish's opinion. (*See* CCFF ¶¶ 950-65).

1205. 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. (PX0353 (Heber, Dep. at 178)).

Response to Finding No. 1205:
Complaint Counsel agrees that biomarkers are looked at as additional evidence, however, Respondents' many studies that collected data on heart-related biomarkers, including ACE, C-reactive protein, oxidized phospholipids, TBARs, and nitric oxide, were on the whole unsupportive of the proposition that POM Products benefit heart health. (CCFF ¶¶ 960-61).

3. Summary of Conclusions

1206. 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. (PX0025-0005).

Response to Finding No. 1206:
Complaint Counsel disagrees with the conclusion drawn. The record shows that no competent and reliable scientific evidence supports claims that POM Juice, POMx Pills,

or POMx Liquid 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. (CCFF ¶¶ 950-65).

1207. 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. (PX0025-0005; PX0355 (Ornish, Dep. at 42); Ornish, Tr. 2374-75).

Response to Finding No. 1207:
Complaint Counsel disagrees with the conclusion drawn. The evidence as a whole shows that there is no reliable evidence that POM Juice decreases arterial plaque, lowers blood pressure, or increases blood flow to the heart. (CCFF ¶ 950-965).

1208. 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. (PX0025-0005).

Response to Finding No. 1208:
Complaint Counsel does not disagree, except to note that Respondents make claims that POM Products treat, prevent, or reduce the risk of heart disease, prostate cancer, and erectile dysfunction as set forth in the Complaint. (CX1426; CCFF ¶¶ 325-578).

1209. There 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, based on the biological mechanism of prolonging the half-life of nitric oxide in vasculature. (PX0192-00045; PX0353 (Heber, Dep. at 76-80)).

Response to Finding No. 1209:
Complaint Counsel disagrees with the conclusion drawn. There is no reliable evidence that POM Juice decreases arterial plaque, lowers blood pressure, or increases blood flow to the heart. (CCFF ¶ 965). The evidence as a whole shows that Respondents' research does not provide evidence that POM Juice or POMx Liquid extract will treat, prevent, or reduce the risk of heart disease, through any mechanism. (CCFF ¶¶ 964, 950-65). The proposed finding mischaracterizes Dr. Heber's testimony. Dr. Heber testified that "the

body of research on pomegranate juice and extract . . . provides support for *potential* benefits for heart disease . . .” (PX0353 (Heber, Dep. 78-79) (emphasis added)). The proposed finding is unsupported by PX0192-00045.

1210. 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 (1) decreasing arterial plaque; (2) lowering blood pressure, and/or (3) improving blood flow to the heart. (PX0025-0005; Ornish, Tr. 2374-75; PX0355 (Ornish, Dep. at 42); PX0192-0045; PX0353 (Heber, Dep. at 76-80)).

Response to Finding No. 1210:

The proposed finding is unsupported by the cited evidence and incomplete. Drs. Ornish and Heber did not conclude that the POM Products are “likely to prevent” heart disease. Rather, Dr. Ornish’s opinion was that the POM Products are “likely to be beneficial in maintaining cardiovascular health and is . . . likely to help reduce the risk of cardiovascular disease.” (PX0025-0005; Ornish, Tr. 2374-75). Similarly, Dr. Heber’s opinion was that POM Products “have significant health benefits for cardiovascular systems” or “potential health benefits for heart disease.” (PX0192-0044-45; PX0353 (Heber, Dep. at 76-80)). Dr. Heber also stated in his report that he agreed with Dr. Stampfer that “claims that pomegranate juice and extract have not been proven absolutely effective to treat, prevent, or reduce the risk of heart disease . . . based solely on evidence from large double-blind placebo-controlled trials[.]” (PX0192-0044). Moreover, Complaint Counsel disagrees with the conclusion drawn. There is no reliable evidence that POM Juice decreases arterial plaque, lowers blood pressure, or increases blood flow to the heart. (CCFF ¶ 965). The evidence as a whole shows that Respondents’ research does not provide evidence that POM Juice, POMx Pills, or POMx Liquid extract will treat, prevent, or reduce the risk of heart disease. (CCFF ¶¶ 964, 950-65).

1211. 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.

Response to Finding No. 1211:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs.

F. Complaint Counsel's Expert on Cardiovascular Disease/Health, Dr. Frank Sacks, Fails to Rebut Dr. Ornish's and Dr. Heber's Conclusions that Competent and Reliable Scientific Evidence Exists to Support Respondent's Alleged Claims on Arterial Plaque, Blood Pressure, and Blood Flow

1. Dr. Sacks Adopts a Flawed and Unsupported Drug Standard to Evaluate a Natural Food's Effects on Cardiovascular Health

(a) Dr. Sacks Requires RCTs In All Circumstances, Regardless of the Study Cost, Safety, or Potential Benefit of the Product

1212. Dr. Sacks testified that the type of evidence required to substantiate a claim that a product, including a conventional food or dietary supplement, can prevent or reduce the risk of heart disease would be only results of appropriately analyzed results of well-designed, well-conducted, double-blinded, controlled human clinical studies (or RCTs) demonstrating significant changes in valid surrogate markers of cardiovascular health. (Sacks, Tr. 1430-31).

Response to Finding No. 1212:
Complaint Counsel does not disagree, except to note that Dr. Sacks used the word "the," not "only."

1213. Dr. Sacks believes the same level of evidence is needed to show that clinical studies, research, or trials prove that a product prevents or reduces the risk of heart disease. (Sacks, Tr. 1430-31).

Response to Finding No. 1213:
With the noted correction in Response to Finding 1212, Complaint Counsel does not disagree.

1214. Dr. Sacks, who did not previously disclose that he is a consultant to approximately 10 pharmaceutical companies, argues that a product can only be proven safe with large and expensive RCTs, some costing $6, $60 or $600 million, which are still required even if the product is completely safe. (Sacks, Tr. 1530-38).

Response to Finding No. 1214:

The proposed finding mischaracterizes the record insofar as it uses the phrase, "did not previously disclose." Dr. Sacks was fully responsive to all questions posed of him during his deposition (PX0361 (Sacks, Dep. at 15-20), but was never asked about the consultancies referred to in the proposed finding. Complaint Counsel agrees that Dr. Sacks testified that safety must be proven through RCTs. (Sacks, Tr. 1534). Insofar as the proposed finding discusses the cost of RCTs, it is incomplete and thus mischaracterizes the record evidence. Dr. Sacks was asked to agree whether "$600 million" was "in the ballpark of *really large* RCT trials." He said "I think you could go down easily *one or two orders of magnitude to test*. If you just wanted to do just a straight safety test, I think you could drop down one or two orders of magnitude of *that*." Sacks, Tr. 1538 (emphasis added). *See also* Response to Finding 232.

1215. Dr. Sacks concedes that it would be extremely costly to design a RCT study on cardiovascular disease because it would take years or decades to evaluate the effectiveness of an intervention. (PX0361 (Sacks, Dep. at 113)).

Response to Finding No. 1215:
The proposed finding mischaracterizes the evidence. Dr. Sacks agreed that CVD RCTs are very expensive, but in terms of duration he testified, "I don't know, many years. There are studies that can get a favorable result in a year and a half or 2 years." (PX0361 (Sacks Dep. at 113)).

1216. Dr. Sacks, however, admits that he is making a judgment on standard of evidence in this case regardless of the cost of RCTs, whether the product is safe, and irrespective of whether there is a potential (and even substantial) benefit. (Sacks, Tr. 1538-40; 1567).

Response to Finding No. 1216:
The proposed finding mischaracterizes the evidence. Dr. Sacks testified that it is not possible to know whether something is beneficial without the necessary studies, and that you don't know something is safe if you don't do the necessary studies. (Sacks, Tr. 1565-67).

(b) Dr. Sacks Contradicts Himself By Conceding That Health Benefit Claims Can Be Made for Food or Nutrients in the Absence of RCTs and Admits That the Potential Risk Against Possible Benefit Must Be Weighed in Making Such Claims

(1) Dr. Sacks Admits That You Do Not Need a RCT When Evaluating the Health Benefit Claims for a Fruit or Fruit Juice

1217. Dr. Sacks served as the Chair of the Design and Analysis Committee for the DASH ("Dietary Approaches to Stop Hypertension") diet sponsored by the National Heart, Lung and Blood Institute, part of the National Institute of Health. (PX0361a03).

Response to Finding No. 1217:
Complaint Counsel agrees.

1218. The DASH study was a multi-center study to look at the effect of fruits and vegetables in lowering blood pressure and the effect of a total dietary approach in lowering blood pressure, including the reduction of sodium intake. (PX0361 (Sacks, Dep. at 49)).

Response to Finding No. 1218:
Complaint Counsel does not disagree. *See also* Response to Finding 1219.

1219. The DASH diet showed that diets high in fruits and vegetables, among other things, substantially lowered blood pressure in subjects compared to the control group. (Sacks, Tr. 1418).

Response to Finding No. 1219:
The proposed finding is incomplete. Dr. Sacks testified: "DASH is a diet that was designed to lower blood pressure, and it utilized all the evidence available on foods and nutrients to lower blood pressure…this study showed that diets that are *high* in fruits and vegetables, *high* in whole grains, fish, *reduced* in sugar and sugar-sweetened beverages, *reduced* in refined carbohydrates *and* red meat, that diet . . . the diet that is now called the DASH diet, substantially lowered blood pressure compared to the control diet, which was sort of what people eat . . .an average American diet." (Sacks, Tr. 1417-18 (emphasis added)). He further testified, "We tested a diet that had a beneficial effect on *that* diet that had whole food and also some juice, but *we're not going out from the DASH study recommending any particular component. It's a total approach*." (Sacks, Tr. 1544

(emphasis added)). The proposed finding also is irrelevant. Respondents marketed the POM Products as individual products, not as a part of the DASH diet. Finally, Respondents' heart-related RCTs consistently showed no blood pressure benefit. (CCFF ¶ 956).

1220. As part of the DASH diet, fruits were tested and approved as a category. (Sacks, Tr. 1549).

Response to Finding No. 1220:
The proposed finding is irrelevant. *See* Response to Finding 1219. Respondents advertised the POM Products as providing benefits on their own, not as part of a specific diet.

1221. In the DASH diet, Dr. Sacks admits that fruits and fruit juices are treated as the same and participants can pick any one of the fruit juices listed. (Sacks, Tr. 1549-55).

Response to Finding No. 1221:
The proposed finding is unsupported by the cited evidence. Dr. Sacks repeatedly disagreed with Mr. Field's assertions in this regard. (Sacks, Tr. 1549-55). The proposed finding also is irrelevant. The POM products were advertised as having unique benefits, and not advertised as a fruit that could be consumed as part of the DASH diet.

1222. In allowing this flexibility, Dr. Sacks concedes that it is not necessary to conduct RCTs on all individual fruits that a person may decide to consume as part of the DASH diet, because the "category of fruit," including pomegranates, has previously been studied. (Sacks, Tr. 1541-1547).

Response to Finding No. 1222:
The proposed finding is irrelevant. *See* Response to Finding 1219. Complaint Counsel does not disagree that Dr. Sacks stated that although pomegranates were not specifically tested in the DASH diet (Sacks, Tr. 1617), he would include pomegranates as a kind of fruit that can be consumed as a part of the DASH diet. (Sacks, Tr. 1546). However, the finding is irrelevant as the advertising at issue is not for whole pomegranates but for

POM juice and extracts, which were advertised as having unique benefits, not as a part of the DASH diet for reducing blood pressure alone.

1223. Dr. Sacks acknowledges that because the pomegranate is included in a "category of fruit" already tested, it would get a lower and more flexible standard of evidence. (Sacks, Tr. 1546; 1554; PX0361 (Sacks, Dep. at 142-143)).

Response to Finding No. 1223:
Complaint Counsel does not disagree that Dr. Sacks testified that he would not require separate RCTs on *pomegranates* in order to conclude that they are a safe and appropriate part of the DASH diet (Sacks, Tr. 1545-46), despite the fact that they had not specifically been tested in that diet (Sacks, Tr. 1617). *See also* Response to Finding 1219. Nonetheless the finding is irrelevant as the advertising at issue is not for whole pomegranates but POM juice and supplements which were advertised as having unique benefits, and not advertised as a fruit that could be consumed as part of the DASH diet.

1224. Dr. Sacks admits that pomegranates are like blueberries, considered to be in the category of being safe and part of a diet that is rich in fruits and vegetables, and thus has no problem including them in the DASH diet. (Sacks, Tr. 1567-68; PX 361 (Sacks, Dep. at 143)).

Response to Finding No. 1224:
Complaint counsel does not disagree; *see also* Response to Finding 1222.

1225. When looking at the totality of the evidence, which may include RCTs, Dr. Sacks acknowledges that RCTs are not necessary when discussing the benefits of fruit juice or broccoli. (Ornish, Tr. 2331).

Response to Finding No. 1225:
The proposed finding is unsupported by the cited evidence.

1226. Dr. Sacks concedes that it is possible to demonstrate a causal influence between an agent and its effect on humans without the use of RCTs, such as the treatment of infectious diseases. (PX036 (Sacks, Dep. at 135)).

Response to Finding No. 1226:
The proposed finding is incomplete and irrelevant. Dr. Sacks stated that there are exceptions to the need for RCTs, such as in "[t]reatment of infectious disease. . . . You

don't really need statistics to show an effect. I mean if you take someone with a fatal disease and treat them all with an antibiotic that eradicates the fatal organism and all 10 live when you know in the past all 10 would die, these things have happened . . . And then you can pretty well conclude that there is a big favorable effect." (PX0361 (Sacks, Dep at 135)).

(2) Dr. Sacks Has Made Dietary Health Recommendations in the Absence of a RCT or Scientific Agreement

1227. Dr. Sacks has made public health recommendations based on a standard of research that is less than a RCT. (PX0361 (Sacks, Dep. at 130-131)).

Response to Finding No. 1227:

This finding is unsupported by the cited evidence. Dr. Sacks agreed that he has made public health recommendations based on "research that is less than a *double blind* placebo controlled" RCT, specifically, sodium recommendations based on the DASH sodium diet. (PX0361 (Sacks, Dep. at 130-132) (emphasis added)). DASH was a randomized, placebo- controlled study, in which the investigators and measurers were blinded, but where it was difficult to fully blind the consumers because sodium has a distinct taste. (Sacks, Tr. 1587-88). Dr. Sacks stated that the nutrition-based advice he gives does have a randomized clinical trial basis (Sacks, Tr. 1560), and that before making public health messages on cardiovascular disease, he wants to see "definitive results of benefit to a valid surrogate marker or the disease itself, in two or more randomized clinical trials or meta analysis of many trials." (PX0361 (Sacks, Dep. at 130-131)). The proposed finding also is irrelevant. This case has to do with commercial advertising for the purpose of selling Respondents' products, not public health recommendations. Public health authorities must sometimes make nutrient guideline recommendations based on evidence that falls short of RCT "because everyone eats and

the public should be given advice based on the best evidence available." (Stampfer, Tr. 792-93). Even these recommendations, however, "should distinguish recommendations based on good evidence of a causal relation from those that are based on evidence that is suggestive but falls short of a firm causal relation." (CX1293 (Stampfer, Report at 0029-30); *see also* Stampfer, Tr. 876).

1228. Dr. Sacks would recommend to patient with heart failure to reduce his or her intake of sodium even though there are no RCTs proving any benefit. (PX0361 (Sacks, Dep. at 35-38)).

Response to Finding No. 1228:
The proposed finding is irrelevant, incomplete and mischaracterizes the evidence. Dr. Sacks stated that there is good RCT evidence that reduced sodium levels are beneficial for heart disease patients in general, but that the evidence for sodium reductions in heart failure patients specifically was weak. Currently, the National Heart, Lung and Blood Institute ("NHLBI") has dietary sodium guidelines for congestive heart failure patients. As a result, if he treated heart failure patients, Dr. Sacks would work with the patient on sodium intake and carefully monitor him or her. He also has initiated a pilot study to look at the benefits of sodium restrictions on patients with congestive heart failure, in an effort to instigate further research in this area. (PX0361 (Sacks, Dep. at 35-38)).

1229. Dr. Sacks would recommend fish oil or Omega-3, which is indicated to lower triglyceride levels, to a patient to help prevent or reduce the risk of coronary heart disease even though the scientific results are not settled. (PX0361 (Sacks, Dep. at 55-56)).

Response to Finding No. 1229:
The proposed finding is irrelevant. The recommendation by Dr. Sacks is in the context of the doctor – patient relationship not the advertising of products for sale as a treatment or preventative for coronary heart disease. *See also* Response to Finding 1230.

1230. In fact, Dr. Sacks has criticized Omega-3 trials, much like he criticizes Respondents' cardiovascular studies, but still relies upon the science. (Sacks, Tr. 1562-63).

Response to Finding No. 1230:
The proposed finding is irrelevant, incomplete and mischaracterizes the record. Dr. Sacks stated that the cited Omega-6 studies included "lots of" RCTs and had major *strengths* as well as weaknesses. (Sacks, Tr. 1562-64). *See also* Response to Finding 1229.

1231. Dr. Sacks has informed the public that low sodium is an integral component of preventing cardiovascular disease, stroke and kidney disease, even though a previous study he conducted was not realistically blinded. (Sacks, Tr. 1561-62; 1587).

Response to Finding No. 1231:
The proposed finding mischaracterizes the evidence and is incomplete. Counsel for Respondents did not ask about all of the evidence underlying Dr. Sacks' low sodium recommendations. (Sacks, Tr. 1587-88). *See also* Response to Finding 1227.

1232. Dr. Sacks concedes there are clinical practices and guidelines in place today that have not been proven by double-blind, placebo-controlled studies. (PX0361 (Sacks, Dep. at 111)).

Response to Finding No. 1232:
Complaint Counsel does not disagree.

1233. Dr. Sacks admits that it is appropriate to advise the public on the effect of an agent on human health as it relates to cardiovascular disease by using all evidence weighing the likelihood of the benefit against the likelihood of harm. (PX 361 (Sacks, Dep. at 137)).

Response to Finding No. 1233:
Complaint Counsel does not disagree except to note that the question asked was in the context of a series of questions about public health recommendations, wherein Dr. Sacks repeatedly emphasized the importance of well-controlled randomized studies. (*See* PX361 (Sacks, Dep. at 129-37)).

1234. Dr. Sacks agrees that if a study has flaws, this does not disqualify it from consideration; the study may still have major strengths. (Sacks, Tr. 1564).

Response to Finding No. 1234:
Complaint Counsel does not disagree.

(3) Dr. Sacks Concedes that the Potential Risk of a Food Product Must Be Weighed Against Potential Benefit in Making Public Health Recommendations

1235. Dr. Sacks admits that the potential risk of the product must be weighed against the potential benefit and harm of keeping information from the public. (Sacks, Tr. 1530-40; 1558-59; RX 5007).

Response to Finding No. 1235:
The proposed finding is irrelevant and unsupported by the cited evidence. Dr. Sacks agreed in the abstract with the statement of the importance of "assessing the balance" when making product recommendations in the context of public health; there is no basis from this testimony, however, to suggest that he was modifying his repeated opinion that RCT evidence is needed to support efficacy claims. (Sacks, Tr. 1558-59). Additionally, Sacks Tr. 1530-40 does not support the finding, and RX5007 does not support the finding as Dr. Sacks is not an author thereof.

1236. Complaint Counsel's expert on nutrition, Professor Stampfer, authored an article entitled "Evidence-based criteria in the nutritional context," Nutr Rev. 2010 Aug; 68(8):478-84. (RX 5007).

Response to Finding No. 1236:
Complaint Counsel agrees.

1237. In establishing nutrient requirements and dietary guidelines, Dr. Sacks agrees with Professor Stampfer's statement that "it will be important to assess the balance between the potential harm of making any given recommendation and the potential harm of not making it." (Sacks, Tr. 1559; RX 5007).

Response to Finding No. 1237:
The proposed finding is irrelevant. *See* Response to Finding 1235.

1238. In an article entitled "The Importance of Population-Wide Sodium Reduction as a Means to Prevent Cardiovascular Disease and Stroke: A Call to Action From the American Heart Association" published in their journal (Circulation. 2011 Mar 15;123(10):1138-43), Dr. Sacks, as one of the authors, wrote: "Some scientists still question the evidence supporting population-wide sodium reduction. Common arguments include the absence of a major trial with hard clinical outcomes. It is well-known, however, that such trials are not feasible because of logistic, financial, and often ethical considerations." (Sacks, Tr. 1561; PX0361a03).

Response to Finding No. 1238:
Complaint Counsel agrees.

1239. In writing about "financial considerations" in this article, Dr. Sacks conceded that he meant the cost of conducting a major trial. (Sacks, Tr. 1561).

Response to Finding No. 1239:
Complaint Counsel has no specific response.

1240. Dr. Sacks concedes that it is appropriate to advise the public on the effect of an agent on human health as it relates to cardiovascular disease by using all evidence weighing the likelihood of the benefit against the likelihood of harm. (PX0361 (Sacks, Dep. at 137)).

Response to Finding No. 1240:
See Response to Finding 1232.

(c) RCTs Are Not Perfect and Cannot Always Be Implemented in a Double-Blind, Placebo-Controlled Fashion

1241. Dr. Ornish observes, and Dr. Sacks agrees, that it is possible for RCTs to have their own biases. (Ornish, Tr. 2327-28; PX0361 (Sacks, Dep. at 100)).

Response to Finding No. 1241:
Complaint Counsel does not disagree.

1242. RCTs can be beneficial, but they are not perfect and, when dealing with nutrition, they have their own set of limitations as well. (Ornish, Tr. 2329).

Response to Finding No. 1242:
Complaint Counsel does not disagree.

1243. In studying a drug, RCTs are possible because placebos can be used and subjects, therefore, do not know if they are getting a drug or not. (Ornish, Tr. 2328).

Response to Finding No. 1243:
Complaint Counsel has no specific response.

1244. In studying a fruit or a food, however, it is very hard to do a RCT because the subjects know what they are consuming. (Ornish, Tr. 2328).

Response to Finding No. 1244:
The proposed finding mischaracterizes the record. Respondents sponsored several placebo-controlled studies on POM Juice and POMx and Dr. Ornish conducted two RCT trials for Respondents. (*See e.g.*, CCFF ¶¶ 824, 855, 880, 912, 930).

1245. 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. (Ornish, Tr. 2328-29).

Response to Finding No. 1245:
See Response to Finding 1244.

1246. In the DASH diet, researchers accepted the fact that the subjects would know of the sodium contents of their diets; this was a necessary limitation in the study design and illustrates that the intervention cannot be strictly blinded to the subjects. (PX0361 (Sacks, Dep. at 105-106)).

Response to Finding No. 1246:
This finding is irrelevant because, unlike the case in the sodium studies, there is no evidence of blinding problem due to taste in the Respondents' cardiovascular and biomarker studies. (*See* CCFF ¶¶ 875-949). *See also* Response to Finding 1227.

1247. 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)).

Response to Finding No. 1247:
Complaint Counsel does not disagree that Dr. Sacks stated that that blinding is not *always* possible, as in the case of his low sodium studies. Dr. Sacks further stated that, if a study "became unblinded," he would look at the circumstances of the study overall and that, while it is possible that he would conclude that it was not a "fatal flaw," the study would be graded lower. (PX0361 (Sacks, Dep. at 104-05)).

1248. 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)).

Response to Finding No. 1248:
The proposed finding mischaracterizes the record. Dr. Sacks stated that *some* foods could not be studied in a placebo-controlled manner. He did not state or suggest that studies on "foods and nutrients" were, as a category, not able to be studied in a placebo-

controlled manner. (PX0361 (Sacks, Dep. at 111)). He also said that a study that was randomized and controlled but lacked a placebo was "a considerably lower level of evidence." (PX0361 (Sacks, Dep. at 137)). *See also* Response to Finding 1246.

(d) Larger Studies Are Not Necessarily Better and Pilot Studies Can Provide Valid Scientific Evidence

1249. 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)).

Response to Finding No. 1249:
Complaint Counsel has no specific response.

1250. 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)).

Response to Finding No. 1250:
Complaint Counsel has no specific response.

1251. 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)).

Response to Finding No. 1251:
Complaint Counsel objects to deposition testimony cited in the proposed finding as non-designated testimony.

(e) Statistical Significance Defined as a P-Value of 0.05 Is an Arbitrary Convention in the Context of Studying Pomegranate Juice

1252. In evaluating scientific research related to a whole food, it is not necessary to reach statistical significance to have really important information about something like pomegranate juice as opposed to a prescription drug. (Ornish, Tr. 2340).

Response to Finding No. 1252:
Complaint Counsel does not disagree that Dr. Ornish made that statement. In his own studies on pomegranate juice, however, Dr. Ornish used a p-value of 0.05. (CCFF ¶¶ 827, 857; Ornish Tr. 2352-53 (stating that if there had been 200 patients in the Ornish

CIMT study, with the same experience as the first 73, "it would have been at the 0.05 or less, and it would have been a very strong showing")).

1253. The convention of a finding that there be a five percent or less likely due to chance finding is an arbitrary convention. (Ornish, Tr. 2340).

Response to Finding No. 1253:
Complaint counsel did not disagree that Dr. Ornish made that statement, but it is inconsistent with his own practice and accepted principals of scientific research. *See* Response to Finding 1252 and CCFF ¶ 779.

1254. There is nothing magical about the five percent threshold. (Ornish, Tr. 2368)

Response to Finding No. 1254:
See Response to Finding 1253.

1255. When you have a p-value of 0.05, there is a 95 percent probability of validity as opposed to chance. (Ornish, Tr. 2340).

Response to Finding No. 1255:
Complaint Counsel does not disagree, except to refer to Response to Finding 1253.

1256. When you have a p-value of 0.058, there is a 94 percent validity as opposed to chance. (Ornish, Tr. 2340).

Response to Finding No. 1256:
See Response to Finding 1253.

(f) Dr. Sacks Concedes That "Treat" Can Include Nutrition and Exercise Recommendations, "Prevent" Does Not Mean Absolutely Prevent Something in All Cases, and "Prove" Does Not Mean Something Is Proven 100% in 100% of All Subjects

1257. Dr. Sacks agrees that a diet rich in fruits and vegetables protects against cardiovascular disease. (PX0361 (Sacks, Dep. at 141)).

Response to Finding No. 1257:
Complaint Counsel does not disagree, except to note that this finding is irrelevant as it pertains to the POM Products, which are not whole pomegranates. Dr. Sacks stated that "other things, extract[,] juice, whatnot, that is just not the food and that's in a different category. We need a new category of evidence." Asked how juice is different from fruit,

Dr. Sacks said, "Well, I mean, the juice is simply the liquid. It doesn't have the fiber. It may not have the same nutrients that are bound to the fiber in the food, the seeds which you might eat when you eat foods like pomegranate, if you chew the seeds. . . . Juice[s] is a whole other category compared to an intact food." (PX0361 (Sacks, Dep. at 140-41)). (*See also* CCFF ¶¶ 124-26 (Respondents' extensive process for converting pomegranates into POM Juice)).

1258. Doctors routinely recommend to their patients foods, such as spinach, for which there are no clinical trials, but where there are studies on categories of fruits or vegetables. (PX0361 (Sacks, Dep. at 147)).

Response to Finding No. 1258:
Complaint Counsel does not disagree except to reference Responses to Findings 1219 and 1257.

1259. As a practicing clinician, in counseling patients on issues of cardiovascular health or disease, Dr. Sacks initially would emphasize nutritional and other nondrug treatment like exercise, weight loss, improving the quality of the diet. (PX0361 (Sacks, Dep. at 23-24)).

Response to Finding No. 1259:
Complaint Counsel does not disagree.

1260. The treatment of patients with a nutritional emphasis is the accepted sequence of treatment for prevention of cardiovascular disease and recurrent disease. (PX0361 (Sacks, Dep. at 25)).

Response to Finding No. 1260:
Complaint Counsel does not disagree.

1261. According to Dr. Sacks, the term "treat" does not translate into curing a disease, but rather means to ameliorate symptoms of people who have the disease or reduce the risk of a recurrent cardiovascular event. (PX0361 (Sacks, Dep. at 65-66)).

Response to Finding No. 1261:
Complaint Counsel does not disagree that Dr. Sacks stated that this the meaning of the term in the scientific community.

1262. Dr. Sacks defines the term "prevent heart disease," not to suggest that it can prevent heart disease absolutely in all cases, but instead to mean to lower the incidence of a

cardiovascular event, like myocardial infarction or stroke, in proportion to the cases in the population. (PX0361 (Sacks, Dep. at 64-65)).

Response to Finding No. 1262:
Complaint Counsel does not disagree that that Dr. Sacks described the scientific meaning of these terms generally as stated. (PX0361 (Sacks, Dep. 64-65)).

1263. Dr. Sacks understands the term "reduce the risk" of heart disease to mean that one would reduce the probability of getting heart disease over a given amount of time. (PX 361 (Sacks, Dep. at 65)).

Response to Finding No. 1263:
Complaint Counsel does not disagree.

1264. With respect to the meaning of "prove," Dr. Sacks concedes that this does not mean that a 100% of all patients all of the time are benefitted. (PX0361 (Sacks, Dep. at 81)).

Response to Finding No. 1264:
The proposed finding is incomplete. Dr. Sacks agreed it did not mean that 100% of the patients are benefitted; rather that he would describe proof as "evidence from randomized clinical trials and supported by mechanistic studies. . . I mean we prove things in medical research in groups . . .the one group , the treated group, having a better outcome than the control group." (PX0361 (Sacks, Dep. at 81-82)).

(g) 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

1265. Dr. Sacks has never done any studies on the effect of pomegranates, antioxidants, or nitric oxide on human health. (PX0361 (Sacks, Dep. at 57)).

Response to Finding No. 1265:
Complaint Counsel agrees that Dr. Sacks so testified, but *see* CCFF ¶¶ 702-09 and CX1291 (Sacks, Report at 0001-08) regarding Dr. Sacks' expertise, which includes the conduct and publication of numerous studies relating to effect of diet on numerous measures of cardiovascular health.

1266. In preparing his expert report, Dr. Sacks does not know if he has reviewed all of Respondent's research studies on cardiovascular health. (PX0361 (Sacks, Dep. at 78)).

Response to Finding No. 1266:
The proposed finding is mischaracterizes the evidence. *See* CCFF ¶ 709 regarding the voluminous materials that Dr. Sacks reviewed.

1267. Dr. Sacks is not offering any expert opinion regarding any differences between pomegranates and POM juice. (Sacks, Tr. 1547-48; PX0361 (Sacks, Dep. at 77)).

Response to Finding No. 1267:
The proposed finding mischaracterizes the evidence. Expert testimony is not needed to identify differences between pomegranates and POM Juice – they are different as a matter of fact. (CCFF ¶¶ 124-34, 965). Further, Dr. Sacks testified as to the differences between the two products. *See also* Responses to Findings 916 and 1257.

1268. Dr. Sacks is not offering any opinion in this case about the physical properties of pomegranates or pomegranate juice. (Sacks, Tr. 1548).

Response to Finding No. 1268:
The proposed finding is mischaracterizes the evidence. Expert testimony is not needed to identify differences between pomegranates and POM Juice – they are different as a matter of fact. (See CCFF ¶¶ 124-34, 965). Further, Dr. Sacks testified as to the differences between the two products. *See also* Responses to Findings 916 and 1257.

1269. 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. (PX0361 (Sacks, Dep. at 76)).

Response to Finding No. 1269:
The proposed finding mischaracterizes the evidence. See Responses to Findings 201 and 202.

1270. Dr. Sacks does not know the distinction between POMx Liquid and POM Juice. (PX0361 (Sacks, Dep. at 75)).

Response to Finding No. 1270:

Complaint Counsel has no specific response except to note that the record contains substantial evidence as to the difference between these products. (*See* CCFF ¶¶ 124-34, 164-65).

1271. Dr. Sacks has no idea how POM Juice or POMx are made. (Sacks, Tr. 1570; PX 0361 (Sacks, Dep. at 143-145)).

Response to Finding No. 1271:
The proposed finding is irrelevant, as this is an issue as to which expert testimony is not needed. The record contains substantial evidence regarding the manner in which the products are made, including the substantial manufacturing involved in producing POMx from pomegranate mash after the juice is extracted. (*See* CCFF ¶¶ 124-34, 965).

1272. Dr. Sacks does not know that pomegranates have been eaten safely for centuries. (Sacks, Tr. 1570).

Response to Finding No. 1272:
The proposed finding mischaracterizes the evidence insofar as it assumes that pomegranates indeed have been eaten safely for centuries. *See* Response to Finding 201.

1273. Dr. Sacks does not know if anybody has been harmed by eating pomegranates. (Sacks, Tr. 1570-71).

Response to Finding No. 1273:
The proposed finding mischaracterizes the record. *See* Response to Finding 201.

2. Studies by Dr. Michael Aviram and Colleagues

(a) In Vitro and Animal Studies

Aviram M, Dornfeld L, Rosenblat M, Volkova N, Kaplan M, Coleman R, Hayek T, Presser D, and Fuhrman B, *Pomegranate juice consumption reduces oxidative stress, atherogenic modifications to LDL, and platelet aggregation: studies in humans and in atherosclerotic apolipoprotein E-deficient mice*, Am. J. Clin. Nutr. 2000: 71;1062-76 (PX0004)

Fuhrman B, Volkova N, Aviram M, *Pomegranate juice inhibits oxidized LDL uptake and cholesterol biosynthesis in macrophages*, J. Nutrit. Biochem. 16 (2005) 570-576 (PX0015)

1274. Dr. Sacks attempts to dismiss Respondents' *in vitro* and animal science on the grounds that such research cannot predict what effect a treatment will have on humans. (CX1291_0015-0016).

Response to Finding No. 1274:
Complaint Counsel disagrees that Dr. Sacks "dismisses" Respondents' studies, but agrees that Dr. Sacks states *in vitro* and animal studies need to be replicated in humans to show an effect on preventing or treating a disease. (CX1291 (Sacks, Report at 0015-16)).

1275. Dr. Ornish, notes, however, that is important not to generalize too broadly to suggest there are limitation to extrapolating from animal studies because it depends which part of the physiology is being studied. (Ornish, Tr. 2370).

Response to Finding No. 1275:
Complaint Counsel has no specific response.

1276. In some cases, animal physiology is identical to humans, but in other cases, it is different. (Ornish, Tr. 2370).

Response to Finding No. 1276:
Complaint Counsel has no specific response, except that many findings of dietary or drug effects in animals are not confirmed in human testing. (*See* CCFF ¶ 764).

1277. 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)).

Response to Finding No. 1277:
The proposed finding is incomplete. Dr. Ornish testified that "if you had two studies that were done of equal quality, I think the human study would provide more definitive evidence than the animal study." (PX0355 (Ornish, Dep. at 66); s*ee also* CCFF ¶¶ 763-64).

1278. 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)).

Response to Finding No. 1278:
The proposed finding is incomplete. Dr. Sacks testified that an *in vitro* study would not be more useful than a human clinical study because the purpose of a clinical study is to evaluate "the sum [sic] total effect of all the mechanisms that can be activated or repressed by food or nutrient." (PX0361 (Sacks, Dep. at 91-92)). An *in vitro* study would be used to understand a mechanism rather than a "total clinical effect." (PX0361 (Sacks, Dep. at 92); s*ee also* CCFF ¶¶ 763-64)).

1279. 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)).

Response to Finding No. 1279:
Complaint Counsel does not disagree. (*See also* CCFF ¶ 764).

(b) Human Studies

Aviram M and Dornfeld L*, Pomegranate juice consumption inhibits serum angiotensin converting enzyme activity and reduces systolic blood pressure*, 158 Atherosclerosis 195 (2001) (CX 542)

1280. Dr. Sacks believes that CX 542 does not provide reliable evidence of an improvement of ACE or blood pressure because it was not blinded or placebo-controlled, involved a small sample size, and lasted two weeks. (Sacks, Tr. 1453; CX 1291_0017).

Response to Finding No. 1280:
Complaint Counsel agrees.

1281. Dr. Ornish, however, responds 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).

Response to Finding No. 1281:
Complaint Counsel does not disagree that Dr. Aviram's study should be viewed in the larger context of other studies but disagrees that its findings are congruent and supportive

of other research (*see* CCFF ¶¶ 950-65), and notes that Dr. Ornish agrees with Dr. Sacks that the study "was limited in scope". (PX0025-0009).

1282. Dr. Aviram explains 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. (CX1348 (Aviram, Dep. at 12-13)).

Response to Finding No. 1282:
The proposed finding is incomplete. Dr. Aviram's explanation was made in the context of his "small, pilot-like studies in humans[.]" (CX1358 (Aviram, Dep. at 12)). Complaint Counsel also notes that Dr. Aviram was not an expert in this matter and did not appear at trial.

1283. 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)).

Response to Finding No. 1283:
Complaint Counsel does not disagree.

1284. 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)).

Response to Finding No. 1284:
The proposed finding mischaracterizes Dr. Aviram's testimony. Dr. Aviram testified that "some people think that if it's a pilot study, it's not good enough to substantiate [a] claim." Dr. Aviram did not dispute this statement.

1285. 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)).

Response to Finding No. 1285:
Complaint Counsel has no specific response. (*See also* CCFF ¶ 763-771 (describing various types of studies and their use)).

1286. Dr. Davidson also confirms that RCTs are not the only kinds of studies considered to be valid. (CX1336 (Davidson, Dep. at 232)).

Response to Finding No. 1286:
The proposed finding is irrelevant because Dr. Davidson is not an expert in this matter.

The proposed finding mischaracterizes Dr. Davidson's testimony, which was limited to

his own previous pilot studies. (CX1336 (Davidson, Dep. at 232)).

1287. 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)).

Response to Finding No. 1287:
Complaint Counsel does not disagree that Dr. Davidson testified as such about his own

pilot studies. (CX1336 (Davidson, Dep. at 232). *See also* Response to Finding 1286.

Aviram M, Rosenblat M, Gaitini M, Nitecki S, Hoffman A, Dornfeld L, Volkova N, Presser D, Attias J, Liker H, and Hayek T, *Pomegranate juice consumption for 3 years by patients with carotid artery stenosis reduces common carotid intima media thickness, blood pressure and LDL oxidation*, 23 Clin. Nutr. 423 (2004) (CX 611)

1288. Dr. Sacks disagrees with Dr. Aviram's conclusion that pomegranate juice had a favorable effect in reducing cholesterol in carotid artery lesions because (a) there was no randomized, placebo, control group to compare effects; and (b) people who had been drinking pomegranate juice had deterioration in their atherosclerosis which required them to have surgery, so no claim of benefit can be made. (Sacks, Tr. 1455-56; 1459-60).

Response to Finding No. 1288:
Complaint Counsel does not disagree.

1289. Dr. Sacks' statement that no conclusions can be drawn from the study is extreme. (PX0025-0011).

Response to Finding No. 1289:
Complaint Counsel has no specific response, except to note that Dr. Ornish also states

that "the conclusions of this isolated study should be interpreted with caution due to the

study's limitation." (PX0025-001).

1290. This was the first study ever published indicating that pomegranate juice may affect the progression of carotid atherosclerosis. (PX0025-0011).

Response to Finding No. 1290:
Complaint Counsel has no specific response.

1291. 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).

Response to Finding No. 1291:
The proposed finding is unsupported by the cited evidence.

1292. 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).

Response to Finding No. 1292:
Complaint Counsel has no specific response. (*See also* CCFF ¶¶ 814-21 (analyzing the study)).

1293. Dr. Sacks ignores the value of Dr. Aviram's analysis of carotid lesions in a subgroup of patients who underwent carotid endartherectomy, in which the lesions were surgically removed from the carotid artery. (PX0025-0011).

Response to Finding No. 1293:
Complaint Counsel disagrees. Dr. Sacks testified it is unreasonable to conclude that patients who had undergone endarterectomies benefitted from drinking pomegranate juice. (Sacks, Tr. 1458-60).

1294. In two out of the ten patients on pomegranate juice (after 3 and 12 months) due to clinical deterioration, carotid endartherectomy operation was performed and their carotid lesions were analyzed and compared to lesions obtained from seven patients that did not consume pomegranate juice (not the patients of the placebo group). (PX0025-0011).

Response to Finding No. 1294:
Complaint Counsel has no specific response. *See also* Response to Finding 1293.

1295. The cholesterol content in carotid lesions from the two patients that consumed pomegranate juice was lower by 58% and 20%, respectively, in comparison to lesions obtained from carotid artery stenosis patients that did not consume pomegranate juice. (PX0025-0011).

Response to Finding No. 1295:
Complaint Counsel has no specific response. *See also* Response to Finding 1293. (CCFF ¶¶ 814-21).

1296. Similarly, the lipid peroxides content in lesions obtained from the patients after pomegranate juice consumption for 3 or 12 months was significantly reduced by 61% or 44%, respectively, as compared to lesions from patients that did not consume pomegranate juice. (PX0025-0011).

Response to Finding No. 1296:
Complaint Counsel has no specific response. (*See also* CCFF ¶¶ 814-21 (analyzing the study)).

1297. These findings suggests that oxidative stress, including oxidation of LDL to a form that makes it more likely to cause arterial blockages and cause foam cell production in macrophages (macrophage-derived foam cells play integral roles in all stages of atherosclerosis) may have been reduced by pomegranate juice consumption in these patients. (PX0025-0011).

Response to Finding No. 1297:
Complaint Counsel has no specific response. (*See also* CCFF ¶¶ 814-21 (analyzing the study)).

1298. 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).

Response to Finding No. 1298:
Complaint Counsel objects to the characterization of Dr. Sacks' testimony as complaining. Dr. Sacks testified that although nothing can be used in a control group, "it's not a good design to use nothing." (Sacks, Tr. 1585-86; CCFF ¶ 775).

1299. Dr. Sacks concedes that he has no basis to disagree with Dr. Aviram's numbers. (Sacks, Tr. 1589-90).

Response to Finding No. 1299:
Complaint Counsel has no specific response.

1300. Dr. Sacks confirms that the CIMT test is "a worthy test" and is relevant to cardiovascular health. (Sacks, Tr. 1589-90).

Response to Finding No. 1300:
Complaint Counsel has no specific response, except to note that Dr. Sacks also testified that CIMT measures are not conclusive evidence that an intervention treats existing heart disease. (CCFF ¶ 786).

1301. 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).

Response to Finding No. 1301:
See Response to Finding 1300.

1302. If the study design was not good enough, no peer-reviewed journal, such as the American Journal of Clinical Nutrition, would have published Dr. Aviram's study. (CX1348 (Aviram, Dep. at 28)).

Response to Finding No. 1302:
Complaint Counsel has no specific response.

3. Studies by Dr. Ornish and Colleagues

(a) Sumner M, Elliott-Eller M, Weidner G, Daubenmier JJ, Chew MH, Marlin R, Raisin CJ, and Ornish D, *Effects of pomegranate juice consumption on myocardial perfusion in patients with coronary heart disease*, 96 Am. J. Cardiology 810 (2005) (PX0023)

(1) Myocardial Perfusion (or Blood Flow to the Heart) Is the "Bottom-Line" in Evaluating Cardiovascular Health and Better Predictor and/or Surrogate for Cardiac Events

1303. Dr. Sacks believes that myocardial perfusion is a biologically and clinically interesting process, but is not used as the primary outcome in studies of drug treatment in coronary heart disease or recognized as surrogate marker of therapeutic effects on coronary heart disease. (CX 1291_0020-0021; Sacks, Tr. 1464).

Response to Finding No. 1303:
Complaint Counsel agrees.

1304. Dr. Sacks also complains that: (1) even where blood flow is shown to be improved, it will not necessarily result in improved cardiovascular health, such as reductions in heart attack and stroke; and (2) myocardial perfusion is a measurement that is not commonly used in studies of treatment efficacy. (CX 1291_0021).

Response to Finding No. 1304:
Complaint Counsel agrees, but Complaint Counsel objects to the characterization of Dr. Sacks' report as complaining.

a. Myocardial Perfusion Is the Bottom Line in Cardiovascular Health

1305. Blood flow is essential to life, an important measure of heart disease, and the bottom line in coronary heart disease. (Ornish, Tr. 2331).

Response to Finding No. 1305:
Complaint Counsel has no specific response.

1306. How much blood flow the heart receives is really the "bottom line" in coronary heart disease (along with how well the heart is pumping blood, called the ejection fraction). (PX0025-0012).

Response to Finding No. 1306:
Complaint Counsel does not disagree that this is Dr. Ornish's stated opinion, but disagrees with the conclusion drawn. Blood flow is not a recognized surrogate marker for heart disease. (CCFF ¶ 844). Dr. Heber characterizes the blood flow markers as "intermediate" in his expert report. (CCFF ¶ 844).

1307. Blood carries oxygen and nutrients that feed the heart. (PX0025-0012).

Response to Finding No. 1307:
Complaint Counsel has no specific response.

1308. If the blood flow to the heart (perfusion) is reduced, then the heart is no longer receiving enough blood flow to maintain itself. (PX0025-0012).

Response to Finding No. 1308:
Complaint Counsel has no specific response.

1309. 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. (Ornish, Tr. 2331-32).

Response to Finding No. 1309:
Complaint Counsel does not disagree Dr. Ornish testified as such, but notes that even where blood flow is shown to be improved, it will not necessarily result in improved cardiovascular health, such as reduction in heart attack or stroke. (CCFF ¶ 844).

1310. Dr. Sacks concedes that if blood flow is reduced, then this is not desirable. (PX0361 (Sacks, Dep. at 179)).

Response to Finding No. 1310:

The proposed finding is incomplete. Dr. Sacks also testified that blood flow is not a good surrogate marker for heart disease. (PX0361 (Sacks, Dep. at 179); CCFF ¶ 844)).

1311. If this is temporary, then the person often experiences angina, or chest pain. (PX0025-0012).

Response to Finding No. 1311:
Complaint Counsel has no specific response.

1312. 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." (PX0025-0012).

Response to Finding No. 1312:
Complaint Counsel has no specific response.

1313. 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. (PX0025-0012).

Response to Finding No. 1313:
Complaint Counsel has no specific response.

1314. 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. (Heber, Tr. at 1972-73).

Response to Finding No. 1314:
Complaint Counsel agrees that Dr. Heber testified as such, but notes that Dr. Heber does not hold himself out as an expert in cardiovascular disease. (CCFF ¶ 728).

1315. A surrogate is either a sign or a symptom that is associated along the pathway to a disease. (Heber, Tr. 1973).

Response to Finding No. 1315:
Complaint Counsel has no specific response, except to note that validated surrogate markers for heart disease recognized by the FDA include blood pressure and LDL cholesterol. Most experts also recognize C-reactive protein, HDL, cholesterol, and triglycerides as valid surrogate markers. (CCFF ¶ 785).

1316. The FDA approves of LDL cholesterol as surrogate for cardiovascular disease. (Ornish, Tr. 2334).

Response to Finding No. 1316:
Complaint Counsel does not disagree.

1317. 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. (Ornish, Tr. 2334).

Response to Finding No. 1317:
Complaint Counsel has no specific response.

1318. 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. (Heber, Tr. 1973).

Response to Finding No. 1318:
Complaint Counsel agrees that Dr. Heber testified as such, but notes that Dr. Heber does not hold himself out as an expert in cardiovascular disease. (CCFF ¶ 728). Complaint Counsel also notes that validated surrogate markers for heart disease recognized by the FDA include blood pressure and LDL cholesterol. Most experts also recognize C-reactive protein, HDL, cholesterol, and triglycerides as valid surrogate markers. (CCFF ¶¶ 785-86).

1319. 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. (Heber, Tr. 1973).

Response to Finding No. 1319:
See Response to Finding 1318.

1320. 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. (Heber, Tr. 1973-74).

Response to Finding No. 1320:
Complaint Counsel has no specific response.

1321. In comparing myocardial perfusion and LDL cholesterol, myocardial perfusion is more closely connected as a surrogate for cardiovascular disease. (Ornish, Tr. 2334).

Response to Finding No. 1321:
Complaint Counsel does not disagree that Dr. Ornish testified as such, but disagrees with the conclusion drawn because myocardial perfusion is not a recognized surrogate marker of heart disease. (CCFF ¶ 844). An improvement in blood flow does not necessarily result in improved cardiovascular disease or reductions in heart attack. (CCFF ¶ 844). In addition, the Deputy Editor of JAMA told Dr. Ornish that the use of myocardial perfusion as an outcome measure was a flaw in the study because it is an intermediate endpoint. (CCFF ¶ 841).

1322. 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. (Heber, Tr. 1974).

Response to Finding No. 1322:
Complaint Counsel has no specific response.

1323. There are a number of people who have low cholesterol levels, but get heart disease. (Ornish, Tr. 2334-35).

Response to Finding No. 1323:
Complaint Counsel has no specific response.

1324. About 50 percent of the people who die from a heart attack actually have cholesterol in the normal range. (Heber, Tr. 1974).

Response to Finding No. 1324:
Complaint Counsel agrees that Dr. Heber testified as such, and notes that Dr. Heber does not hold himself out as an expert in cardiovascular disease. (CCFF ¶ 728).

1325. There are people who have high cholesterol levels who do not have heart disease, and the same is true blood pressure. (Ornish, Tr. 2334-35).

Response to Finding No. 1325:
Complaint Counsel has no specific response.

1326. When measuring myocardial perfusion, researchers are actually measuring what matters most, which is how much blood flow the heart is getting. (Ornish, Tr. 2334-35).

Response to Finding No. 1326:

Complaint Counsel does not disagree that this is Dr. Ornish's stated opinion, but notes blood flow is not a recognized surrogate marker for heart disease. (CCFF ¶ 844).

1327. Dr. Sacks concedes that proper blood flow from the coronary artery and to the heart is fundamental to lowering the risk of cardiovascular disease. (Sacks, Tr. 1593).

Response to Finding No. 1327:
Complaint Counsel agrees that Dr. Sacks testified as such, but notes that in Dr. Ornish's MP Study, two out of three markers for blood flow (SSS and SRS) were unchanged. (CCFF ¶ 827).

b. Myocardial Perfusion Is a Better Scientific Test Than Coronary Angiography

1328. 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. (PX0025-0012).

Response to Finding No. 1328:
Complaint Counsel agrees Dr. Ornish states such in his report, but Complaint Counsel disagrees with the conclusion drawn. Myocardial perfusion is not a validated surrogate marker for heart disease. (CCFF ¶ 844). Validated surrogate markers for heart disease recognized by the FDA include blood pressure and LDL cholesterol. Most experts also recognize C-reactive protein, HDL, cholesterol, and triglycerides as valid surrogate markers. (CCFF ¶¶ 785-86). Moreover, this section of Dr. Ornish's report responds to Dr. Sacks' expert report, however, Dr. Sacks did not recommend the use of coronary angiographies, and therefore the proposed finding is irrelevant.

1329. Coronary angiography measures how much blockage is in the coronary arteries that feed the heart. (PX0025-0012).

Response to Finding No. 1329:
Complaint Counsel has no specific response.

1330. However, the degree of blockage is only one of several mechanisms that affect perfusion, or blood flow to the heart. (PX0025-0012).

Response to Finding No. 1330:
Complaint Counsel has no specific response.

1331. 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). (PX0025-0012).

Response to Finding No. 1331:
Complaint Counsel has no specific response.

1332. 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. (PX0025-0012).

Response to Finding No. 1332:
Complaint Counsel has no specific response.

1333. 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. (PX0025-0012).

Response to Finding No. 1333:
The proposed finding is irrelevant. Contrary to Dr. Ornish's suggestion, Dr. Sacks did

not recommend the use of coronary angiographies in his expert report.

1334. 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. (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).

Response to Finding No. 1334:
Complaint Counsel has no specific response.

1335. 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%; $p < .01$)." (PX0025-0012-13).

Response to Finding No. 1335:
Complaint Counsel has no specific response.

1336. This study was published in *Circulation*, the American Heart Association's lead scientific journal. (PX0025-0013).

Response to Finding No. 1336:
Complaint Counsel has no specific response.

1337. 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." (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).

Response to Finding No. 1337:
Complaint Counsel has no specific response.

1338. 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. (Ornish, Tr. 2333-34).

Response to Finding No. 1338:
Complaint Counsel has no specific response.

(2) Measures of SSS, SDS, and SRS

1339. 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). (Ornish, Tr. 2341; PX0025-0013).

Response to Finding No. 1339:
Complaint Counsel agrees.

1340. "Ischemia" and "jeopardized" mean that part of the heart muscle (myocardium) is not receiving enough blood flow. (PX0025-0014).

Response to Finding No. 1340:
Complaint Counsel does not disagree.

1341. "Infarcted" means part of the heart muscle has died and turned into scar tissue and is nonfunctioning. (PX0025-0014).

Response to Finding No. 1341:
Complaint Counsel does not disagree.

1342. "Hibernating" means part of the heart muscle is also nonfunctioning and on the way to becoming infarcted. (PX0025-0014).

Response to Finding No. 1342:
Complaint Counsel has no specific response.

1343. SDS is considered a valid surrogate for coronary heart disease. (Ornish, Tr. 2341- 42).

Response to Finding No. 1343:
Complaint Counsel disagrees. Myocardial perfusion measured by SSS, SRS, and SDS is not a valid surrogate marker for heart disease. (CCFF ¶ 844). Even where blood flow is shown to be improved, it will not necessarily result in improved cardiovascular health, such as reductions in heart disease and stroke. (CCFF ¶ 844). Further, it is not appropriate to focus only on SDS data, and ignore SRS and SSS data. (CCFF ¶ 849). A reported change in SDS data alone may not be clinically meaningful. (CCFF ¶¶ 848-49, CX1291 (Sacks, Report at 0022)).

1344. Dr. Sacks complains, however, that Dr. Ornish's study shows significant changes in only one of the three measures at the end of the study –SDS, but not in SRS or SSS. (CX1291_0021).

Response to Finding No. 1344:
Complaint Counsel does not disagree, but Complaint Counsel objects to the characterization of Dr. Sacks' report as complaining.

1345. Dr. Sacks also argues the protocol for the study did not identify whether the primary endpoint would be SSS, SRS, or SDS or some other measurement calculated from the imaging data. (Sacks, Tr. 1475).

Response to Finding No. 1345:

The proposed finding mischaracterizes Dr. Sacks' testimony. Dr. Sacks testified only that the study protocol did not identify SDS as a primary endpoint. (Sacks, Tr. 1475; CCFF ¶ 846).

1346. 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). (PX0025-0013).

Response to Finding No. 1346:
Complaint Counsel disagrees and notes that, contrary to the proposed finding, Dr. Ornish confirms that "[the protocol] did not specify that changes in SDS would be the primary endpoint measure[.]" (PX0025-0014).

1347. 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. (Ornish, Tr. 2341).

Response to Finding No. 1347:
Complaint Counsel disagrees and notes that, on the contrary, Dr. Sumner admitted that SDS was chosen as a "key variable" *after* the three month testing was completed. (CCFF ¶ 847).

1348. 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. (Ornish, Tr. 2342).

Response to Finding No. 1348
The proposed finding mischaracterizes the cited evidence and is incorrect. Dr. Ornish testified that Dr. Sacks' report comments that *Braunwald Heart Disease* cardiology text book states that *SRS* is a good predictor. (Ornish, Tr. 2342 (emphasis added)). However, Dr. Sacks' report actually states that the textbook notes that *SSS* is a particularly good predictor of natural history outcomes. (CX1291 (Sacks, Report at 0022) (emphasis added)). Complaint Counsel does not disagree that Dr. Ornish testified that that was not the question he was attempting to answer in his study.

1349. 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. (Ornish, Tr. 2342-43)

Response to Finding No. 1349:
Complaint Counsel has no specific response, but notes Dr. Ornish concedes that SDS specifically was not identified as the primary endpoint in the protocol. (CCFF ¶ 845).

1350. 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? (PX0025-0014).

Response to Finding No. 1350:
Complaint Counsel does not disagree that such was stated in Dr. Ornish's report, but notes Dr. Ornish concedes that SDS specifically was not identified as the primary endpoint in the protocol. (CCFF ¶ 845). Nonetheless, the reported changes in SDS measures may not be clinically meaningful because the authors did not show that the patients experienced improvement in their clinical symptoms. (CCFF ¶ 849).

1351. 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. (PX0025-0014).

Response to Finding No. 1351:
Complaint Counsel disagrees. A study protocol should identify the primary endpoint in advance to prevent the researcher from picking and choosing among results. (CCFF ¶ 846). In this study, the .05 *p*-value of SDS was not persuasive because there were three possible outcome measures (SSS, SRS, and SDS) and only one barely met significance. Dr. Sacks explained that it is not appropriate to focus only on SDS data and ignore the SSS and SRS data. (CCFF ¶ 848). Although SSS shows the presence of dead cardiac tissue, which reveals if a patient had a silent attack, this information is not shown in the SDS measure. Changes in SDS measures may not be clinically meaningful because the

authors did not show that the patients experienced improvement in their clinical symptoms. (CCFF ¶ 849).

1352. 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. (PX0025-0014).

Response to Finding No. 1352:
See Response to Finding 1351.

1353. 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. (CX1344 (Sumner, Dep. at 181)).

Response to Finding No. 1353:
Complaint Counsel has no specific response, except to note that Dr. Sumner admitted SDS was determined to be the "key variable" after three months of testing was completed. (CX1344 (Sumner, Dep. at 13, 16-21); CCFF ¶ 847).

1354. Dead heart muscle does not get better, so the condition was not going to improve from pomegranate juice or from any other intervention. (PX0025-0014).

Response to Finding No. 1354:
Complaint Counsel does not disagree.

1355. Pomegranate juice improves blood flow to the heart but it does not bring dead tissue back to life. (PX0025-0014).

Response to Finding No. 1355:
Complaint Counsel has no specific response.

1356. 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. (PX0025-0014).

Response to Finding No. 1356:
Complaint Counsel has no specific response.

1357. 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. (PX0025-0014).

Response to Finding No. 1357:
Complaint Counsel disagrees. (*See* CCFF ¶¶ 846-48).

1358. 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. (PX0025-0014).

Response to Finding No. 1358:
Complaint Counsel does not disagree that Dr. Ornish stated such in his report, but notes that myocardial perfusion is not a recognized surrogate marker for heart disease, and that even where blood flow improves, it will not necessarily result in improved cardiac health. (CCFF ¶ 844).

(3) Alleged Differences at Baseline for SRS and SSS Did Not Affect the Outcome of Dr. Ornish's Study

1359. Dr. Sacks critiques Dr. Ornish's study on the grounds that apparently there was a discrepancy in the baseline values of SRS and SSS, the two components of the SDS. (CX1291_0022; Sacks, Tr. 1461-62).

Response to Finding No. 1359:
Complaint Counsel does not disagree.

1360. Dr. Sacks, as a result, complains that it could be predicted that the control group, having worse coronary perfusion than the pomegranate group at baseline, would have a more accelerated form of the disease and show worsening on follow-up. (CX1291_0022; Sacks, Tr. 1469-70).

Response to Finding No. 1360:
Complaint Counsel does not disagree, but Complaint Counsel objects to the characterization of Dr. Sacks' testimony as complaining. Dr. Sacks made these accurate observations based on the large discrepancy in the SSS and SRS baseline values. (CCFF ¶ 850).

1361. Dr. Ornish explains, however, there was no difference in SRS and SDS at baseline, only a difference in SSS. (Ornish, Tr. 2343; PX0025-0015).

Response to Finding No. 1361:
Complaint Counsel disagrees with the conclusion. Dr. Sacks found that the SRS baseline data for the pomegranate juice group was 1.9 ± 2.6, whereas the baseline SRS for the placebo group was 3.8 ± 4.7. (CX1291 (Sacks, Report at 0023); CCFF ¶¶ 850-51).

1362. Although there was a difference in SSS at baseline, Dr. Ornish employed an "analysis of variance," which took into account any baseline differences. (Ornish, Tr. 2343).

Response to Finding No. 1362:
Complaint Counsel does not disagree that Dr. Ornish testified as such, but notes that the large discrepancy in the SSS and SRS values were large enough to be statistically significant. (CCFF ¶ 850). This imbalance in values shows that randomization did not produce active and placebo groups that were similar on relevant characteristics and therefore, it could be predicted that the control group, having worse coronary perfusion than the POM Juice group at baseline to start with, would have a more accelerated form of the disease and show worsening on follow-up. (CCFF ¶¶ 850-51).

1363. 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. (Ornish, Tr. 2343; PX0025-0015).

Response to Finding No. 1363:
See Response to Finding 1362. Complaint Counsel also notes that Dr. Ornish did not identify a primary endpoint measure in the protocol. (CCFF ¶ 845).

1364. 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. (Ornish, Tr. 2343-44).

Response to Finding No. 1364:
Complaint Counsel agrees, and notes that Dr. Sacks opined that a statistical adjustment of the results for the large discrepancy in baseline values should have been attempted and the dissimilarity should have been reported in the article. (CX1291 (Sacks, Report at 0022-23).

1365. In his myocardial perfusion study, there were no differences between the groups in their cholesterol, blood pressure, blood sugar, and weights levels at baseline. (Ornish, Tr. 2344-45).

Response to Finding No. 1365:
Complaint Counsel has no specific response.

1366. 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. (Ornish, Tr. 2344; PX0025-0015).

Response to Finding No. 1366:
Complaint Counsel has no specific response.

1367. 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. (Ornish, Tr. 2344).

Response to Finding No. 1367:
Complaint Counsel does not disagree Dr. Ornish testified as such, but Complaint Counsel disagrees with the conclusion drawn. It could be predicted that the control group, having worse coronary perfusion than the POM Juice group at baseline to start with, would have a more accelerated form of the disease and show worsening on follow-up. (CCFF ¶ 851).

1368. 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." (PX0025-0015).

Response to Finding No. 1368:
Complaint Counsel does not disagree Dr. Ornish states such, but also notes that Dr. Sacks explains the importance of a protocol to identify the primary outcomes in advance to prevent a researcher from cherry-picking positive results and ignoring negative ones; especially "in any study involving a large number of variables, it is likely that some will be positive, simply due to chance." (CX1291 (Sacks, Report at 21); CCFF ¶ 846).

1369. 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." (PX0025-0015).

Response to Finding No. 1369:
The proposed finding mischaracterizes the evidence. As Drs. Sacks and Stampfer note, it could be predicted that the control group, having worse coronary perfusion than the POM Juice group at baseline to start with, would have a more accelerated form of the disease and show worsening on follow-up. (CCFF ¶ 851).

1370. Thus, controlling for baseline differences is built into this analysis. (PX0025-0015; Ornish, Tr. 2394).

Response to Finding No. 1370:
See Response to Finding 1369. Complaint Counsel also notes that Dr. Sacks opined that a statistical adjustment of the results for the large discrepancy in baseline values should have been attempted and the dissimilarity should have been reported in the article. (CX1291 (Sacks, Report at 0022-23)).

1371. 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. (PX0025-0015).

Response to Finding No. 1371:
Complaint Counsel disagrees. *See* Response to Finding 1370.

(4) Any Purported Omission of Patient Data Did Not Alter the Results of Dr. Ornish's Study

1372. Dr. Sacks attempts to discredit Dr. Ornish's study for only providing data on 39 patients although 45 persons planned to be enrolled in the study. (CX1291_0022).

Response to Finding No. 1372:
Complaint Counsel has no specific response.

1373. Dr. Sacks concedes that Dr. Ornish's study provides some rationale for removing four patients' data, but still argues the study offers no explanation for why the remaining two original patients were not included in the final data analysis. (CX1291_0022).

Response to Finding No. 1373:
Complaint Counsel has no specific response.

1374. According to Dr. Sacks, alterations in the original sample size may be critical when there is a borderline "p" value. (CX1291_0022).

Response to Finding No. 1374:
Complaint Counsel agrees.

1375. Dr. Sacks argues that Dr. Ornish's study did not follow the "intention-to-treat" analysis, which he regards as the standard for clinical trial analysis, to include data on all patients originally randomized to treatment or control, even data on dropouts. (CX1291_0022; Sacks, Tr. 1469).

Response to Finding No. 1375:

Complaint Counsel agrees.

1376. 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. (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).

Response to Finding No. 1376:
Complaint Counsel agrees.

1377. Dr. Ornish agrees that a mistake was made in not reporting data on the remaining 41 patients. (PX0025-0015).

Response to Finding No. 1377:
Complaint Counsel agrees.

1378. 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. (PX0025-0015; Ornish, Tr. 2347-48).

Response to Finding No. 1378:
Complaint Counsel does not disagree Dr. Ornish stated such, but Complaint Counsel disagrees with the conclusion drawn. Dr. Ornish testified that "we went back and we looked at the outcomes of when all 43 [*sic*] patients were included, and it didn't change them . . . but somehow in the actual writing up of the paper, two of the patients were left out." However, Dr. Ornish did not produce data to support his testimony or publish an erratum. (Ornish, Tr. 2347-48).

1379. If anything, the results were more statistically significant and even stronger because the sample size was slightly larger. (Ornish, Tr. 2347-48; 2394).

Response to Finding No. 1379:
Complaint Counsel disagrees. *See* Response to Finding 1378. Complaint Counsel also notes that in light of the problems in the design and conduct of the Ornish MP Study, the study does not even support the conclusion that pomegranate juice had a favorable effect on blood flow to the heart. (CCFF ¶ 854). Based on the principles of clinical study

design and conduct, the Ornish MP Study results would be interpreted as having no effect on any measure of cardiac health. (CCFF ¶ 854).

1380. The idea that clinical trials must use the intention to treat analysis or they are not valid is a rather extreme position, especially because this is a randomized, double-blind, placebo-controlled trial, which is considered to be the most rigorous experimental design. (PX0025-0015-0016).

Response to Finding No. 1380:
Complaint Counsel does not disagree Dr. Ornish stated such in his report, but Complaint Counsel disagrees with the conclusion drawn. In light of the unavailable data from four patients, alterations in the original sample size may be critical when there is a borderline "p" value. The standard for clinical trial analysis called "intention-to-treat," includes considering data from all patients originally randomized and data on dropouts. (CX1291 (Sacks, Report at 0022)).

1381. 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. (Ornish, Tr. 2350-51; PX0025-0016).

Response to Finding No. 1381:
Complaint Counsel has no specific response.

1382. 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. (Ornish, Tr. 2350-51).

Response to Finding No. 1382:
Complaint Counsel disagrees. Dr. Sacks did not assert that the study was not a RCT. Rather, Dr. Sacks acknowledged the study was designed as an RCT but errors, admitted by Dr. Ornish in the conduct of the study, were inconsistent with widely-accepted standards for conduct of clinical trials. (CCFF ¶ 852). Therefore, the interpretation of the study that is consistent with principles of clinical study design and conduct, is that

pomegranate juice treatment had no effect on any measure of cardiac health. (CCFF ¶ 853).

1383. Most of Dr. Sacks' own research would not meet this standard. (PX0025-0016).

Response to Finding No. 1383:
The proposed finding is irrelevant. The issue is whether the research conducted by Respondents supports their claims that POM Products treat, prevent, or reduce the risk of heart disease, which experts have concluded do not. (CX1426; CCFF ¶¶ 950-65).

1384. Dr. Ornish used the intention-to-treat method in reporting all available data. (Ornish, Tr. 2349).

Response to Finding No. 1384:
The proposed finding mischaracterizes the evidence. Dr. Ornish admitted that 41 patients completed the study, but that the published report provided data on only 39 patients. One of the patients whose data was excluded had a silent heart attack while drinking pomegranate juice. Dr. Ornish admitted this was a mistake. (CCFF ¶ 831).

1385. 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. (Ornish, Tr. 2349).

Response to Finding No. 1385:
Complaint Counsel has no specific response, except to note that Dr. Sacks did not suggest that Dr. Ornish should have used the "last value carried forward."

1386. 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. (PX0025-0016 *citing* Julious SA, Mullee MA. Issues with using baseline in last observation carried forward analysis. Pharmaceut. Statist. 2008; 7: 142–146.).

Response to Finding No. 1386:
See Response to Finding 1385.

1387. 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. (Ornish, Tr. 2349).

Response to Finding No. 1387:

Complaint Counsel has no specific response.

1388. But when evaluating a fruit juice, it is not necessary to go to the extreme of biasing against showing the effect. (Ornish, Tr. 2349-50).

Response to Finding No. 1388:
Complaint Counsel has no specific response.

1389. Dr. Ornish also used the per-protocol method as well and reported all available data. (Ornish, Tr. 2350).

Response to Finding No. 1389:
The proposed finding mischaracterizes the evidence. Dr. Ornish admitted that 41 patients completed the study, but that the published report provided data on only 39 patients. One of the patients whose data was excluded had a silent heart attack while drinking pomegranate juice. Dr. Ornish admitted this was a mistake. (CCFF ¶ 831).

(5) The Unblinding of Patients or Lack of Placebo Does Not Diminish the Validity of Dr. Ornish's Study

1390. Dr. Sacks challenges Dr. Ornish's study on the grounds that seven or eight of the patients in the placebo group were unblinded before their three-month data was collected. (CX1291_0023; Sacks, Tr. 1476-77).

Response to Finding No. 1390:
Complaint Counsel does not disagree, except to note that Dr. Sacks found that "[t]his is inconsistent with widely-accepted standards of conduct for clinical trials." (CX1291 (Sacks, Report at 0023)).

1391. Dr. Sacks also complains that two other patients in the placebo group did not, in fact, receive a placebo treatment. (CX1291_0023; Sacks, Tr. 1476-77).

Response to Finding No. 1391:
Complaint Counsel does not disagree, but Complaint Counsel objects to the characterization of Dr. Sacks' testimony as complaining. Dr. Sacks made these accurate observations based on Dr. Ornish's testimony and evidence in the record. (CCFF ¶ 832).

See also Response to Finding1390.

1392. 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. (Ornish, Tr. 2345).

Response to Finding No. 1392:
The proposed finding mischaracterizes Dr. Sacks' testimony. Dr. Sacks testified that "accumulatively, [all the problems in the study] have an adverse impact on the validity of the results. . . . I don't think these results really support a statement that there was any benefit to the cardiovascular system or to perfusion, cardiovascular health." (PX0361 (Sacks, Dep. at 196); *see also* Sacks, Tr. 1625).

1393. 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. (PX0025-0016).

Response to Finding No. 1393:
Complaint Counsel has no specific response.

1394. 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"). (PX0025-0016; (CX1339 (Ornish, Dep. at 148-149)).

Response to Finding No. 1394:
Complaint Counsel disagrees. Dr. Ornish admitted that at least eight patients were unblinded before their three-month test dates – meaning the patients knew whether they were in the active or placebo groups. (CCFF ¶ 833). Study patients also received notices showing what group they were assigned to, and alerted the study staff to their assignments. (CCFF ¶ 833; *see also* CX0555 (Dr. Liker and Mr. Resnick were made aware of the unblinding problems).

1395. 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. (Ornish, Tr. 2345-46; (CX1339 (Ornish, Dep. at 148-149)).

Response to Finding No. 1395:
Complaint Counsel has no specific response.

1396. 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. (Ornish, Tr. 2346; (CX1339 (Ornish, Dep. at 148-149)).

Response to Finding No. 1396:
Complaint Counsel disagrees. The purpose of blinding is ensuring 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. Double-blinding is the blinding of both patients and investigators, which is optimal to prevent bias. (CCFF ¶ 777).

1397. 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. (Ornish, Tr. 2347).

Response to Finding No. 1397:
See Response to Finding 1396.

1398. Although these minor discrepancies were not optimal, they do not undermine the validity of the study or its conclusions. (PX0025-0016).

Response to Finding No. 1398:
Complaint Counsel disagrees with the conclusion drawn. All of the problems in design and conduct of this study, including the discrepant results of the SSS, SRS, and SDS measures, amount to the interpretation that this study had no effect on any measure of cardiac health, which is consistent with the principles of clinical study design and conduct. (CCFF ¶ 854).

(6) The Results of Dr. Ornish's Study Remain Valid Despite a Three-Month Testing Period

1399. Dr. Sacks notes that Dr. Ornish's study originally was designed to last for 12 months, with measurements at baseline, three months, and 12 months, but was halted after three months due to funding shortfalls. (CX1291_0023).

Response to Finding No. 1399:
Complaint Counsel does not disagree, but notes that the record shows that despite Dr. Ornish's insistence that his funding got cut, it appears PMRI experienced cost-over-runs. The agreed-to budget for the study was set at $708,437 as early as May 2003, which was the amount PMRI was paid. Dr. Ornish wanted to "quit while we were ahead" and halt the study on February 4, 2004. (CCFF ¶¶ 837, 839).

1400. Dr. Sacks speculates that the study was terminated under unusual circumstances because, according to correspondence, at the time, the p-value was considered significant rather than at the time the trial was originally set to end. (CX1291_0023-0024).

Response to Finding No. 1400:
Complaint Counsel agrees, and notes that the record evidence shows that Dr. Ornish terminated the study at 3 months, when the results were significant, rather than 12 months as originally designed. (CCFF ¶ 837).

1401. Dr. Sacks suggests the shortened study period and failure to report the planned duration is inconsistent with widely-accepted standards for conduct of clinical trials and undermines any confidence in the findings. (CX1291_0024; Sacks, Tr. 1474-75).

Response to Finding No. 1401:
Complaint Counsel agrees.

1402. 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. (PX0025-0017).

Response to Finding No. 1402:
Complaint Counsel does not disagree that Dr. Ornish stated such in his report, but notes that PMRI was paid the agreed-to amount of $708,437. (CCFF ¶ 839).

1403. 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. (PX0025-0017; Ornish, Tr. 2351-52).

Response to Finding No. 1403:
See Response to Finding 1402.

1404. 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. (PX0025-0017).

Response to Finding No. 1404:
See Response to Finding 1400.

1405. 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. (PX0025-0017).

Response to Finding No. 1405:
Complaint Counsel disagrees. Dr. Ornish wanted to "quit while we were ahead" and halt the study on February 4, 2004. (CCFF ¶ 837).

1406. 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. (PX0025-0017).

Response to Finding No. 1406:
The proposed finding is incomplete. Dr. Ornish noted that "[f]urther 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 of time." (PX0025-0017).

1407. Bias is not an issue because outside factors precluded obtaining twelve-month data. (PX0025-0017).

Response to Finding No. 1407:
Complaint Counsel disagrees with the conclusion drawn. The publish report did not disclose that the study was prematurely terminated before the 12 month plan. "[I]t's essential to state what the original plan and what was actually done. . . . Otherwise, the study could . . . develop bias." (CCFF ¶¶ 837, 853).

(7) The Results of Dr. Ornish's Myocardial Perfusion Study Remain Valid Despite Dr. Sacks' Overall Criticisms

1408. Dr. Sacks is not a cardiologist and not even an expert on technique Dr. Ornish used. (Sacks, Tr. 1591).

Response to Finding No. 1408:
The proposed finding mischaracterizes the record insofar as it is intended to suggest that Dr. Sacks is not fully qualified to provide expert opinions on subjects related to cardiovascular disease. Among other things, Dr. Sacks is a Professor of Cardiovascular

Disease Prevention at the Harvard School of Public Health; has taught Cardiovascular Disease Epidemiology and Nutrition and Cardiovascular Disease; has engaged in substantial research and writing related to CVD and CHD; has served as a principal investigator in federally-funded studies relating to nutrition and CVD/CHD; is the chair of the Nutrition Committee of the American Heart Association; is a member of an NIH panel that is revising national guidelines for the prevention and treatment of cardiovascular disease; and is a member of several professional societies relating to cardiovascular and coronary health. (CX1291_0001-02, 0005-07). In addition, Dr. Sacks was accepted as an expert in nutrition, cardiovascular disease, including coronary heart disease, cholesterol disorders, hypertension, and analysis of clinical studies. (Sacks, Tr. 1429).

1409. Despite his criticisms, Dr. Sacks nevertheless concedes that the concerns he raises regarding the unblinding of patients, the change in duration of the study, or the use of per protocol analysis are just demerits, none of which are fatal to the study. (Sacks, Tr. 1602-03; PX0361 (Sacks, Dep. at 201-202)).

Response to Finding No. 1409:
The proposed finding mischaracterizes Dr. Sacks' testimony. Dr. Sacks testified that "accumulatively, [all the problems in the study] have an adverse impact on the validity of the results. . . . I don't think these results really support a statement that there was any benefit to the cardiovascular system or to perfusion, cardiovascular health." (PX0361 (Sacks, Dep. at 196); *see also* Sacks, Tr. 1625).

1410. Dr. Sacks also tries to discredit Dr. Ornish's study on the grounds that other factors, such as blood pressure, cholesterol, inflammatory biomarkers, and oxidative stress were not improved. (CX1291_0024).

Response to Finding No. 1410:
Complaint Counsel agrees the study resulted in no improvements in blood pressure, cholesterol, inflammatory biomarkers, and oxidative stress. (CCFF ¶¶ 825, 829).

1411. 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).

Response to Finding No. 1411:
Complaint Counsel disagrees. These factors are considered as part of the evidence considered to support the conclusion that pomegranate juice treatment had no effect on any measure of cardiac health. (CX 1291 (Sacks, Report at 0024); CCFF ¶¶ 829, 854).

1412. Indeed, Dr. Sacks concedes the lack of statistical significance for a positive result is not proof of a negative. (Sacks, Tr. 1608).

Response to Finding No. 1412:
The proposed finding is incomplete. When asked about the results of individual studies, Dr. Sacks testified that a lack of statistical significance or positive result does not *prove* a negative. (*See e.g.*, Sacks Tr. 1608-09 (regarding Ornish CIMT study)). In this case, however, Respondents' RCTs repeatedly found no improvement in CIMT, blood pressure, and biomarkers of inflammation and oxidation. (CCFF ¶¶ 825, 829, 870-71, 882-84, 903-04, 918-19, 933, 942, 946-49, 951, 956, 960). Such evidence does not prove that the efficacy claims were affirmatively false, but it does substantially undermine the Respondents' weak affirmative evidence on efficacy. Further, this evidence supports the conclusion that the establishment claims were false.

1413. No single study is perfect and virtually all studies have limitations. (PX0025-0005).

Response to Finding No. 1413:
Complaint Counsel has no specific response.

1414. Dr. Ornish explains that an unbiased doctor could not throw out his positive myocardial perfusion study because of the criticisms raised by Dr. Sacks. (Ornish, Tr. 2351).

Response to Finding No. 1414:
Complaint Counsel has no specific response, except to note that cardiovascular disease experts would not consider this study to support the proposition that pomegranate juice

provides a heart disease benefit, either in terms of prevention or treatment. (CCFF ¶ 854).

(b) The Unpublished Beverage Study II, June 21, 2003 ("Bev II") (CX 754)

1415. Dr. Sacks complains that Dr. Ornish's unpublished Bev II Study, designed to measure CIMT in 200 patients for a period of one year, showed no statistically significant changes to CIMT, elasticity, blood pressure, body mass index, cholesterol, HDL, and TG at the end of the trial. (CX 754; Sacks, Tr. 1484-1486).

Response to Finding No. 1415:
Complaint Counsel agrees, but Complaint Counsel objects to the characterization of Dr. Sacks' testimony as complaining. Dr. Sacks made these accurate observations based on the study results. (CX0754; CCFF ¶¶ 857-58).

1416. 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. (Ornish, Tr. 2352).

Response to Finding No. 1416:
Complaint Counsel does not disagree Dr. Ornish testified as such.

1417. 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. (Ornish, Tr. 2352).

Response to Finding No. 1417:
Complaint Counsel does not disagree that Dr. Ornish testified the funding was cut, but notes that the cited evidence does not support the statement in the proposed finding that "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)".

1418. 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. (Ornish, Tr. 2352-54).

Response to Finding No. 1418:

The proposed finding is incomplete. Dr. Ornish testified that "what's unfortunate and perhaps a little ironic is that we did show in *one* of the measures in the carotid artery that there was an improvement, and it was significant to the 0.13 level as opposed to the 0.15 level. *If that degree of change had occurred in the larger number of patients that we had projected, . . . it would have been* a very strong study showing that pomegranate juice affected the progression of carotid disease." (Ornish, Tr. 2352-53 (emphasis added)).

1419. Dr. Sacks agrees that the Bev II Study concept and study design were fine and the measurements read by good institutions. (Sacks, Tr. 1603).

Response to Finding No. 1419:
Complaint Counsel does not disagree.

1420. 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. (Ornish, Tr. 2352-54).

Response to Finding No. 1420:
The proposed finding is incomplete. *See* Response to Finding 1418. (*See also* CCFF ¶¶ 869-70).

1421. In the Bev II Study, Dr. Ornish also found a similar, almost statistically significant improvement in the elasticity of the arteries. (Ornish, Tr. 2353).

Response to Finding No. 1421:
Complaint Counsel agrees Dr. Ornish testified as such, but notes that the study results showed that pomegranate juice treatment did not improve CIMT or the other tested parameters including elasticity. (CCFF ¶ 870).

1422. 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. (Ornish, Tr. 2353-54).

Response to Finding No. 1422:
Complaint Counsel agrees Dr. Ornish testified as such, but notes this is Dr. Ornish's hypothesis and he admits this is speculation on his part. (CCFF ¶ 872).

1423. 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. (PX0025-0019; (CX1339 (Ornish, Dep. at 70-71; 81-82).

Response to Finding No. 1423:
Complaint Counsel agrees Dr. Ornish states as such, but notes that the null results of the study are not rendered irrelevant by the fact that the study was smaller than originally planned. (CCFF ¶ 873).

1424. 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. (PX0025-0019).

Response to Finding No. 1424:
Complaint Counsel agrees Dr. Ornish states as such, but notes the null results of this study confirm that the purportedly positive results of Dr. Aviram's unrandomized, uncontrolled 19-patient CIMT/BP Study lack credibility. (CCFF ¶ 871). Consistent with the Ornish CIMT study results, Dr. Davidson's CIMT Study confirmed that pomegranate juice had no significant benefit on CIMT at 18 months. (CCFF ¶ 882).

1425. 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. (Sacks, Tr. 1607-08; PX0361 (Sacks, Dep. at 210)).

Response to Finding No. 1425:
The proposed finding is incomplete. Dr. Sacks testified that the study "may have been underpowered, it may not have been underpowered." (Sacks, Tr. 1607). In addition, Dr. Ornish hypothesized that if he had been provided funding for 200 patients, the study would not have been underpowered and would have shown a significant effect, but he admits this is speculation on his part. (CCFF ¶ 872).

1426. 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. (Sacks, Tr. 1608-09).

Response to Finding No. 1426:
The proposed finding is incomplete. Dr. Sacks also agreed that a lack of statistical significance means that pomegranate juice was not proven to work in this study. (Sacks, Tr. 1608-09).

4. Studies by Dr. Davidson and Colleagues

(a) Davidson MH, Maki KC, Dicklin MR, Feinstein SB, Witchger MS, Bell M, McGuire DK, Provost JC, Liker H, and Aviram M, 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) (PX0014)

(1) Dr. Sacks Cannot Dismiss Dr. Davidson's Findings Because the Composite Measure of CIMT Was Allegedly Not Listed as the Primary Outcome Endpoint in the Original Protocol

1427. Dr. Sacks criticizes Dr. Davidson's study because it reports a statistically significant change in the composite measurements of the IMT at 12 months (and statistically significant changes in the anterior and composite measurements in a certain subgroup of patients at 18 months), not the posterior wall measurements as purportedly identified in the study protocol. (CX1291_0027; Sacks, Tr. 1498; CX 716_0028; CX1336 Davidson Dep. at 10-11, 16)).

Response to Finding No. 1427:
The proposed finding mischaracterizes the record insofar as it suggests that Dr. Sacks did not consider the Davidson CIMT study to be carefully designed or well conducted. To the contrary, Dr. Sacks concluded that the Davidson CIMT study provided competent and reliable evidence that consumption of pomegranate juice did not improve CIMT in subjects with one or more cardiovascular risk factors. (*See* CCFF ¶ 903-904). The proposed finding mischaracterizes the record insofar as it suggests that the Davidson CIMT study found a statistically significant difference in CIMT progression *rates* at 12

months. In fact, the data show that there was *not* a statistically significant difference between the active and placebo groups in terms of CIMT progression rates at 12 months. (*See* CCFF ¶ 886, 906). Finally, the proposed finding is not supported by CX0716 and CX1336, neither of which mention Dr. Sacks.

1428. Although Dr. Sacks acknowledges that the composite rate for all measured carotid artery walls demonstrated a significantly smaller value at 12 months in the pomegranate juice group, he discounts the importance of this finding because (a) it was not the primary endpoint measure, and (b) "this difference was no longer significant at the end of the study." (Sacks, Tr. 1498-99; CX1291_0028; PX0025-0019).

Response to Finding No. 1428:
The proposed finding mischaracterizes the record. As Dr. Sacks explained, the absolute CIMT *value* in the POM Juice group was smaller than that of the placebo group at 12 months, but the CIMT progression *rate* was not between the two groups at that time or at 18 months. (*See* CCFF ¶ 885, 886, 906). Indeed, the Davidson CIMT report clearly states that the purpose of the study was to "assess the influence of pomegranate juice consumption on . . . (CIMT) progression *rates*." (CX1065_0001).

1429. Dr. Ornish explains, however, that the composite rate for all measured carotid artery walls should have been the primary endpoint measure in Dr. Davidson's study because it includes all measurements of CIMT, not just the posterior wall. (PX0025-0020).

Response to Finding No. 1429:
Complaint counsel does not disagree that Dr. Ornish made this statement.

1430. In his deposition, Dr. Davidson believed that 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)).

Response to Finding No. 1430:
The proposed finding mischaracterizes the evidence. Shortly after that, Dr. Davidson testified that the "composite" endpoint was first identified as the primary outcome variable in November 2005 (CX1336 (Davidson, Dep. at 140-43) (referring to CX0775_0007)). This was after he had conducted an Interim Analysis of data for the

first 150 patients to complete 12 months of the study and which showed that the "composite" of the *right and left anterior*, and *right and left posterior* common carotid artery had the most favorable results. (CX0775_0003). Until this time, the primary endpoint had been identified as difference between the POM and placebo groups in CIMT progression rates in the "left and right *posterior* wall" of the common carotid artery. (CX0775_0001; CX0716_0028). Nonetheless, this mid-course change in the endpoints did not turn out to be helpful to Respondents, as there was no significant difference in progression rates between the active and placebo groups at either 12 months or 18 months. (CCFF ¶¶ 882, 886).

1431. Another secondary outcome measure identified in the protocol was the composite CIMT, combining the common and internal carotid artery and carotid bifurcation. (CX1336 (Davidson, Dep. at 17); CX1291_0027).

Response to Finding No. 1431:
Complaint Counsel has no specific response except to note that the study did not, in fact, measure carotid bifurcation. (See CX1065_0001, Figure 1, showing that the "region of interest" was 1 cm from the bifurcation).

1432. Here, Dr. Davidson's composite measure was clearly stated *a priori* as a secondary hypothesis in the study protocol: "The secondary outcome variables will include the difference 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 (Smilde 2001), in mm/year." (PX0025-0020; CX0716_0028).

Response to Finding No. 1432:
Complaint Counsel has no specific response except to note that the study did not measure carotid bifurcation. See Response to Finding 1431.

1433. Dr. Sacks concedes that secondary outcome variables are included in a clinical trial because they are often considered to be an important secondary manifestation of disease secondary to what is declared as primary. (PX0361 (Sacks, Dep. at 212).

Response to Finding No. 1433:
Complaint Counsel has no specific response.

1434. Dr. Sacks confirms that the use of secondary outcome variables are generally accepted method in conducting clinical trials. (PX0361 (Sacks, Dep. at 213).

Response to Finding No. 1434:
Complaint Counsel has no specific response.

1435. Dr. Sacks admits that when a secondary outcome variable is stated in advance, this increases the credibility of the result because it eliminates the chance of cherry picking results that are later found to be positive. (PX0361 (Sacks, Dep. at 213).

Response to Finding No. 1435:
Complaint Counsel has no specific response.

1436. As such, Dr. Davidson's finding at 12 months is not likely to be just a chance finding of having measured lots of different parameters; it is the most clinically meaningful. (PX0025-0020).

Response to Finding No. 1436:
Complaint Counsel has no specific response except to note that there was no statistically

significant difference between the POM and placebo groups in the rate of change in

composite CIMT rates at 12 months or 18 months. (*See* CCFF ¶¶ 882, 886).

1437. Because Dr. Davidson's composite measure was listed as a secondary outcome, Dr. Sacks cannot conclude that the findings were somehow "due to chance." (PX0025-0020).

Response to Finding No. 1437:
See Response to Finding 1436.

1438. Dr. Sacks also admits that one reason that the posterior wall CIMT was chosen as the primary endpoint initially was not because it was the best measure, but because it was easier to obtain: "One reason to use posterior wall measurements as the primary outcome is that they do not require injection of a contrast agent like anterior wall measurements do." (CX1291_0029; PX0025-0020).

Response to Finding No. 1438:
See Response to Finding 1436.

1439. Because the investigators were successful in obtaining anterior wall measurements on a larger group of patients than expected, it would be extreme to say that this finding was not important or clinically relevant simply because it was not stated as the primary endpoint measure *a priori* but was stated as a secondary endpoint measure a priori. (PX0025-0020).

Response to Finding No. 1439:

See Response to Finding 1436.

1440. By examining the composite measurement, Dr. Davidson did not believe this calculation would be the most likely to present a positive result, but simply that it would give him more walls and more power to seen an effect if there was one. (CX1336 (Davidson, Dep. at 142)).

Response to Finding No. 1440:
See Response to Finding 1430.

(2) The Lack of a Statistical Significance Finding at 18 months Does Not Diminish Dr. Davidson's Study or the Conclusion that Pomegranate Juice Can Affect Arterial Plaque

1441. Dr. Sacks complains there was no significant effect of pomegranate juice on CIMT of the anterior, posterior, or composite carotid artery at the end of the trial. (Sacks, Tr. 1491).

Response to Finding No. 1441:
Complaint Counsel objects to the characterization of Dr. Sacks' testimony as complaining. Dr. Sacks accurately reported Dr. Davidson's findings as set forth in CX1065. (*See also* CCFF ¶ 882).

1442. The fact that differences in the composite measurement of CIMT were not statistically significant at 18 months does not change the fact that these differences were statistically significant after 12 months. (PX0025-0020; PX0014-0005).

Response to Finding No. 1442:
The proposed finding mischaracterizes the record in suggesting that there was a difference in the composite progression rate at 12 months; as set forth in CCFF ¶ 886, there was only a trend (p=0.0544) at this point. *See also* Responses to Findings 1427 and 1428.

1443. Dr. Davidson's protocol called for measurements at both 12 months and 18 months. (Heber, Tr. 1980-81).

Response to Finding No. 1443:
Complaint Counsel agrees.

1444. A likely explanation for the difference in the CIMT progression rate for the intervention group could be that compliance for drinking pomegranate juice declined significantly after the first year. (PX0025-0020; PX0014-0005).

Response to Finding No. 1444:
The proposed finding is unsupported, as it reflects pure speculation. (*See* CCFF ¶ 907; PX0025 (Ornish, Rep. at 0021) (stating that "these explanations are speculative")).

1445. 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).

Response to Finding No. 1445:
Complaint Counsel has no specific response.

1446. 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).

Response to Finding No. 1446:
The proposed finding mischaracterizes the record insofar as it is designed to support a conclusion that there were compliance issues in the Davidson CIMT study. *See* Response to Finding 1444.

1447. It is also possible that patients in the control group may have started drinking pomegranate juice after one year. (PX0025-0020).

Response to Finding No. 1447:
The proposed finding is mischaracterizes the record insofar as it is designed to support a conclusion that there were compliance issues in the Davidson CIMT study. *See* Response to Finding 1444.

1448. Although there was not objective evidence of noncompliance, Dr. Davidson believes the fact that the antioxidant measures were positive at 52 weeks, but not positive at the end of the study, suggests that the subjects may have not been taking the pomegranate juice at the end of the study. (CX1336 (Davidson, Dep. at 174-75)).

Response to Finding No. 1448:
The proposed finding is mischaracterizes the record. First, participants in the Davidson CIMT study completed diaries showing study product consumption. (CCFF ¶ 880). Dr. Davidson evaluated the diaries, and they showed high levels of compliance. (CCFF ¶ 907). Dr. Davidson agreed that possibility of noncompliance was simply a "hypothesis"

(CX 1336 (Davidson, Dep. at 198)), and that because there was no evidence to support the hypothesis, the issue was not discussed in the published study. (CX1336 (Davidson, Dep. at 188)).

1449. The indeterminate result at 18 months is not proof of the negative; it does not prove that pomegranate juice does not have an effect. (Heber, Tr. 1981).

Response to Finding No. 1449:
Complaint Counsel does not disagree that Dr. Heber made that statement, but refers to Responses to Findings 49 and 50. Further, the proposed finding mischaracterizes the record insofar as it suggests that the result at 18 months was "indeterminate;" instead, the results provided strong evidence that POM Juice did not improve CIMT in subjects with one or more cardiovascular risk factors. (*See* CCFF ¶¶ 903-05).

1450. If a hypothesis is not proved in a particular study, it does not mean the hypothesis is wrong; it just means the researcher did not prove it in that study. (Heber, Tr. 1981).

Response to Finding No. 1450:
Complaint Counsel does not disagree that Dr. Heber made that statement, but refers to Responses to Findings 49 and 50.

(3) The Lack of Statistical Significance re other Biomarkers

1451. Dr. Sacks complains there were no significant effects of pomegranate juice compared to the control group on measures of inflammation and oxidative stress, including blood pressure and TBARS. (Sacks, Tr. 1492-93; CX1291_0028).

Response to Finding No. 1451:
Complaint Counsel objects to the characterization of Dr. Sacks' testimony as complaining. Dr. Sacks accurately reported the results of these measures, contained in Dr. Davidson's study report. Complaint Counsel agrees that the study results showed no significant effects of pomegranate juice on blood pressure and on seven measures of inflammation and oxidative stress, including two measures of TBARS and PON. (CX1065_0003, Table 2).

1452. Dr. Sacks also speculates that Dr. Davidson's study did not replicate improvement in LDL oxidation, increase in paraoxonase activity, and decrease in TBARS found in Dr. Aviram's studies. (Sacks, Tr. 1507).

Response to Finding No. 1452:
Complaint Counsel disagrees to the characterization of Dr. Sacks' testimony as "speculation," as Dr. Sacks' testimony accurately reports the results of the Davidson study. (*See* CX1065_0003, Table 2).

1453. 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).

Response to Finding No. 1453:
The proposed finding mischaracterizes the record. There was no statistically significant improvement in the composite CIMT in the overall study sample. (CCFF ¶ 882).

1454. 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).

Response to Finding No. 1454:
Complaint Counsel does not disagree that Dr. Heber made that statement, but refers to Response to Finding 50.

1455. Dr. Sacks concedes that the absence of positive results with respect to indicators of inflammation of oxidative stress, fasting lipoproteins, or blood pressure does not prove the negative. (PX0361 (Sacks, Dep. at 223-24)).

Response to Finding No. 1455:
Complaint Counsel does not disagree that Dr. Sacks made that statement, but refers to Response to Finding 50.

(4) Post Hoc or Subgroup Analyses Like Dr. Davidson's, Are Commonly Done and Provide Useful Information

1456. Dr. Sacks challenges Dr. Davidson's post hoc analysis, in which Dr. Davidson found a statistically significant lower anterior and/or composite IMT progression rates at the end of the study in a certain subgroup of patients, because it was not "pre-planned" and because patients with metabolic syndrome within that subgroup did not show a benefit. (CX1291_0028-30).

Response to Finding No. 1456:
Complaint Counsel agrees. (*See also* CCFF ¶¶ 887, 908-11).

1457. 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).

Response to Finding No. 1457:
The proposed finding mischaracterizes the evidence insofar as it is designed to support a conclusion that the subgroup data substantiates Respondents' advertising. The subgroup data must be confirmed in a future investigation. (CCFF ¶¶ 887, 908-11).

1458. 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).

Response to Finding No. 1458:
Complaint Counsel does not disagree that Dr. Ornish made this assertion, but refers to Response to Finding 1457.

1459. 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).

Response to Finding No. 1459:
Complaint Counsel does not disagree that Dr. Ornish made this assertion, but refers to Response to Finding 1457.

1460. In scientific research, post-hoc analysis is routine. (Heber, Tr. 1984).

Response to Finding No. 1460:
Complaint Counsel agrees, but refers to Response to Finding 1457.

1461. 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)).

Response to Finding No. 1461:
Complaint Counsel agrees, but refers to Response to Finding 1457.

1462. Dr. Davidson commonly performs subgroup analyses in the studies in which he is the lead investigator. (CX1336 (Davidson, Dep. at 221)).

Response to Finding No. 1462:
Complaint Counsel agrees but refers to Response to Finding 1457.

1463. 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)).

Response to Finding No. 1463:
Complaint Counsel agrees but refers to Response to Finding 1457.

1464. 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).

Response to Finding No. 1464:
See Response to Finding 1457.

1465. 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).

Response to Finding No. 1465:
See Response to Finding 1457.

1466. 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)).

Response to Finding No. 1466:
See Response to Finding 1457.

1467. Dr. Sacks does not discount Dr. Davidson's subgroup analysis. ((PX0361 (Sacks, Dep. at 268)).

Response to Finding No. 1467:
The proposed finding is incomplete. Dr. Sacks stated, "I've already discussed in detail the issues of the subgroup analysis and I'm not discounting it. I think it just needs to be tested in another study for it to attain validity." (PX0361 (Sacks, Dep. at 268)). Sacks also stated that "most subgroup analysis don't turn out to be true, and . . . that's why they have to be confirmed." (Sacks, Tr. 1615).

1468. 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)).

Response to Finding No. 1468:
See Response to Finding 1457.

1469. 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).

Response to Finding No. 1469:
The proposed finding mischaracterizes Dr. Heber's testimony. Dr. Heber specifically stated that if there's a potential benefit in this study, "you could definitely communicate that *in your publication*." (Heber, Tr. 1984-85 (emphasis added)). This is significantly different than advertising the *post hoc* results to the public.

1470. 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).

Response to Finding No. 1470:
The proposed finding is unsupported by the cited evidence.

1471. 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).

Response to Finding No. 1471:
Complaint Counsel has no specific response except to note that (1) Respondents' 2009 Medical Research Portfolio Review stated that there was no CIMT improvement in the overall population, and that there was only a 2-5% decrease in the "hi-risk" category (CCFF ¶ 902); and (2) Respondents' advertising touted a 30% plaque reduction in its advertising until at least 2009. (CCFF ¶ 674).

1472. 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)).

Response to Finding No. 1472:

Complaint Counsel has no specific response except to note that there is a common sense distinction between advertising that represents that a product has efficacy for heart disease, and a doctor's recommendation within the confines of the doctor-patient relationship to try a particular product or intervention.

1473. The subgroup in which a benefit was found is a group having more oxidative stress, so there was more likely to see a benefit in that subgroup. (CX1336 (Davidson, Dep. at 222)).

Response to Finding No. 1473:
Complaint Counsel has no specific response except to refer to Response to Finding 1457.

1474. The benefits occurred at a composite endpoint, but they also appeared directionally in the same way for both the anterior and posterior wall, which means there are two artery walls showing the same consistent effect. (CX1336 (Davidson, Dep. at 222)).

Response to Finding No. 1474:
Complaint Counsel has no specific response except to refer to Response to Finding 1457.

1475. There was also a benefit on the inflammatory marker of CRP, which is a surrogate for cardiovascular disease. (CX1336 (Davidson, Dep. at 222)).

Response to Finding No. 1475:
Complaint Counsel has no specific response except to refer to Response to Finding 1457.

1476. There were two independent biomarkers showing an effect in the same subgroups, which leads Dr. Davidson to believe the benefit in these subgroups are real and need to be verified with further research. (CX1336 (Davidson, Dep. at 221-22)).

Response to Finding No. 1476:
Complaint Counsel agrees. (*See also* CCFF ¶ 900 (Respondent document estimating that the probability of success of follow-up study in high-risk subjects to be "20-80%")).

1477. Dr. Davidson also notes that when researchers try to look at an effect of a treatment, they have to make sure they are using it in the patients that are having a problem that the treatment can address. (CX1336 (Davidson, Dep. at 222-23)).

Response to Finding No. 1477:
Complaint Counsel agrees that Dr. Davidson so stated.

1478. 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)).

Response to Finding No. 1478:
Complaint Counsel agrees that Dr. Davidson so stated; however, Respondents estimated that the likelihood of success in a future trial ranged between 20-80%. (*See* CCFF ¶ 900).

1479. 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)).

Response to Finding No. 1479:
Complaint Counsel agrees that Dr. Davidson so stated.

(5) Correcting for Multiple Comparisons Was Not Necessary

1480. Dr. Sacks critiques Dr. Davidson's study on the grounds that no correction for multiple comparisons were made. (Sacks, Tr. 1504-05).

Response to Finding No. 1480:
Complaint Counsel objects to the characterization of Dr. Sacks' statement that there was no correction for multiple comparisons as a "critique." (See Sacks, Tr. 1504-05). Indeed, Dr. Davidson's publication specifically 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." (*See* CCFF ¶ 887).

1481. According to Dr. Davidson, it was not appropriate to make any corrections for multiple comparisons because he already stated in the study that these were hypothesis-generating findings. (CX1336 (Davidson, Dep. at 81)).

Response to Finding No. 1481:
The proposed finding is not supported by the cited evidence. Dr. Davidson did *not* state that it was "not appropriate" to do the corrections. Instead, he said that it was "appropriate not to" have to make the correction for multiple comparisons since the publication said that the subgroup analysis was exploratory and hypothesis generating. (CX1336 (Davidson, Dep. at 81)).

1482. Dr. Sacks concedes that many researchers do not correct for multiple comparisons in their studies. (PX0361 (Sacks, Dep. at 228)).

Response to Finding No. 1482:
The proposed finding is incomplete. At trial, Dr. Sacks explained, "Correction for multiple comparisons, it's especially important when a high degree of confidence in the results is needed. Now, when is that? Well, you need a high degree of confidence in the results when you want to make a public health recommendation or to recommend that . . .people change their behavior, like drink a particular juice to improve their health. Then you need to adhere to a high standard, and a high standard requires correcting for multiple comparisons. Now, if you do an exploratory study of various mechanisms, then . . .it's not so critical." He also explained that the subgroup data in the Davidson study are not adequate to support claims that POM Juice or POMx prevent, reduce the risk of or treat cardiovascular disease or coronary heart disease in the subpopulations identified in Figure 3 of Dr. Davidson's IMT report. (Sacks, Tr. 1506-07; CX1065_0005, Figure 3).

(6) Dr. Sacks Cannot Challenge a Benefit to the High-Risk Subgroup Based on Data from the Metabolic Syndrome Group

1483. In Dr. Davidson's study, a subgroup of patients demonstrated a 4 to 9 percent statistically significant improvement in CIMT at the end of the study, depending on whether one looked at the anterior or posterior wall of the artery in terms of thickness. (Heber, Tr. 1982).

Response to Finding No. 1483:
Complaint Counsel has no specific response, except to refer to Response to Finding 1480.

1484. Dr. Sacks complains, however, that the pomegranate juice subjects with metabolic syndrome were not among the sub-populations who had significantly lower CIMT values after treatment. (CX1291_0028).

Response to Finding No. 1484:
Complaint Counsel objects to the characterization of Dr. Sacks' testimony as complaining. Dr. Sacks accurately stated, based on review of Dr. Davidson's data, that

pomegranate juice subjects with metabolic syndrome were not among the sub-populations who had significantly lower CIMT values after treatment. (CX1291_0028; CX1065).

1485. Metabolic syndrome is an umbrella term, which probably affects 50 percent of people between the ages of 45 and 65, and includes anyone with three of the five criteria, such as increased waist circumference, high blood sugar, high blood pressure, high triglycerides, and low HDL. (Heber, Tr. 2006).

Response to Finding No. 1485:
The proposed finding is also consistent with Dr. Sacks' statements: at least 3 of the criteria must be met. (CX1291_0028-29).

1486. The subgroup in Dr. Davidson's study included people with high triglycerides and low HDL cholesterol. (Heber, Tr. 2006).

Response to Finding No. 1486:
The proposed finding is unsupported by the cited evidence.

1487. Individuals with these factors typically have metabolic syndrome, suffering from high triglyceride and low HDL, and meeting one other criteria like a large waist circumference, a high blood sugar, an intermediate range or high blood pressure. (Heber, Tr. 2006).

Response to Finding No. 1487:
The proposed finding is unsupported by the cited evidence.

1488. The measure of high triglyceride is the most sensitive index of increased oxidative stress, so a high triglyceride/low HDL population would make sense as the group that would have increased oxidative stress and would benefit more from the consumption of pomegranate juice. (Heber, Tr. 2006).

Response to Finding No. 1488:
Complaint Counsel has no specific response, except to refer to CX1291 (Sacks, Report at_0029) (stating that "the finding that pomegranate juice did not significantly reduce the CIMT progression rate in patients. . .who had metabolic syndrome suggests that high-risk patients are not necessarily benefitted by the treatment.").

1489. In criticizing Dr. Davidson, Dr. Sacks contradicts himself: although he claims post hoc analyses are not reliable, he must think that post hoc analyses have scientific value even if not at the same level of rigor as endpoint measures declared *a priori*, so he undercuts

his earlier, more extreme argument that the statistically significant improvements in composite rate for all measured carotid artery walls should not be considered as valid evidence. (PX0025-0022).

Response to Finding No. 1489:
Complaint Counsel has no specific response to this argument made in Dr. Ornish's expert report, as it represents a mischaracterization of Dr. Sacks' report.

1490. The finding that pomegranate juice did not significantly reduce CIMT in metabolic syndrome patients does not detract from the fact that there were significantly lower CIMT progression rates for pomegranate versus control subjects at the end of the study in certain subpopulations with higher CVD risk factors, such as those in the highest tertiles for apolipoprotein B, TG, TG to HDL ratio, total cholesterol to HDL ratio, as well as a purported marker of antioxidant function, PD-AAPH. (PX0025-0022).

Response to Finding No. 1490:
Complaint Counsel has no specific response except to refer to CCFF ¶¶ 887, 908-11.

1491. In addition, the fact that pomegranate juice did reduce carotid artery blockages in subgroups with these cardiac risk factors is not diminished by the fact that it did not reduce carotid artery blockages in all subgroups of risk factors, such as those with metabolic syndrome. (PX0025-0022).

Response to Finding No. 1491:
Complaint Counsel has no specific response except to refer to CCFF ¶¶ 887, 908-11.

1492. These are of interest more from the standpoint of having a better understanding of the mechanisms by which pomegranate juice may be beneficial than on whether or not pomegranate juice is beneficial in reducing carotid artery blockages (atherosclerosis). (PX0025-0022).

Response to Finding No. 1492:
Complaint Counsel has no specific response except to refer to CCFF ¶¶ 887, 908-11.

1493. The "bottom line" is improvements (reductions) in carotid artery blockages from drinking pomegranate juice, which were statistically significant in composite rate for all measured carotid artery walls in these patients. (PX0025-0022).

Response to Finding No. 1493:
Complaint Counsel has no specific response except to refer to CCFF ¶¶ 887, 908-11.

1494. Dr. Sacks concedes that subgroup benefited in Dr. Davidson's study could include millions of people in the United States alone, but still takes the extreme position that such information cannot be disseminated. (Sacks, Tr. 1613-16).

Response to Finding No. 1494:

Complaint Counsel objects to the characterization of Dr. Sacks' testimony as "extreme." Further, the proposed finding is incomplete and mischaracterizes the record. Dr. Sacks stated that the subgroup data were in fact in the public domain, published as part of Dr. Davidson's study, but that the key issue is how to interpret them. Both Dr. Sacks and Dr. Davidson stated that the subgroup data need to be confirmed in a future investigation (Sacks, Tr. 1613-16; CX1065_0006). As Dr. Sacks noted, most subgroup analyses don't turn out to be true. (Sacks, Tr. 1615).

(7) Conclusions

1495. Dr. Sacks' overall criticisms of the Davidson study are without merit. (PX0025-0019-0021; *infra* RFF 1427-1494).

Response to Finding No. 1495:
The proposed finding mischaracterizes the record. Dr. Sacks stated that Davidson's CIMT study was carefully designed and that there was no evidence of critical problems in the conduct or analysis of the study, except its over-emphasis on the subgroup results. He opined that the Davidson CIMT study provides competent and reliable evidence that consumption of pomegranate juice did not improve CIMT in subjects with one or more cardiovascular risk factors. (CCFF ¶ 903). Dr. Stampfer concluded "it seems clear that this is a null study, and that's what the authors concluded." (CCFF ¶ 904). Drs. Ornish and Heber also agreed that the study showed no significant effect on overall CIMT progression rates. (CCFF ¶ 905).

1496. Dr. Davidson's study was conducted and evaluated in an objective manner by people qualified to do so. (CX1336 (Davidson, Dep. at 227)).

Response to Finding No. 1496:
Complaint counsel agrees.

1497. Dr. Davidson has recommended pomegranate juice or POMx to patients who fit the high-risk profile. (CX1336 (Davidson, Dep. at 225)).

Response to Finding No. 1497:
Complaint counsel agrees. This recommendation by a medical professional to a patient, however, does not support the conclusion that Respondents' efficacy claims are substantiated.

1498. There are no adverse risks of taking pomegranate juice. (CX1336 (Davidson, Dep. at 226)).

Response to Finding No. 1498:
The proposed finding mischaracterizes the evidence. Dr. Davidson said that he had not identified any such risks. (CX1336 (Davidson, Dep. at 226)). *See also* Response to Finding 201.

1499. To see the effect of an antioxidant therapy like pomegranate juice, the intervention needs to be used in a population with high oxidative stress, and the more oxidative stress present, the more likely it will be to see a benefit with the treatment. (CX1336 (Davidson, Dep. at 228-29)).

Response to Finding No. 1499:
Complaint Counsel has no specific response.

1500. Testing an intervention in populations with higher levels of oxidative stress has been in a theme in Dr. Davidson's findings and it is consistent with other research. (CX1336 (Davidson, Dep. at 228-29)).

Response to Finding No. 1500:
Complaint Counsel has no specific response.

1501. Dr. Davidson's study does not suggest in any way that pomegranate juice affirmatively does not benefit the heart. (CX1336 (Davidson, Dep. at 229)).

Response to Finding No. 1501:
Complaint Counsel has no specific response except to refer to Response to Finding 50.

1502. Nobody at POM or Roll ever suggested anything to Dr. Davidson regarding this study that he thought was scientifically unsound or inappropriate. (CX1336 (Davidson, Dep. at 230)).

Response to Finding No. 1502:
Complaint Counsel has no specific response.

1503. Dr. Davidson's study was approved and published in a reputable journal, which meant that editors were satisfied with the responses to the reviewers comments. (CX1336 (Davidson, Dep. at 230)).

Response to Finding No. 1503:
Complaint Counsel agrees. *See* CCFF ¶ 890-891 and 887, with regard to the reviewer's comments and the careful way in which Dr. Davidson qualified his findings.

1504. A peer-reviewed journal would have only published Dr. Davidson's study if it believed the data was worth publishing and significant. (CX1352 (Heber, Dep. at 199-200)).

Response to Finding No. 1504:
Complaint Counsel has no specific response.

(b) Dr. Davidson's Unpublished "BART" (or Flow-Mediated Vasolidation) Study

1505. Brachial artery reactivity testing or "BART" is a measurement of how much the brachial artery dilates (enlarges) after a blood pressure cuff is inflated, and then released. This is also called flow mediated dilation ("FMD") testing. (JX 3; CX1336 (Davidson, Dep. at 34-35)).

Response to Finding No. 1505:
Complaint Counsel agrees; *see also* CCFF ¶ 912.

1506. The brachial artery is a major blood vessel of the arm. (JX 3).

Response to Finding No. 1506:
Complaint Counsel agrees; *see also* CCFF ¶ 912.

1507. Flow mediated dilation (or "FMD") is the amount by which the brachial artery dilates (gets larger) after the blood pressure cuff is deflated. (JX 3).

Response to Finding No. 1507:
Complaint Counsel agrees; *see also* CCFF ¶ 912.

1508. Dr. Davidson studied the effect of POM pomegranate juice on 45 patients (from his IMT study) for 13 weeks using the BART measurement. (PX0019; CX1336 (Davidson, Dep. at 37)).

Response to Finding No. 1508:
Complaint Counsel agrees; *see also* CCFF ¶¶ 912-19.

1509. At the end of 13 weeks, no statistically significant differences were observed between or within the treatment groups. (PX0019; Sacks, Tr. 1510; CX1336 (Davidson, Dep. at 87)).

Response to Finding No. 1509:
Complaint Counsel agrees; *see also* CCFF ¶¶ 912-19 with regard to the BART/FMD findings with regard to blood pressure, ACE, PON, and TBARS, none of which changed significantly following pomegranate juice consumption.

1510. Although he acknowledges that Dr. Davidson's BART study was carefully designed and did not have any critical problems, Dr. Sacks complains that BART is not a reliable marker of heart health, although of interest, is not a valid or generally recognized surrogate marker of coronary heart disease. (1291_0031; Sacks, Tr. 1510-11).

Response to Finding No. 1510:
Complaint Counsel objects to the characterization of Dr. Sacks' testimony as complaining. Further, Dr. Sacks stated that although BART/FMD is not a reliable marker of surrogate health, the study does provide relevant information. FMD is a measure of nitric oxide; if pomegranate juice meaningfully affected nitric oxide metabolism, one would have expected to see a positive result in the FMD testing. (*See* CCFF ¶¶ 916-19).

1511. Dr. Sacks also suggests that Dr. Davidson's BART study showed no effect on blood pressure or ACE, which is somehow inconsistent with Dr. Aviram's prior research. (Sacks, Tr. 1512-13).

Response to Finding No. 1511:
Complaint Counsel agrees that the Davidson BART study findings as to blood pressure and ACE contradict Dr. Aviram's ACE/BP findings. (CCFF ¶ 917).

1512. In response, if Dr. Sacks believes that "brachial artery reactivity, although of interest, is not a valid or generally recognized surrogate marker of coronary heart disease," then the study's findings that there were no statistically significant differences between the groups is irrelevant. (PX0025-0024).

Response to Finding No. 1512:
The proposed finding mischaracterizes the record for the reasons stated in CCFF ¶¶ 916-19.

1513. 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)).

Response to Finding No. 1513:
See Response to Finding 50.

5. The Overweight Study Conducted by Dr. Heber and Dr. Hill Demonstrates POMx's Safety and Antioxidant Effect and Does Not Contradict Respondents' Previous Scientific Research

1514. In 2007, in a study entitled "Safety and Antioxidant Activity of Pomegranate Ellagitannin-Enriched Polyphenol Dietary Supplement in Overweight Individuals with Increased Waist Size" by Dr. Heber, et al., J. Agric. Food Chem. 2007, 55, 10050–10054, 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. (CX0934).

Response to Finding No. 1514:
Complaint Counsel has no specific response except to refer to CCFF ¶¶ 920-43.

1515. 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. (CX0934).

Response to Finding No. 1515:
The proposed finding mischaracterizes the record. According to the study protocol and the clinical study report, the San Diego arm of the study was designed to measure changes in antioxidant levels due to POMx consumption. (*See* CCFF ¶¶ 929-31; CX0819, CX0859). At the end of the study, there were no significant changes in the markers of oxidant stress or inflammation that were measured. (*See* CCFF ¶¶ 929-31; CX0819, CX0859). Dr. Heber's insistence on calling the San Diego site the "safety site" (CX0934_0003), and his willingness to publish an article on the results of the Denver and San Diego studies without making reference to the null results of the antioxidant measures in the latter studies supports the conclusion that Dr. Heber's long relationship with Respondents has impaired his professional independence. (*See also* CCFF ¶¶ 724-25).

1516. 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." (CX0934_0003).

Response to Finding No. 1516:
Complaint Counsel has no specific response.

1517. At the Denver site, where antioxidant activity was measured, 22 overweight subjects received two POMx capsules per day for four weeks. (CX0934_0003).

Response to Finding No. 1517:
Complaint Counsel has no specific response except to refer to CCFF ¶¶ 922-28 and 940-41.

1518. 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. (CX0934_0003-0004).

Response to Finding No. 1518:
Complaint Counsel does not disagree that Dr. Heber made this assertion in the published report. (CX0934_0003-04). However, according to the Preliminary Data Analysis, the change in TBARS was "of borderline significance [and had] not been adjusted for the number of comparisons made." (*See* CCFF ¶ 926).

1519. In conducting this study, Dr. Hill decided that TBARS (would be the best measure of antioxidant activity after reviewing literature and consulting with colleagues, specifically researchers at the National Jewish Hospital who have expertise in antioxidant activity. (CX 1342; Hill, Dep. at 41-42))

Response to Finding No. 1519:
Complaint Counsel has no specific response.

1520. A higher level of TBARS is bad while a lower level of TBARS is good. (CX 1342; Hill, Dep. at 42)).

Response to Finding No. 1520:
Complaint Counsel has no specific response.

1521. Together, the authors concluded that POMx is safe and effective in reducing oxidative stress in humans through the measure of TBARS. (CX0934_0004).

Response to Finding No. 1521:

The proposed finding mischaracterizes the record and is incomplete. The finding of efficacy in CX0934 was based on the uncorrected TBARS data from the unblinded, unrandomized Denver site. When Dr. Heber submitted the manuscript to the journal for publication, however, he was aware that the data from the blinded, controlled San Diego site showed no change in the markers of oxidative stress and inflammation that were measured, including C-reactive protein, oxidized phospholipids, lipoprotein (a), and nitric oxide. Dr. Heber did not include this information in the published report. (CCFF ¶¶ 933-38; CX0934). Dr. Heber's insistence on calling the San Diego site the "safety site" (CX0934_0003), his failure to report that the TBARS data in the Denver site was of borderline significance and uncorrected, and his willingness to publish an article on the results of the Denver and San Diego studies without making reference to the null results of the antioxidant measures in the latter studies supports the conclusion that Dr. Heber's long relationship with Respondents has impaired his professional independence. (*See* CCFF ¶¶ 724-27, 926, 929-938).

(b) Dr. Sacks' Complaints Regarding the Denver Site Study Lack Merit

1522. Although he acknowledges there was a decrease in TBARS, Dr. Sacks complains the change in TBARS was of only borderline significance and that the analysis was not adjusted for the number of comparisons being made. (Sacks, Tr. 1514; CX1291_0033).

Response to Finding No. 1522:
Complaint Counsel objects to the characterization of Dr. Sacks' testimony as complaining. Dr. Sacks made these accurate observations based on a review of the study data analysis contained in Dr. Hill's Preliminary Data Analysis. (See CX0877_0002-03; CCFF ¶¶ 925-28).

1523. Dr. Sacks also complains that at the Denver site, the other factors measured –including diastolic and systolic blood pressure, TG, HDL, LDL, CRP, and PON – did not change during the trial. (CX1291_0033).

Response to Finding No. 1523:
Complaint Counsel objects to the characterization of Dr. Sacks' testimony as complaining. *See* Response to Finding 1522.

1524. Dr. Sacks further points to a preliminary data report which suggests the researchers "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." (CX1291_0033).

Response to Finding No. 1524:
See Response to Finding 1522.

1525. Finally, Dr. Sacks suggests that the lack of a control group renders the study's finding unreliable. (CX1291_0035).

Response to Finding No. 1525:
See Response to Finding 1522 and CCFF ¶¶ 940-41.

(2) Even If Considered a "Pilot" Study, the Results Are Still Valid

1526. 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. (CX1342 (Hill, Dep. at 48)).

Response to Finding No. 1526:
Complaint Counsel does not disagree that Dr. Hill so testified. Nonetheless, Complaint Counsel objects to Dr. Hill's testimony insofar as he offers expert opinion testimony. Dr. Hill was not qualified as an expert, and indeed, Respondents did not produce him for examination at trial, although he was identified on Respondents' witness list. Accordingly, pursuant to Federal Rule of Evidence 701, his testimony must be disregarded to the extent that he attempts to offer opinions that are based on scientific, technical, or other specialized knowledge within the scope of Federal Rules of Evidence 702.

1527. 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. (CX1342 (Hill, Dep. at 48)).

Response to Finding No. 1527:

See Response to Finding 1526.

1528. If there is no effect shown, then this allows the investigators to address any concerns regarding the study. (CX1342 (Hill, Dep. at 46-47)).

Response to Finding No. 1528:
See Response to Finding 1526.

1529. In short, there is no difference between a pilot study and regular study if there is statistical significance. (CX1342 (Hill, Dep. at 49)).

Response to Finding No. 1529:
See Response to Finding 1526.

1530. In Dr. Hill's study, the effect was large enough that he saw a statistically significant difference. (CX1342 (Hill, Dep. at 47)).

Response to Finding No. 1530:
See Response to Finding 1526.

1531. If he received a difference that was not significant, then Dr. Hill would not have been able to publish his results. (CX1342 (Hill, Dep. at 47)).

Response to Finding 1531:
See Response to Finding 1526.

1532. A "pilot" study does not mean that it is not as scientifically valid as a larger study. (PX1339 (Ornish, Dep. at 23; 119-20).

Response to Finding No. 1532:
Complaint Counsel objects to the deposition testimony (PX1139 (Ornish, Dep. at 23)) cited in the proposed finding as non-designated testimony. The proposed finding is unsupported by the other cited evidence, because in the designated testimony on that page, Dr. Ornish stated that an unblinded, uncontrolled study is "a pilot study in the sense that it is was premature study. You can't really draw any real conclusions from it." (PX1139 (Ornish, Dep. at 119-20)).

(3) The Lack of a Placebo Control Group Does Not Render the Results Unreliable

1533. In a pre/post test design, the effect of an intervention is measured on a person before and after he/she receives the intervention. (CX1342 (Hill, Dep. at 45)).

Response to Finding No. 1533:
Complaint Counsel does not disagree.

1534. In a control group design, one group would receive the intervention while another group would receive a placebo, and the results of both groups would then be compared. (CX1342 (Hill, Dep. at 45)).

Response to Finding No. 1534:
Complaint Counsel does not disagree.

1535. Neither the pre/post nor control group design is a better than the other. (CX1342 (Hill, Dep. at 45)).

Response to Finding No. 1535:
See Response to Finding 1526. Dr. Hill was not qualified as an expert in this matter.

(*See also* CCFF ¶¶ 773-75 (elements of an RCT)).

1536. The two approaches are apples and oranges: each provides different information, 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. (CX1342 (Hill, Dep. at 100-101, 133)).

Response to Finding No. 1536:
See Response to Finding 1526.

1537. A placebo-controlled trial is more costly and requires a lot more effort to conduct. (CX1342 (Hill, Dep. at 45)).

Response to Finding No. 1537:
See Response to Finding 1526.

1538. Given that Dr. Hill did not have information that would allow him to adequately power this trial, the pre/post trial design was the most efficient approach and would provide the outcome needed. (CX 1342 (Hill, Dep. at 45-46)).

Response to Finding No. 1538:
See Response to Finding 1526.

1539. 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. (CX 1342 (Hill, Dep. at 131)).

Response to Finding No. 1539:
See Response to Finding 1526.

1540. To suggest that "the lack of a control group render its findings unreliable" is to belie the premise of a pilot study, which is to generate preliminary findings that can be used to justify doing a larger, more expensive intervention with a control group. (PX0025-0024)

Response to Finding No. 1540:
Complaint Counsel agrees that Dr. Ornish made the statement that the purpose of a pilot study is to generate preliminary findings that can be used to justify doing a larger, more expensive intervention with a control group. (PX0025 (Ornish, Report at 0024)).

Further, Complaint Counsel notes that when Respondents attempted to replicate the Denver TBARS in larger, controlled studies, their efforts were repeatedly unsuccessful. (*See* CCFF ¶¶ 825, 884, 949).

(4) Adjusting for the Number of Comparisons Made Is Not Common Among the Scientific Community

1541. The analysis or adjustment for comparisons made is a very conservative approach and not always made. (CX 1342 (Hill, Dep. at 102-103, 141)).

Response to Finding No. 1541:
See Responses to Findings 1482 and 1526.

1542. In fact, it is probably more frequently not made, than made. (CX 1342 (Hill, Dep. at 102-103, 141)).

Response to Finding No. 1542:
See Responses to Findings 1482 and 1526.

1543. 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)).

Response to Finding No. 1543:
See Responses to Findings 1482 and 1526.

(5) The Absence of Statistically Significant Changes in Certain Lipids, Which Are Not Primary Endpoints, Does Not Prove the Negative

1544. At the Denver site, as a safety issue, heart rate and blood pressure were measured just to make sure there were no problems among the patients. (CX 1342 (Hill, Dep. at 71-72)).

Response to Finding No. 1544:

See Response to Finding 1526.

1545. If there was a subject who had a very high heart rate, then he or she would be tested. (CX 1342 (Hill, Dep. at 71-72)).

Response to Finding No. 1545:
Complaint Counsel has no specific response.

1546. Similarly, if someone had an elevated blood pressure, he or she would be sent to a doctor and not used in the study. (CX 1342 (Hill, Dep. at 71-72)).

Response to Finding No. 1546:
Complaint Counsel has no specific response.

1547. In his deposition and at trial, Dr. Sacks repeatedly conceded that the absence of positive information of change, does prove the negative. (RFF 1455, 1513, 1553).

Response to Finding No. 1547:
Complaint Counsel has no specific response except to refer to Response to Finding 50.

(6) Dr. Sacks' Criticisms Regarding the San Diego Site Study Should Be Dismissed

1548. Although he concedes that Dr. Heber's San Diego study is "well-designed" and "there is no evidence of problems with its conduct," Dr. Sacks complains that the study measured the markers of oxidized phospholipids, oxidized LDL/HDL, serum nitric oxide, PON, and others, none of which, according to Dr. Sacks, are valid surrogate marker of cardiovascular disease or response of disease to treatment. (CX1291_0034-0035).

Response to Finding No. 1548:
Complaint Counsel objects to the characterization of Dr. Sacks' testimony as a complaint.

Dr. Sacks was called upon to provide his expert testimony regarding the evidence, and he

did so in an objective and knowledgeable fashion. His testimony with regard to the lack

of change in the markers measured is fully consistent with Dr. Heber's findings in

CX1254. (CCFF ¶ 933).

1549. Dr. Sacks also argues that Dr. Heber's San Diego study did not show (or include) any statistically significant changes in nitric oxide measures, blood pressure, inflammatory or antioxidant markers. (Sacks, Tr. 1516-29).

Response to Finding No. 1549:

Dr. Sacks objects to the characterization of Dr. Sacks' testimony as arguing. Further, the proposed finding mischaracterizes the record. The San Diego RCT included measures of nitric oxide, blood pressure, and inflammatory/antioxidant markers measures, and the data showed that there were no statistically significant changes in these markers at the end of the study. (Sacks, Tr. 1516-19; CCFF ¶¶ 929-33). Dr. Heber's published article, which purported to report on the results at both the uncontrolled Denver site and the controlled San Diego site, did not make any reference to the antioxidant/inflammatory data obtained from the San Diego Site. (CCFF ¶¶ 937-38).

1550. Dr. Heber, however, properly qualified his safety findings when he wrote: "This study demonstrates in *preliminary* fashion that a pomegranate ellagitannin enriched polyphenol (POMx) dietary supplement is safe when ingested by healthy human subjects in amounts up to 1420 mg/day providing a total of 870 mg of GAEs/day for 28 days. No adverse events related to the dietary supplement consumption or changes in hematology, serum chemistry, or urinalyses were observed." (PX0025-0025; CX0934_0004).

Response to Finding No. 1550:
Complaint Counsel has no specific response.

1551. In this context, Dr. Heber's comments about this study are appropriately qualified and accurate. (PX0025-0025).

Response to Finding No. 1551:
The proposed finding is incomplete and, as a result, mischaracterizes the record. Dr. Ornish also stated that he assumed that Dr. Heber was citing the Denver study regarding efficacy and the San Diego study regarding safety. He "agreed with Dr. Sacks that the San Diego study did not demonstrate efficacy since there were no significant changes in biomarkers." (PX0025-0025).

1552. Contrary to Dr. Sacks' assertions, the study did evaluate the biomarker of TBARS, which as Dr. Heber wrote, is "strongly predictable of cardiovascular events in people with stable coronary artery disease, independent of traditional risk factors and inflammatory markers." (PX0025-0025; CX0934_0004).

Response to Finding No. 1552:

The proposed finding mischaracterizes the record insofar as it suggests that Dr. Sacks asserted that the Denver study did not measure TBARS. (*See* CX1291 (Sacks, Report at 0033)).

1553. With respect to the lack of significantly significant changes with respect to blood pressure and other biomarkers, such as TG, HDL, LDL, CRP, and PON, Dr. Sacks concedes the absence of information does not prove the negative. (PX0361 (Sacks, Dep. at 238; 243)).

Response to Finding No. 1553:
See Response to Finding 50.

6. Dr. Sacks Cannot Summarily Dismiss Respondents' Diabetes Studies on the Grounds That They Are Not RCTs

1554. Respondents have sponsored numerous studies evaluating the effect of pomegranate juice and/or its derivatives on persons with diabetes. (PX0038; PX0127; PX0128; CX 0765; CX1055).

Response to Finding No. 1554:
Complaint Counsel has no specific response except to note that PX0128 is a mouse study involving pomegranate oil and that PX0038 and CX0765 do not state that they were sponsored by Respondents; indeed, CX0765 states that it was sponsored by D-Cure.

1555. The antioxidant effect of pomegranate juice is likely to be observed in persons with diabetes because they have the highest level of oxidative stress among all cardiovascular patients. (CX1348 (Aviram, Dep. at 54)).

Response to Finding No. 1555:
The proposed finding is unsupported by the cited evidence. Further, Complaint Counsel objects to Dr. Aviram insofar as he offers expert opinion testimony. Dr. Aviram was not qualified as an expert, and indeed, Respondents did not produce him for examination at trial, although he was identified on Respondents' witness list. Accordingly, pursuant to Federal Rule of Evidence 701, his testimony must be disregarded to the extent that he attempts to offer opinions that are based on scientific, technical, or other specialized knowledge within the scope of Federal Rules of Evidence 702.

1556. Dr. Sacks attempts to discredit the value of three of Respondents' diabetes studies—PX0038 (Concentrated Pomegranate Juice Improves Lipid Profiles in Diabetic Patients with Hyperlipidemia); PX0127 (Consumption of Wonderful Variety Pomegranate Juice and Extract by Diabetic Patients Increases Paraoxonase 1 Association with High-Density Lipoprotein and Stimulates Its Catalytic Activities); CX0765 (Anti-oxidative effects of pomegranate juice (P J) consumption by diabetic patients on serum and on macrophages)—on the grounds that they are not RCTs, the study size is too small, and duration is too limited in scope. (CX1291_036-37; Sacks, Tr. 1521-1523).

Response to Finding No. 1556:
Complaint Counsel agrees with the finding except insofar as it uses the phrase "attempts to discredit." As Dr. Sacks opined, these studies are not RCTs, and the study sizes were too small, and of too limited duration, to show that pomegranate juice, which is high in sugar, is safe for consumption by diabetics. Additionally, they did not provide reliable scientific support for claims that POM Juice or POMx prevents, reduces the risk of, or treats heart disease. (CX1291 (Sacks, Report at 0035-37)).

1557. Dr. Sacks suggests that a qualified scientist cannot conclude that changes reported in these studies were due to pomegranate juice or POMx consumption because, without a control group, one does not know if the observed changes are due to the pomegranate agent or just would have happened that way. (Sacks, Tr. 1523).

Response to Finding No. 1557:
Complaint Counsel agrees that Dr. Sacks opined, with regard to PX0127, CX0765, and a second study by Dr. Esmaillzadeh, that the results were not reliable because, among other things, they did not include a control group. (Sacks, Tr. 1521-24; CX1291 (Sacks, Report at 0035-37)).

1558. In conclusion, Dr. Sacks suggests that none of the published studies on pomegranate products by diabetics provide scientific support for claims that POM juice or POMx prevents, reduces the risk of, or treats heart disease. (Sacks, Tr. 1524).

Response to Finding No. 1558:
Complaint Counsel agrees that Dr. Sacks so concluded, but objects insofar as the finding uses the term "suggests." Moreover, when Dr. Heber attempted to test the POM Products

on diabetics in an RCT, he was not able to show significant differences so he did not publish the study. (CCFF ¶¶ 846-49).

1559. 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).

Response to Finding No. 1559:
Complaint Counsel objects to reliance on the testimony of Dr. Aviram to support expert opinion for the reasons set forth in Response to Finding 1555. Insofar as it relates to Dr. Heber and Dr. Ornish, the proposed finding is unsupported by the cited evidence and mischaracterizes the record. Further, to the extent that Drs. Heber and Ornish now make the argument that RCTs are not necessary, such testimony represents revisionist history. Dr. Heber repeatedly sought and obtained funding from Respondents to conduct RCTs on their juice and extracts, and he never told Respondents that RCTs were not appropriate or necessary or appropriate to study the effects of those products on various areas of health. (CCFF ¶¶ 1110-11). Similarly, when called upon to test the health benefits of POM Juice, Dr. Ornish developed and conducted two RCTs; indeed, he takes credit for encouraging the Resnicks to do these studies. (CCFF ¶¶ 822, 824, 855, 1118).

7. Respondents' Scientific Research on Cardiovascular Health Is Not Inconsistent

(a) The Findings by Dr. Aviram and Dr. Davidson on IMT Are Not Contradictory

1560. Dr. Davidson's finding of a 4 to 9% improvement in a subgroup of high risk patients without significant plaque is consistent with Dr. Aviram's 30% improvement in people with significant plaque and stenosis. (Heber, Tr. 1975-76; 1983-84).

Response to Finding No. 1560:
Complaint Counsel does not disagree that Dr. Heber so testified. It should be noted, however, that Drs. Ornish and Sacks agreed that the conclusions of Dr. Aviram's CIMT study "should be interpreted with caution due to the study's limitations." (PX0025

(Ornish, Report at 0011); CX1291 (Sacks, Report at 0019)). Furthermore, neither Dr. Davidson's nor Dr. Ornish's CIMT RCTs showed a statistically significant improvement in CIMT. (CCFF ¶ 951).

1561. In the 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. (Heber, Tr. 1975-76; 1983-84).

Response to Finding No. 1561:
Complaint Counsel has no specific response except to note the substantial limitations of Dr. Aviram's CIMT study, of which Respondents were aware. (CCFF ¶¶ 805-21).

1562. The general definition of plaque is 1.5 millimeters in thickness of the CIMT. (Heber, Tr. 1980).

Response to Finding No. 1562:
Complaint Counsel has no specific response.

1563. The average thickness of the CIMT in Dr. Davidson's his patients in the study was .85 millimeters. (Heber, Tr. 1980)

Response to Finding No. 1563:
Complaint Counsel has no specific response except to note that the target audience for Respondents' advertising was not limited to people with actual plaque or stenosis; rather it consisted of "people that have heart disease or cancer in their family, or have a fear of having it themselves." (CCFF ¶ 300).

1564. Dr. Davidson's protocol actually excluded people with significant stenosis or plaque from his study. (Heber, Tr. 1819).

Response to Finding No. 1564:
See Response to Finding 1563.

1565. As a result, Dr. Aviram and Dr. Davidson's studies are really apples and oranges: they used the same surrogate (CIMT) in a different group of patients. (Heber, Tr. (Heber, Tr. 1975-76).

Response to Finding No. 1565:
See Responses to Findings 1561 and 1563.

1566. 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. (Heber, Tr. 1983-84).

Response to Finding No. 1566:
See Responses to Findings 1561 and 1563.

1567. As a result, seeing a smaller result in the at-risk group than in the carotid artery stenosis group is not that surprising. (Heber, Tr. 1983-84).

Response to Finding No. 1567:
Complaint Counsel has no specific response except to refer to Response to Finding 1561.

1568. 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. (CX_1348 (Aviram, Dep. at 74)).

Response to Finding No. 1568:
Insofar as Dr. Aviram is offering expert opinion evidence, *see* Response to Finding 1559.

1569. Dr. Davidson does not believe that his findings contradict any of the previous studies conducted by Dr. Aviram, Dr. Sumner, Dr. Ornish, Dr. Ignarro, Dr. Kaplan, or Dr. Rosenblat and he believes his findings are consistent. (CX1336 (Davidson, Dep. at 227-228)).

Response to Finding No. 1569:
Complaint Counsel reiterates the objection, made at the deposition, that this testimony reflects expert opinion from a fact witness. (CX1336 (Davidson, Dep. at 227-228)). Further, it mischaracterizes the evidence as Dr. Davidson was not speaking about all of the evidence by Drs. Aviram, Ignarro, Kaplan, or Rosenblat that have been identified by Respondents in their Proposed Finding 1100. (*Compare* CX1336 (Davidson, Dep. at 227-228 *with* Respondents' Proposed Finding 1100).

(b) Dr. Aviram's Positive Findings on Blood Pressure Are Not Contradicted by Subsequent Research Sponsored by Respondents

1570. 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).

Response to Finding No. 1570:

Complaint Counsel does not disagree that Dr. Heber so testified.

1571. 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).

Response to Finding No. 1571:
Complaint Counsel does not disagree that Dr. Heber so testified; however, he also admitted that "he does not know what kind of evidence experts in the field would require to support a claim that a product could lower blood pressure." (*See* CCFF ¶ 728). Further, there is *no* indication Dr. Aviram's studies, reporting on blood pressure results, used "special equipment and personnel." (*See* CX0542 and CX0611).

1572. In Dr. Ornish's myocardial perfusion study, the primary endpoint was blood flow, not blood pressure, so one cannot conclude there was no effect of pomegranate juice on blood pressure in his study. (Heber, Tr. 2101-02; PX0353 (Heber, Dep. at 173)).

Response to Finding No. 1572:
The proposed finding mischaracterizes the record. As noted in Response to Finding 1571, Dr. Heber lacks expertise with regard to blood pressure. Further, this testimony does not appear consistent with Dr. Heber's assertion that one must look to the "entire body of scientific evidence;" the "totality of scientific. . .evidence that is competently performed." (PX0192-0044; Heber, Tr. 2058). Dr. Ornish himself concluded that "blood pressure. . .did not improve" in this study. (PX0025 (Ornish, Report at 17)).

1573. In Dr. Davidson's BART study, the primary endpoint was flow-mediated dilation, not blood pressure, and therefore any results for blood pressure cannot be relied upon as negative evidence to the contrary. (Heber, Tr. 2106-07; PX0353 (Heber, Dep. at 173)).

Response to Finding No. 1573:
The proposed finding mischaracterizes the record. As previously noted, Dr. Heber lacks expertise with regard to blood pressure and asserted that one must consider the "entire body of scientific evidence." *See* Response to Finding 1571. If only the data from the "primary endpoint" of a study is relevant, it is contradictory that Dr. Heber is willing to

rely on the PSADT and plasma nitric oxide levels in the Pantuck prostate cancer study (*compare* Heber, Tr. 2141 and PX0192 (Heber, Report at 0027)) *with* CX0666 (Pantuck protocol identifying PSADT and laboratory endpoints as "secondary"), or the SDS results in the Ornish MP Study, which were not specifically identified as an endpoint for the study (*compare* PX0192 (Heber, Report at 0037) *with* CCFF ¶ 845).

XV. RESPONDENTS' PROSTATE HEALTH CLAIMS ARE SUBSTANTIATED

1577. 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. (PX0161; PX0353 (Heber, Dep. at 84-85); deKernion, Tr. 3126; PX0351 (deKernion, Dep. at 41-42); Heber, Tr. 2012).

Response to Finding No. 1577:
Complaint Counsel has no specific response except to note that Respondents' expert Dr. deKernion did not dispute that there are no clinical studies, research and/or trials proving these claimed benefits. (*See* CCFF ¶ 1038).

1578. Additionally, competent and reliable scientific evidence supports the conclusion that 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 the Challenged Products inhibit the clinical development of prostate cancer cells in men who have not been diagnosed. (deKernion, Tr. 3126; PX0351 (deKernion, Dep. at 76-77); PX0206 at 12; Heber, Tr. 2156).

Response to Finding No. 1578:
The proposed finding is unsupported by the record as a whole in that: 1) the POM Products have not been studied in healthy men to determine their effect on prostate cancer; 2) Respondents' expert Dr. deKernion testified that there is no clinical study proving that the POM Products prevent or reduce the risk of prostate cancer; and 3) Respondents have admitted that they have "no data on prostate cancer prevention, prior to radiation or prostatectomy." (*See* CCFF ¶¶ 1000, 1010, 1017-1018, 1022, 1026, 1037-1038, 1047).

1579. Further, because pomegranate juice is a fruit and not a pharmaceutical drug, physicians who treat patients concerned with prostate health would not hold pomegranate juice to the standards of safety and efficacy traditionally required by the FDA for approval of a pharmaceutical (performance of a large, randomized, double-blind, placebo controlled clinical trial ("RCT")) before recommending pomegranate juice to their patients. (PX0206).

Response to Finding No. 1579:
The proposed finding is unsupported by the cited evidence.

A. Summary of Complaint Counsel's Allegations Regarding Respondents Prostate Health Advertisements

1580. Complaint Counsel allege that Respondents have falsely represented, expressly or by implication, that clinical studies, research, and/or trials prove that:

> C. Drinking eight ounces of POM Juice, or taking one POMx Pill or one teaspoon of POMx Liquid, daily, prevents or reduces the risk of prostate cancer, including by prolonging prostate-specific antigen doubling time ("PSADT"); and
>
> D. Drinking eight ounces of POM Juice, or taking one POMx Pill or one teaspoon of POMx Liquid, daily, treats prostate cancer, including by prolonging PSADT. (CX1426_0018-0020).

Response to Finding No. 1580:
Complaint Counsel has no specific response except to note that the proposed finding does not accurately restate the allegations in the Complaint.

B. Respondents Deny Complaint Counsel's Allegations That Their Advertisements Are False and Misleading

1581. 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 reduces the risk of prostate cancer and (2) treats prostate cancer. (PX0364-0004-0006).

Response to Finding No. 1581:
Complaint Counsel agrees that Respondents made this denial in their Answer, but Complaint Counsel disagrees with this conclusion.

1582. Respondents dispute Complaint Counsel's allegations or characterizations regarding Respondents' science and aver there is substantial scientific research indicating the health benefit of their products and substantiating their advertising and promotional materials. (PX0364-0004-0006).

Response to Finding No. 1582:
Complaint Counsel agrees that Respondents made this denial in their Answer, but

Complaint Counsel disagrees with this conclusion.

1583. Respondents deny Complaint Counsel's allegations that their advertising and promotional materials make the claim that drinking eight ounces of POM Juice, or taking one POMx Pill or one teaspoon of POMx Liquid, daily (1) prevents or reduces the risk of prostate cancer, including by prolonging PSADT; (2) treats prostate cancer, including by prolonging PSADT. (PX0364-0004-0006).

Response to Finding No. 1583:
Complaint Counsel agrees that Respondents made this denial in their Answer, but

Complaint Counsel disagrees with this conclusion.

C. Competent and Reliable Scientific Evidence Supports Respondents' Claims

1. Overview of Pomegranates and its Effects on Prostates

(a) Prostate Function and Prostate Cancer

1584. The prostate is a gland that's located in the male pelvis that is an organ of sexual function and fertility. (Eastham, Tr. 1236).

Response to Finding No. 1584:
Complaint Counsel agrees.

1585. Prostate cancer occurs when cells of the prostate, typically the glandular cells, become cancerous, which means they have uncontrolled cell growth. (Eastham, Tr. 1236).

Response to Finding No. 1585:
Complaint Counsel agrees.

1586. Last year about 220,000 men were diagnosed with prostate cancer in the United States. (Eastham, Tr. 1237).

Response to Finding No. 1586:
Complaint Counsel agrees.

1587. Approximately one in six men over the age of 60 will be diagnosed with prostate cancer each year. (Eastham, Tr. 1238-39).

Response to Finding No. 1587:
Complaint Counsel agrees.

1588. The average age of prostate cancer diagnosis is in the sixties. (Eastham, Tr. 1239).

Response to Finding No. 1588:
Complaint Counsel agrees.

1589. About 30,000 men die from prostate cancer each year. (Eastham, Tr. 1239).

Response to Finding No. 1589:
Complaint Counsel agrees.

1590. Although there has been a trend toward improved survival, prostate cancer remains the second most common cause of cancer death in men in the United States, accounting for 11% of all cancer deaths. (PX0061).

Response to Finding No. 1590:
The proposed finding is unsupported by the cited evidence.

1591. Prostate cancer does not have a typical course. (Eastham, Tr. 1236).

Response to Finding No. 1591:
Complaint Counsel agrees.

1592. There are many prostate cancers that, while they are seen under the microscope they do not represent a threat to the life expectancy or the quality of life of the patient. (Eastham, Tr. 1236).

Response to Finding No. 1592:
Complaint Counsel agrees.

1593. Blood levels of prostate specific antigen (PSA) are measured in healthy men to assess their risk of prostate cancer. (Stampfer, Tr. 774).

Response to Finding No. 1593:
Complaint Counsel agrees.

1594. PSA is a protein that's derived almost exclusively from the prostate and is widely used for screening for the risk of prostate cancer. (Stampfer, Tr. 774).

Response to Finding No. 1594:
Complaint Counsel agrees.

1595. PSA is also used after diagnosis of prostate cancer to monitor the progression of disease. (Stampfer, Tr. 774).

Response to Finding No. 1595:
Complaint Counsel agrees.

1596. For men that have low or intermediate-risk prostate cancer or even some high-risk patients, patients that have clinically localized disease, meaning, based on a clinical evaluation of the man that the cancer is only in the area of the prostate, but it's of a risk that is beyond monitoring, those men are candidates for potentially curative therapies. (Eastham, Tr. 1237).

Response to Finding No. 1596:
Complaint Counsel agrees.

1597. The two mainstays of cure are either radical prostatectomy, surgical removal of the prostate, or radiation therapy to the prostate. (Eastham, Tr. 1237; PX0061-0001).

Response to Finding No. 1597:
Complaint Counsel agrees.

1598. Although this is adequate for permanent disease control in many patients, a significant number of patients relapse and ultimately develop metastatic disease. (PX0061-0001).

Response to Finding No. 1598:
The proposed finding is unsupported by the cited evidence.

1599. However, approximately one third of prostate cancer patients with clinically confined cancer that are treated with radical prostatectomy will develop a biochemical recurrence. (PX0061-0001).

Response to Finding No. 1599:
Complaint Counsel agrees but notes that the proposed finding is unsupported by the cited evidence. (*See* CCFF ¶ 979).

1600. There are limited treatment options for patients who have undergone primary therapy with curative intent and who have progressive elevation of their PSA without documented evidence of metastatic disease. (PX0061-0002).

Response to Finding No. 1600:
The proposed finding is unsupported by the cited evidence.

1601. Early initiation of hormonal ablation is associated with significant morbidity and effect on quality of life, including fatigue, hot flashes, loss of libido, decreased muscle mass, and osteoporosis with long-term use. (PX0061-0002).

Response to Finding No. 1601:
The proposed finding is unsupported by the cited evidence.

1602. Strategies to delay clinical prostate cancer progression and prolong the interval from treatment failure to hormonal ablation would be of paramount importance. (PX0061-0002).

Response to Finding No. 1602:
The proposed finding is unsupported by the cited evidence.

1603. A combination of epidemiologic and basic science evidence strongly suggests that diet and plant-derived phytochemicals may play an important role in prostate cancer prevention or treatment. (PX0061-0002).

Response to Finding No. 1603:
The proposed finding is unsupported by the cited evidence.

1604. Epidemiologic studies suggest that a reduced risk of cancer is associated with the consumption of a phytochemical-rich diet that includes fruits and vegetables. (PX0061-0002).

Response to Finding No. 1604:
The proposed finding is unsupported by the cited evidence.

1605. Fresh and processed fruits and food products contain high levels of a diverse range of phytochemicals of which polyphenols, including hydrolyzable tannins (ellagitannins andgallotannins) and condensed tannins (proanthocyanidins), and anthocyanins and other flavonoids make up a large proportion. (PX0061- 0002).

Response to Finding No. 1605:
The proposed finding is unsupported by the cited evidence.

1606. Several phytochemicals have been proposed as potential chemoprevention agents based on animal and laboratory evidence of antitumor effects. (PX0061-0002).

Response to Finding No. 1606:
The proposed finding is unsupported by the cited evidence.

1607. Suggested mechanisms of anticancer effects of polyphenols include the inhibition of cancer cell growth by interfering with growth factor receptor signaling and cell cycle progression, promotion of cellular differentiation, modulation of phosphodiesterase/ cyclooxygenase pathways, inhibition of kinases involved in cell signaling, and inhibition of inflammation. (PX0061-0002).

Response to Finding No. 1607:
The proposed finding is unsupported by the cited evidence.

(b) Mechanism of Action of Pomegranates in the Prostate

1608. The pomegranate (Punica granatum L.) fruit has been used for centuries in ancient cultures for its medicinal purposes. (PX0061-0002).

Response to Finding No. 1608:
The proposed finding is unsupported by the cited evidence.

1609. Pomegranate fruits are widely consumed fresh and in beverage forms as juice and wines. Commercial pomegranate juice shows potent antioxidant and antiatherosclerotic properties attributed to its high content of polyphenols, including ellagic acid in its free and bound forms (as ellagitannins and ellagic acid glycosides), gallotannins, and anthocyanins (cyanidin, delphinidin, and pelargonidin glycosides) and other flavonoids (quercetin, kaempferol, and luteolin glycoside). (PX0061-0002).

Response to Finding No. 1609:
The proposed finding is unsupported by the cited evidence.

1610. The most abundant of these polyphenols is punicalagin, an ellagitannin implicated as the bioactive constituent responsible for >50% of the potent antioxidant activity of the juice. Punicalagin is abundant in the fruit husk and, during processing, is extracted into pomegranate juice in significant quantities reaching levels. (PX0061-0002).

Response to Finding No. 1610:
The proposed finding is unsupported by the cited evidence.

1611. Ellagic acid and tannins have been shown previously to exhibit in vitro and in vivo anticarcinogenic properties, such as induction of cell cycle arrest and apoptosis, as well as the inhibition of tumor formation and growth in animals. (PX0061-0002).

Response to Finding No. 1611:
The proposed finding is unsupported by the cited evidence.

(2) In Vivo Research Has Demonstrated That POM Reduces Inflammation in Prostate Tumors (Inflammation in the Human Is A Key Step in Prostate Cancer Progression)

1612. For centuries, pomegranates have been used in traditional Chinese medicine as anti-inflammatory agents. (PX01929-0016, 0018).

Response to Finding No. 1612:
The proposed finding is unsupported by the cited evidence.

1613. A large body of literature has linked inflammation to prostate carcinogenesis at all stages of the development of prostate cancer from normal tissue to advanced cancer. (PX0192 at 0029; PX0070-0001).

Response to Finding No. 1613:
Complaint Counsel has no specific response.

1614. Inflammation in the human is a key step in prostate cancer progression. (CX1352 (Heber, Dep. at 257-258); PX0070-0001).

Response to Finding No. 1614:
Complaint Counsel has no specific response.

1615. Areas of chronic inflammation are almost universally present in pathologic specimens of the prostate, including biopsy cores in men prior to the diagnosis of prostate cancer, transurethral resection chips, and total prostatectomy specimens. (PX0192-0029).

Response to Finding No. 1615:
Complaint Counsel has no specific response.

1616. 98 percent of prostate tumors removed at surgery for cancer have evidence of inflammation. (CX1352 (Heber, Dep. at 257-258); PX0192-0029-0030).

Response to Finding No. 1616:
Complaint Counsel has no specific response.

1617. In vivo research has demonstrated that POM reduces inflammation in the prostate tumor. (CX1352 (Heber, Dep. at 257-258); Heber, Tr. 1992).

Response to Finding No. 1617:
Complaint Counsel has no specific response.

(3) In Prostate Cancer Tumors Treated with POM, Nuclear Factor Kappa B Decreased Causing a Decrease in Tumor Growth

1618. One of the most well-established signaling pathways mediating inflammatory responses relevant to cancer is the nuclear factor-κB (NF-κB) pathway. (PX0192-0030; deKernion, Tr. 3046-47; Heber, Tr. 1992; PX0070-00001).

Response to Finding No. 1618:
Complaint Counsel does not disagree that Dr. Heber and Dr. deKernion testified as such.

1619. This unique protein was the subject of Nobel Prize-winning research by Dr. David Baltimore who identified the protein's unique ability to both receive a signal from the outside of a cell and translate that signal into genetic programming of inflammatory proteins that secreted by cells. (PX0192-0030; Heber, Tr. 1992).

Response to Finding No. 1619:
Complaint Counsel does not disagree that Dr. Heber testified as such.

1620. The activity of NF-κB is regulated by another protein inhibitor called IκB, which binds to and sequesters NF-κB family members in the fluid part of the cell away from DNA called the cytoplasm. (PX0192-0030; PX0070-0001).

Response to Finding No. 1620:
Complaint Counsel has no specific response except to note that the study cited involved

in vitro and animal research.

1621. When the NF-κB pathway is activated, IκB is chemically modified by an enzyme called IκB kinase, which adds a phosphorus atom at specific amino acids on the IkB protein (serine residues 32 and 36). (PX0192-0030; PX0070-0001).

Response to Finding No. 1621:
Complaint Counsel has no specific response except to note that the study cited involved

in vitro and animal research.

1622. Once altered the inhibitory protein IκB is degraded and NF-κB is free to move to the nucleus, where it functions to activate genetic mechanisms after binding to DNA resulting in the secretion of proinflammatory signaling proteins. (PX0192-0030; PX0070- 0001).

Response to Finding No. 1622:
Complaint Counsel has no specific response except to note that the study cited involved

in vitro and animal research.

1623. While normal activation of NF-κB is temporary in response to a stimulus meant to activate immune function, constant or constitutive activation has been observed in breast cancer, liver cancer, melanoma, Hodgkin's disease, and cervical cancer. (PX0192 -0030; PX0070-0001).

Response to Finding No. 1623:
Complaint Counsel has no specific response except to note that the study cited involved

in vitro and animal research.

1624. Direct genetic evidence in mouse models of colon and liver cancer have established that NF-κB activation within tumor cells or infiltrating inflammatory cells is required for tumor initiation or promotion. (PX0192-0030; PX0070-0001).

Response to Finding No. 1624:
Complaint Counsel has no specific response except to note that the study cited involved

in vitro and animal research.

1625. Importantly, activation of NF-κB is observed in primary prostate cancer specimens as evidenced by its presence in the nucleus of cells where the genes reside and represents an independent risk factor for recurrence of prostate cancer after radical prostatectomy. (PX0192-0030; PX0070-0001).

Response to Finding No. 1625:
Complaint Counsel has no specific response except to note that the study cited involved *in vitro* and animal research.

1626. Pomegranate extract (PE) has been shown to inhibit NF-κB in normal human cells, including chondrocytes, epidermal keratinocytes, and vascular endothelial cells. (PX0192 -0031; PX0070-0002).

Response to Finding No. 1626:
Complaint Counsel has no specific response except to note that the study cited involved animal research. Moreover, Dr. deKernion conceded that even where the *in vitro* and animal evidence is strong and shows that an agent's mechanism of action works, this evidence does not prove that the agent works in humans. (deKernion, Tr. 3063-64). Data from RCTs provide the best evidence of a causal relationship between a nutrient and a disease outcome in humans. (*See* CCFF ¶¶ 763-71).

1627. Pomegranate extract inhibits both continuous (constitutive) and stimulated (cytokineinduced)NF-κB activity in prostate cancer cells *in vitro*. Importantly, the NF-κB-inhibitory effect of pomegranate extract was necessary for the maximal cell killing effects of PE. (PX0192-0031; Heber, Tr. 1993; PX0070-0002).

Response to Finding No. 1627:
See Response to Finding 1626.

1628. In tumors treated with pomegranate extract the NF-kappaB decreased, therefore causing decrease of tumor growth. (deKernion, Tr. 3046-47; Heber, Tr. 1993).

Response to Finding No. 1628:
Complaint Counsel does not disagree that Dr. deKernion and Dr. Heber testified as such.

1629. There is an absolute linear connection between the polyphenol mechanisms in pomegranate extract and the decrease in tumor growth. (deKernion, Tr. 3046-47; Heber, Tr. 1993).

Response to Finding No. 1629:
Complaint Counsel does not disagree that Dr. deKernion and Dr. Heber testified as such.

1630. NF-Kappa B is not the only mechanism of action of pomegranate polyphenols, but it is one of the major ones accounting probably anywhere from 70 to 85 percent of the inhibition of prostate cancer cell growth in cell culture. (PX0353 (Heber, Dep. at 122)).

Response to Finding No. 1630:
Complaint Counsel does not disagree that Dr. Heber testified as such.

1631. The mechanisms of action of the Challenged Products on inflammation and nuclear factor kappa B, contributes to the total body of research constituting competent and reliable scientific evidence that the Challenged Products, supports prostate health and could play a role in prevention. (PX0161 at 0011-0012; PX0353 (Heber, Dep. at 84-91); PX0192 - 0031; PX0206-0012; PX0070).

Response to Finding No. 1631:
Complaint Counsel has no specific response except to note that Complaint Counsel's experts reviewed the totality of the evidence, including the studies cited above, and concluded that there is not enough reliable scientific evidence to substantiate Respondents' claims. (*See* CCFF ¶ 1037). Complaint Counsel's experts opined that *in vitro* and animal studies alone are not sufficient to show that the tested product will prevent or treat human disease. Data from RCTs provide the best evidence of a causal relationship between a nutrient and a disease outcome in humans. (*See* CCFF ¶¶ 763-71). Moreover, Respondents' expert Dr. deKernion did not dispute that there are no clinical studies, research and/or trials proving these claimed benefits. (*See* CCFF ¶ 1038).

D. Brief Summary of Basic Science Studies and Prostate Health

1632. Pre-clinical laboratory studies, including in vitro and in-vivo mouse models are critical to a preliminary assessment of a new treatment. (PX0161-0008-0009).

Response to Finding No. 1632:
Complaint Counsel does not disagree that Dr. deKernion opined as such.

1633. The pre-clinical laboratory evidence to support an effect of POM on prostate cancer is robust. (PX0161-0009).

Response to Finding No. 1633:
Complaint Counsel does not disagree that Dr. deKernion opined as such.

1634. Preclinical research and studies involved in vitro growing of human tumor cells in petri dishes in laboratories, adding POM and POM products and determining the effect on the human tumor cells. (deKernion, Tr. 3044).

Response to Finding No. 1634:
Complaint Counsel does not disagree that Dr. deKernion testified as such.

1635. These initial studies (further outlined below) showed a significant decrease in growth, increase in apoptosis, (programmed tumor death), decrease in inflammation, factors which are all related to cancer. (deKernion, Tr. 3044-45).

Response to Finding No. 1635:
Complaint Counsel does not disagree that Dr. deKernion testified as such.

1636. Subsequent research involved in vivo study. A human tumor is grown in immune deficient mice, an environment, which behaves as though it were in a human. In these studies which used LAPC4, a particular prostate tumor line, researchers demonstrated that when a prostate tumor is grown in mice and pomegranate extract and pomegranate products are added, the tumors markedly decrease. (deKernion, Tr. 3045).

Response to Finding No. 1636:
Complaint Counsel does not disagree that Dr. deKernion testified as such except to note that Dr. deKernion also testified that even where the *in vitro* and animal evidence is strong and shows that an agent's mechanism of action works, this evidence does not prove that the agent works in humans. (deKernion, Tr. 3063-64).

1637. These were not studies of animal glands but were studies of human prostate tissue put in animals. All of these studies showed that POM had an antitumor effect on human tumors. (deKernion, Tr. 3049).

Response to Finding No. 1637:
Complaint Counsel does not disagree that Dr. deKernion testified as such.

1638. In 2001, Agensys, a biotech company, performed early preclinical research for POM investigating the effect of pomegranate juice and prostate cancer. (deKernion, Tr. 3115; Tupper Tr. 1034; PX0065).

Response to Finding No. 1638:
Complaint Counsel does not disagree except to note that this *in vitro* and animal research was unpublished. (CX0666_0008). Moreover, Dr. deKernion conceded that even where the *in vitro* and animal evidence is strong and shows that an agent's mechanism of action

works, this evidence does not prove that the agent works in humans. (deKernion, Tr. 3063-64). Data from RCTs provide the best evidence of a causal relationship between a nutrient and a disease outcome in humans. (*See* CCFF ¶¶ 763-71).

1639. Agensys found that *in vitro* pomegranate juice consumption "substantially inhibits prostate cancer cells." (PX0065-0036).

Response to Finding No. 1639:
Complaint Counsel has no specific response except to note that this *in vitro* and animal research was unpublished (*see* CX0666_0008) and the proposed finding misquotes the cited evidence. Moreover, Dr. deKernion conceded that even where the *in vitro* and animal evidence is strong and shows that an agent's mechanism of action works, this evidence does not prove that the agent works in humans. (deKernion, Tr. 3063-64). Data from RCTs provide the best evidence of a causal relationship between a nutrient and a disease outcome in humans. (*See* CCFF ¶¶ 763-71).

1640. Agensys *in vivo* research found that pomegranate juice consumption "retards the growth of subcutaneous and orthotopic prostate tumors in mice." (PX065-0037).

Response to Finding No. 1640:
See Response to Finding 1638.

1641. In a study entitled, "Pomegranate Ellagitannin-Derived Metabolites Inhibit Prostate Cancer Growth and Localize to the Mouse Prostate Gland" Dr.'s Navindra Seeram, Arie Belledegrum, David Heber, and colleagues evaluated the effects of pomegranate extract on prostate cancer growth in severe combined immunodeficient mice injected with human prostate cancer cells. (PX0069).

Response to Finding No. 1641:
Complaint Counsel has no specific response except to note that the study cited involved animal research. Moreover, Dr. deKernion conceded that even where the *in vitro* and animal evidence is strong and shows that an agent's mechanism of action works, this evidence does not prove that the agent works in humans. (deKernion, Tr. 3063-64). Data

from RCTs provide the best evidence of a causal relationship between a nutrient and a disease outcome in humans. (*See* CCFF ¶¶ 763-71).

1642. The study showed that pomegranate extract significantly inhibited prostate cancer in the mice as compared to the control. (PX0069).

Response to Finding No. 1642:
See Response to Finding 1641.

1643. Researchers also found that ellagic acid and synthesized urolithins from the pomegranate extract were shown to inhibit the growth of human prostate cancer cells in vitro. (PX0069).

Response to Finding No. 1643:
See Response to Finding 1641.

1644. The researchers further concluded that the chemopreventive potential of pomegranate ellagitannins and localization of their bioactive metabolites in mouse prostate tissue suggest that the pomegranate may play a role in prostate cancer treatment and chemoprevention. (PX0069).

Response to Finding No. 1644:
The proposed finding is incomplete in that the researchers also stated "[t]his warrants future human tissue bioavailability studies and further clinical studies in men with CaP [prostate cancer]." (PX0069-0001).

1645. In a study entitled, "Pomegranate polyphenols down-regulate expression of androgen-synthesizing genes in human prostate cancer cells overexpressing the androgen receptor", Doctors Hong, Seeram, and Heber examined the effects of pomegranate polyphenols from POMx Pill and POM Wonderful 100% pomegranate juice on the expression of androgen enzymes and androgen receptors. (PX0068).

Response to Finding No. 1645:
Complaint Counsel has no specific response except to note that the cited study involved *in vitro* research. Moreover, Dr. deKernion conceded that even where the *in vitro* and animal evidence is strong and shows that an agent's mechanism of action works, this evidence does not prove that the agent works in humans. (deKernion, Tr. 3063-64). Data from RCTs provide the best evidence of a causal relationship between a nutrient and a disease outcome in humans. (*See* CCFF ¶¶ 763-71).

1646. Recurrent prostate tumors advance to an androgen- independent state where they progress in the absence of circulating testosterone leading to advanced cancer. (PX0068).

Response to Finding No. 1646:
Complaint Counsel has no specific response.

1647. During the development of the androgen-independent state, prostate cells are known to increase intracellular testosterone synthesis which maintains cancer cell growth in the absence of significant amounts of circulating testosterone. Over expression of androgen receptor to produce testosterone occurs in androgen-independent prostate cancer. (PX0068).

Response to Finding No. 1647:
Complaint Counsel has no specific response.

1648. POM polyphenols from either POMx Pill or POM Wonderful 100% pomegranate juice significantly inhibited gene expression and androgen receptors as a potential mechanism for maintaining healthy prostate cells. (PX0068).

Response to Finding No. 1648:
See Response to Finding 1645.

1649. The researchers concluded that, "these results suggest that pomegranate polyphenols may be particularly helpful in the subgroup of patients with androgen-independent prostate cancer." (PX0068).

Response to Finding No. 1649:
See Response to Finding 1645.

1650. A study by Doctors Rettig, Heber, et al., entitled, "Pomegranate extract inhibits androgen-independent prostate cancer growth through a nuclear factor-kappaB-dependent mechanism" evaluated POMx Pill and POM Wonderful 100% pomegranate juice and found that their consumption was linked to reduction in cancer growth and decreased plasma PSA levels. (PX0070).

Response to Finding No. 1650:
Complaint Counsel has no specific response except to note that the cited study involved *in vitro* and animal research. Moreover, Dr. deKernion conceded that even where the *in vitro* and animal evidence is strong and shows that an agent's mechanism of action works, this evidence does not prove that the agent works in humans. (deKernion, Tr. 3063-64). Data from RCTs provide the best evidence of a causal relationship between a nutrient and a disease outcome in humans. (*See* CCFF ¶¶ 763-71).

1651. As discussed above, one of the most well-established signaling pathways mediating inflammatory responses relevant to cancer is the NF-kB pathway, which serves as a predictor for recurrence of prostate cancer after radical prostatectomy. (PX0070).

Response to Finding No. 1651:
Complaint Counsel has no specific response except to note that the cited study involved *in vitro* and animal research.

1652. POMx inhibited NF kB and cancer cell viability in a dose response fashion in vitro and Human LAPC4 prostate cancer xenograft mouse model, and this was similar to juice. (PX0070).

Response to Finding No. 1652:
See Response to Finding 1650.

1653. Based on the results reported, the researchers concluded "that pomegranate juice could have potential as a dietary agent to prevent the emergence of androgen-independence," thus potentially prolonging life expectancy of prostate cancer patients, and suggested "that this may be a high priority area for future clinical investigation." (PX0070).

Response to Finding No. 1653:
See Response to Finding 1650.

1654. In a study by Dr. Sartippour, et al., entitled, "Ellagitannin-Rich Pomegranate Extract Inhibits Angiogenesis In Prostate Cancer In Vitro And In Vivo" the in vivo results showed that POMx Pill inhibits prostate tumor growth compared to control in immunodecifient mice injected with human prostate cancer cells. (PX0071).

Response to Finding No. 1654:
Complaint Counsel has no specific response except to note that the cited study involved *in vitro* and animal research. Moreover, Dr. deKernion conceded that even where the *in vitro* and animal evidence is strong and shows that an agent's mechanism of action works, this evidence does not prove that the agent works in humans. (deKernion, Tr. 3063-64). Data from RCTs provide the best evidence of a causal relationship between a nutrient and a disease outcome in humans. (*See* CCFF ¶¶ 763-71).

1655. The mice were given a dose comparable, using caloric demand scaling, to that found in POMx and taken by humans. (PX0071).

Response to Finding No. 1655:

Complaint Counsel has no specific response except to note that the cited study involved *in vitro* and animal research.

1656. POMx was shown to significantly decrease the overall blood vessel density in mouse tumors or angiogenesis, which is important to slow prostate cancer cell growth linked directly to PSA doubling time. (PX0071).

Response to Finding No. 1656:
Complaint Counsel disagrees with the conclusion drawn as the cited evidence does not mention PSADT.

1657. In vitro results showed that POMx pill significantly inhibited proliferation of human prostate cancer cells at low ug/ml concentrations. (PX0071).

Response to Finding No. 1657:
See Response to Finding 1654.

1658. The researchers concluded, "these findings strongly suggest the potential of pomegranate ellagitannins for prevention of the multi-focal development of prostate cancer as well as to prolong survival in the growing population of prostate cancer survivors of primary therapy." (PX0071).

Response to Finding No. 1658:
Complaint Counsel does not disagree that the article states as such but notes that the cited study involved *in vitro* and animal research. Moreover, Dr. deKernion conceded that even where the *in vitro* and animal evidence is strong and shows that an agent's mechanism of action works, this evidence does not prove that the agent works in humans. (deKernion, Tr. 3063-64). Data from RCTs provide the best evidence of a causal relationship between a nutrient and a disease outcome in humans. (*See* CCFF ¶¶ 763-71).

1659. The findings from Respondents pre-clinical research, which has demonstrated an effect of pomegranates on prostate cancer tumors, contributes to the total body of research constituting competent and reliable scientific evidence that the Challenged Products, supports prostate health and could play a role in prevention. (PX0161- 0011-0012; PX0353 (Heber, Dep. at 84-91).

Response to Finding No. 1659:
Complaint Counsel has no specific response except to note that Complaint Counsel's experts reviewed the totality of the evidence, including the studies cited above, and

concluded that there is not enough reliable scientific evidence to substantiate Respondents' claims. (*See* CCFF ¶ 1037). Complaint Counsel's experts opined that *in vitro* and animal studies alone are not sufficient to show that the tested product will prevent or treat human disease. Data from RCTs provide the best evidence of a causal relationship between a nutrient and a disease outcome in humans. (*See* CCFF ¶¶ 763-64, 771). Moreover, Respondents' expert Dr. deKernion did not dispute that there are no clinical studies, research and/or trials proving these claimed benefits. (*See* CCFF ¶ 1038).

E. Respondents Human Clinical Trials and Prostate Health

1. In 2006, Dr. Allan Pantuck, of the UCLA Medical School, Published the Results of the First Human Clinical Trial on Pomegranate Juice With Men With Rising PSA Doubling Time Following Radical Prostatectomy and Found That Pomegranate Juice Consumption Produced a Dramatic Lengthening of PSA Doubling Time, an Effective Marker for Recurrence and Death From Prostate Cancer

1660. After successful preclinical trials, research on prostate health with POM progressed to human clinical trials. (deKernion, Tr. 3050).

Response to Finding No. 1660:
Complaint Counsel has no specific response except to note that Dr. deKernion did not call the preclinical trials "successful."

1661. In a study entitled, "Phase II Study of Pomegranate Juice for Men with Rising Prostate-Specific Antigen following Surgery or Radiation for Prostate Cancer," Dr. Allan Pantuck and his colleagues of UCLA Medical School found that through the consumption of pomegranate juice, the mean PSA doubling time significantly increased with treatment from a mean of 15 months at baseline to 54 months post-treatment. (PX0060).

Response to Finding No. 1661:
Complaint Counsel has no specific response.

1662. Patients were treated with 8 oz per day of POM Wonderful 100% pomegranate juice until disease progression end points. (PX0060).

Response to Finding No. 1662:

Complaint Counsel has no specific response.

1663. Clinical end points were effect on serum PSA, serum-induced proliferation and apoptosis of prostate cancer cells, serum lipid peroxidation, and serum nitric oxide levels. (PX0060).

Response to Finding No. 1663:
Complaint Counsel has no specific response.

1664. Mean PSA doubling time significantly increased with treatment from a mean of 15 months at baseline to 54 months post treatment. (PX0060).

Response to Finding No. 1664:
Complaint Counsel has no specific response except to note that without a placebo control group 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. (*See* CCFF ¶¶ 1003-04).

1665. PSA doubling time is a mathematical expression of the rapidity with which the prostate specific antigen (PSA) is rising, and is an expression of the rapidity of growth and number of prostate tumor cells. (deKernion, Tr. 3050).

Response to Finding No. 1665:
Complaint Counsel has no specific response.

1666. The doubling time for PSA is a measure of the likelihood of recurrence of the tumor after a man has had his prostate removed. (deKernion, Tr. 3051).

Response to Finding No. 1666:
Complaint Counsel has no specific response.

1667. The presence of detectable PSA after radical prostatectomy or other radical treatment usually indicates cancer is present. (deKernion, Tr. 3051).

Response to Finding No. 1667:
The proposed finding is incomplete in that Dr. deKernion also testified that sometimes a detectable PSA after radical prostatectomy is due to a small piece of the prostate having been left behind. Complaint Counsel also notes that biochemical recurrence does not always result in clinical progression. (*See* CCFF ¶ 979).

1668. PSA doubling time provides an expression of how those tumor cells are going to behave. (deKernion, Tr. 3051-52).

Response to Finding No. 1668:
Complaint Counsel does not disagree that Dr. deKernion testified as such.

1669. The longer the PSA doubling time, the less dangerous the growth of the cancer (deKernion, Tr. 3052).

Response to Finding No. 1669
Complaint Counsel has no specific response except to note that Complaint Counsel's and Respondents' experts agreed that the majority of men with a PSADT of less than 3 months is likely to develop metastatic disease and die of prostate cancer and that men with a long PSADT of 15 months (the average pretreatment PSADT of the men in the Pantuck Phase II Prostate Cancer Study) have a lower risk of progression. (*See* CCFF ¶¶ 981-82).

1670. In vitro assays comparing pretreatment and post treatment patient serum on the growth of the prostate cancer line LNCaP showed a 12% decrease in cell proliferation and a 17% increase in apoptosis, a 23% increase in serum nitric oxide, and significant reductions in oxidative state and sensitivity to oxidation of serum lipids after versus before pomegranate juice consumption. (PX0060).

Response to Finding No. 1670:
Complaint Counsel has no specific response except to note that *in vitro* studies alone are insufficient to show that a tested product will prevent or treat disease. (*See* CCFF ¶ 764).

1671. The study was the first clinical trial of pomegranate polyphenol antioxidants in patients with prostate cancer. (PX0060).

Response to Finding No. 1671:
Complaint Counsel has no specific response.

1672. The statistically significant prolongation of PSA doubling time, coupled with corresponding laboratory effects on prostate cancer in vitro cell proliferation and apoptosis as well as oxidative stress, provides good indication of a relationship between pomegranate polyphenol antioxidants and prostate health. (PX0060).

Response to Finding No. 1672:
The proposed finding mischaracterizes the conclusion drawn in that the cited evidence does not discuss the relationship between pomegranate polyphenol antioxidants and "prostate health."

1673. Dr. Pantuck's study was published in the Journal of Clinical Cancer Research an extremely well regarded peer reviewed journal. It is considered one of if not the finest clinical cancer journals. (CX1352 (Heber Dep. at 268-269); (PX0060).

Response to Finding No. 1673:
Complaint Counsel objects to the deposition testimony cited in the proposed finding as non-designated testimony.

1674. The process and rigor for being published in the Journal of Clinical Cancer Research is very high. (CX1352 (Heber, Dep. at 268)).

Response to Finding No. 1674:
Complaint Counsel objects to the deposition testimony cited in the proposed findings as non-designated testimony.

1675. Dr. Heber testified that Dr. Pantuck's study is considered, "a very highly esteemed paper." (CX1352 (Heber, Dep. at 268)).

Response to Finding No. 1675:
Complaint Counsel objects to the deposition testimony cited in the proposed findings as non-designated testimony.

(b) Dr. Allan Pantuck Long's Term Follow-Up Study demonstrated that for those who continued on pomegranate juice maintained a lengthening of their PSA doubling time compared to men who did not continue on pomegranate juice

1676. In 2008 Dr. Pantuck presented a report of an abstract to the American Society of Clinical Oncology entitled, "Long Term Follow Up of Pomegranate Juice for Men with Prostate Cancer and Rising PSA Shows Durable Improvement in PSA Doubling Time." (PX0061).

Response to Finding No. 1676:
Complaint Counsel has no specific response.

1677. Dr. Pantuck and his colleagues found a durable increase in PSA doubling time from men who continued to take pomegranate juice following the Phase II trial. (PX0061).

Response to Finding No. 1677:
The proposed finding is unsupported by the cited evidence in that, without a placebo group, it is not possible to conclude that the effect observed is attributable to POM Juice.

Without a placebo arm, it is impossible to control for confounding factors that may have impacted PSADT. (*See* CCFF ¶¶ 1003-05, 1012).

1678. Mean PSA doubling time for the entire cohort continued to show a significant increase following treatment, from a mean of 15.4 at baseline to 60 months post-treatment, while the median PSA slope decreased 60% from 0.06 to 0.024. (PX0061).

Response to Finding No. 1678:
Complaint Counsel does not disagree that the cited article states as such.

1679. Patients remaining on study ("active") were compared to those no longer on study ("non-active"). (PX0061).

Response to Finding No. 1679:
Complaint Counsel does not disagree that the cited article states as such.

1680. At baseline, mean PSA doubling times were similar between Active and Non-Active patients. However, post-treatment PSA DT prolongation was greater and the decline in median PSA slope was larger in Active compared to Non-Active patients. (PX0061).

Response to Finding No. 1680:
Complaint Counsel does not disagree that the cited article states as such.

1681. The study demonstrated that for those who continued on pomegranate juice maintained a lengthening of their PSA doubling time compared to men who did not continue on pomegranate juice. (PX0061; Eastham, Tr. 1305; CX1341 (Pantuck, Dep. at 136).

Response to Finding No. 1681:
The proposed finding is unsupported by the cited evidence in that, without a placebo group, it is not possible to conclude that the effect observed is attributable to POM Juice. Without a placebo arm, it is impossible to control for confounding factors that may have impacted PSADT. (*See* CCFF ¶¶ 1003-05, 1012).

(c) Dr. Allan Pantuck Supports the Findings of His Pomegranate Research That PSA Doubling Time Was Prolonged for Men With Prostate Cancer When They Were Given Pomegranate Juice

1682. Dr. Pantuck's deposition was taken in this matter on December 15, 2010. (CX1341).

Response to Finding No. 1682:
Complaint Counsel agrees.

1683. Dr. Pantuck attended college at Columbia University and medical school at Robert Woods Johnson Medical School. (CX1341 (Pantuck Dep. at 20-21)).

Response to Finding No. 1683:
Complaint Counsel has no specific response.

1684. Dr. Pantuck also has a Masters Degree in Clinical Research from UCLA Medical School. (CX1090_0001).

Response to Finding No. 1684:
Complaint Counsel has no specific response.

1685. Dr. Pantuck is an associate professor of Urology at UCLA Medical School and maintains a clinical practice at UCLA. (CX1341 (Pantuck Dep. at 22)).

Response to Finding No. 1685:
Complaint Counsel has no specific response.

1686. Dr. Pantuck's clinical appointments include: Attending Urologist at Harbor-UCLA Medical Center, Attending Urologist Wadsworth Veterans Affairs Medical Center, and Attending Urologist, UCLA Medical Center. (CX1090_0004).

Response to Finding No. 1686:
Complaint Counsel has no specific response.

1687. Dr. Pantuck's professional societies and memberships include the American Society of Clinical Oncology, American Urological Association, Jonsson Comprehensive Cancer Center, and the Society of Urologic Oncology. (CX1090_0002).

Response to Finding No. 1687:
Complaint Counsel has no specific response.

1688. Dr. Pantuck served as editor of Advances in the Management of Renal Cell Carcinoma. Proceedings of the Irish Society of Surgical Oncology. (2003) (CX1090_0003).

Response to Finding No. 1688:
Complaint Counsel has no specific response.

1689. Dr. Pantuck has been a reviewer for journals such as the British Journal of Urology International, The Journal of Urology, Clinical Cancer Research, and Urologic Oncology. (CX1090_0003).

Response to Finding No. 1689:
Complaint Counsel has no specific response.

1690. In deposition 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)).

Response to Finding No. 1690:
Complaint Counsel has no specific response.

1691. Dr. Pantuck, stated that the design of the study was for subjects to serve as their own control. Patients had a specific PSA doubling time prior to treatment; patients would then be treated and measured for any change in their doubling time after treatment. (CX1341 (Pantuck, Dep. at 78)).

Response to Finding No. 1691:
Complaint Counsel has no specific response.

1692. Dr. Pantuck further testified that the study showed evidence that the growth of the cancer had been altered by POM. (CX1341 (Pantuck, Dep. at 119)).

Response to Finding No. 1692:
Complaint Counsel has no specific response.

1693. 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)).

Response to Finding No. 1693:
Complaint Counsel has no specific response.

1694. 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)).

Response to Finding No. 1694:
Complaint Counsel has no specific response.

2. Dr. Michael Carducci, of Johns Hopkins School of Medicine, Conducted a Clinical Trial on Pomegranate Extract with Men With Rising PSA Doubling Time Following Primary Therapy And Found that POMx Demonstrated Antitumor Effects in Prostate Cancer and Significantly Increased PSA Doubling Time

1695. In 2011 Dr. Michael Carducci presented the abstract of his clinical research study entitled, "A Phase II Study of Pomegranate Extract for Men with Rising Prostate-specific Antigen Following Primary Therapy" at the disease specific meeting of the American Society of Clinical Oncology. (PX0175).

Response to Finding No. 1695:
Complaint Counsel has no specific response.

1696. Dr. Carducci and colleagues found that pomegranate extract (POMx) demonstrated antitumor effects in prostate cancer. (PX0175).

Response to Finding No. 1696:
The proposed finding is incomplete as the researchers stated that POMx "demonstrates promising antitumor effects in prostate cancer."

1697. The study was a multi-center, double blind Phase II randomized trial that studied men with rising PSA and without metastases. They were given either high or low dose POMx, stratified by baseline PSADT and Gleason score, and with no restrictions for PSADT and no upper limit PSA value. (PX0175).

Response to Finding No. 1697:
Complaint Counsel has no specific response except to note that this was a dose response study so there was blinding as to which dose of POMx was given. However, there was no placebo control. (*See* CCFF ¶¶ 1013-17).

1698. Men were treated until progression or for 18 months. PSA levels were obtained every 3 months. (PX0175).

Response to Finding No. 1698:
Complaint Counsel has no specific response.

1699. The clinical trial showed that POMx treatment significantly increased the PSA doubling time by over 6 months in both treatment arms. (PX0175).

Response to Finding No. 1699:
The proposed finding mischaracterizes the record as a whole with respect to the findings of the study. Both arms of the Carducci Dose Study received POMx and there was no statistically significant treatment difference in PSADT between the two dose groups. So, there was no dose effect which was the purpose of the study. Again, without a placebo, it is unclear whether the effect observed within the treatment groups was attributable to POMx. (*See* CCFF ¶¶ 1013-20, 1022-25).

1700. The 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)).

Response to Finding No. 1700:

Complaint Counsel has no specific response except to note that there was no dose response effect and Dr. Carducci testified that without a placebo, he cannot be sure that the effect on PSADT observed in his study is attributable to POMx. (*See* CCFF ¶¶ 1018-19).

(b) Dr. Michael Carducci Supports the Findings of His Pomegranate Research That PSA Doubling Time Was Prolonged for Men with Prostate Cancer When They Were Given Pomegranate Extract

1701. Dr. Michael Carducci's deposition was taken in this matter on December 13, 2010. (CX1340).

Response to Finding No. 1701:
Complaint Counsel agrees.

1702. Dr. Carducci is a graduate of Georgetown University and Wayne State University Medical School. (CX1340 (Carducci, Dep. at 13-14)).

Response to Finding No. 1702:
Complaint Counsel has no specific response.

1703. Dr. Carducci did a residency in internal medicine at the University of Colorado in Denver. (CX1340 (Carducci, Dep. at 14)).

Response to Finding No. 1703:
Complaint Counsel has no specific response.

1704. After completing a year as chief resident at the University of Colorado he accepted a fellowship in oncology at Johns Hopkins University. (CX1340 (Carducci, Dep. at 14)).

Response to Finding No. 1704:
Complaint Counsel has no specific response.

1705. Dr. Carducci is currently a professor of oncology and urology at the Johns Hopkins School of Medicine, in Baltimore, Maryland. (CX1340 (Carducci, Dep. at 14-15)).

Response to Finding No. 1705:
Complaint Counsel has no specific response.

1706. Within the Cancer Center, he leads two programs, the prostate cancer/genitourinary cancer program and chemical therapeutics. (CX1340 (Carducci, Dep. at 14-15)).

Response to Finding No. 1706:

Complaint Counsel has no specific response.

1707. Dr. Carducci has conducted 40-50 clinical trials relating to prostate cancer. (CX1340 (Carducci, Dep. at 15)).

Response to Finding No. 1707:
Complaint Counsel has no specific response.

1708. He has published approximately 80 articles related to prostate cancer. (CX1340 (Carducci, Dep. at 15-16)).

Response to Finding No. 1708:
Complaint Counsel has no specific response.

1709. In his deposition Dr. Carducci testified that POM Wonderful did not look at or manipulate the data analysis of his study. (CX1340 (Carducci, Dep. at 43)).

Response to Finding No. 1709:
Complaint Counsel has no specific response except to note that

See CCFF ¶ 1017).

1710. He stated 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)).

Response to Finding No. 1710:
Complaint Counsel has no specific response.

1711. 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)).

Response to Finding No. 1711:
Complaint Counsel has no specific response except to note that Dr. Carducci testified that the Carducci Dose Study was never designed to prove that POMx prevents, reduces the risk of, or treats prostate cancer. (*See* CCFF ¶ 1018).

1712. Dr. Carducci stated that researchers were looking at safety and whether POMx had an effect on rising PSA. (CX1340 (Carducci, Dep. at 51)).

Response to Finding No. 1712:
Complaint Counsel has no specific response.

1713. He confirmed that the study results as designed and planned were statistically significant. (CX1340 (Carducci, Dep. at 183)).

Response to Finding No. 1713:
Complaint Counsel does not disagree that Dr. Carducci testified as such but notes that the study was designed as a dose-finding study and there was no statistically significant treatment difference in PSADT between the two dose groups. (*See* CCFF ¶¶1017, 1025).

1714. Dr. Carducci was selected to present the results of his study on POMx at a disease specific meeting of the American Society of Clinical Oncology, the American Society of Therapeutic Radiation Oncology and the Society of Urologic Oncology. (CX1340 (Carducci, Dep. at 176)).

Response to Finding No. 1714:
Complaint Counsel has no specific response.

1715. 1500 to 2000 people typically attend this meeting. (CX1340 (Carducci, Dep. at 177)).

Response to Finding No. 1715:
Complaint Counsel has no specific response.

1716. Dr. Carducci's abstract was peer reviewed prior to being selected for presentation. (CX1340 (Carducci, Dep. at 176)).

Response to Finding No. 1716:
Complaint Counsel has no specific response except to note that an invited discussant offered a pointed critique of the study's use of PSADT as an endpoint. (*See* CCFF ¶ 1021).

1717. Only 10 of the highest ranking abstracts or with the most relevance to the audience (out of 500 submitted) are generally selected for an oral presentation. (CX1340 (Carducci, Dep. at 61–62)).

Response to Finding No. 1717:
Complaint Counsel has no specific response.

1718. The findings from Respondents human clinical research, which has demonstrated an effect of pomegranates on prostate cancer including by extending PSA doubling time, contributes to the total body of research constituting competent and reliable scientific evidence that the Challenged Products, support prostate health and could play a role in prevention. (PX0161-0011-0012; PX0353 (Heber, Dep. at 84-91); PX0060; PX0061; PX0175).

Response to Finding No. 1718:
The proposed finding mischaracterizes the evidence as a whole in that both the Pantuck Phase II and Carducci Dose studies lacked a placebo arm. Without a placebo, it is not possible to conclude that the POM Products caused the change in the patients' PSADT. (*See* CCFF ¶¶ 1003-04, 1023).

F. Respondents' Expert Confirms That Respondents' Substantiation Constitutes Competent and Reliable Scientific Evidence

1. Respondents' Proffered Expert

(a) Dr. Jean Dekernion Has for Over 30 Years Been One of The Foremost Leaders in Urological Research and Clinical Practice

1719. Respondents have presented the expert report and expert testimony of Dr. Jean deKernion, a practicing clinician in the field of prostate cancer and prostate health. (PX0161; PX0351; deKernion, Tr. 3039-3127).

Response to Finding No. 1719:
Complaint Counsel has no specific response.

1720. Dr. Jean deKernion is a Doctor of Medicine and obtained his medical degree in 1965 from Louisiana State University School of Medicine in New Orleans, Louisiana. (deKernion, Tr. 3040).

Response to Finding No. 1720:
Complaint Counsel has no specific response.

1721. Dr. deKernion did his residencies in surgery and urology at the university hospitals of Cleveland and the National Cancer Institute. (deKernion, Tr. 3040).

Response to Finding No. 1721:
Complaint Counsel has no specific response.

1722. Dr. deKernion has been a visiting professor at 50 different medical institutions including M.D. Anderson in Houston, Stanford, University of Pennsylvania, and the Cleveland Clinic. (deKernion, Tr. 3041-42).

Response to Finding No. 1722:
Complaint Counsel has no specific response.

1723. Dr. deKernion has been certified by the American Board of Urology since 1975. (PX0161-0002).

Response to Finding No. 1723:
The proposed finding is unsupported by the cited evidence.

1724. Dr. deKernion was from 1981 until his retirement in 2011 Chairman of the Department of Urology and Senior Associate Dean for Clinical Affairs (2001 –2011) at the David Geffen UCLA School of Medicine. (deKernion, Tr. 3039; PX0161-0001).

Response to Finding No. 1724:
Complaint Counsel has no specific response.

1725. Dr. deKernion's responsibilities included the urological clinical and research education of students, residents, and fellows at all levels; a busy practice in urologic oncology, primarily related to prostate cancer but also bladder and kidney cancer; growth and oversight of large and diverse research programs; and administration of programs for the Dean's office and hospital. (PX0161-0001).

Response to Finding No. 1725:
Complaint Counsel has no specific response.

1726. Dr. deKernion served as an advisor to a number of university research programs, and served on a Data and Safety Monitoring Committee (DSMC) for a bladder cancer project. (PX0161-0002).

Response to Finding No. 1726:
Complaint Counsel has no specific response.

1727. During Dr. deKernion's tenure as Chair of the Department of Urology at UCLA, he built a multidisciplinary research portfolio, which ranks among the largest and best in the United States. (PX0161-0003).

Response to Finding No. 1727:
Complaint Counsel has no specific response.

1728. In the role as Chair of the Department of Urology at UCLA, Dr. deKernion had general oversight of funded research projects, as well as mentoring responsibilities for faculty, residents, PhD faculty and PhD students. (PX0161-0003).

Response to Finding No. 1728:
Complaint Counsel has no specific response.

1729. Dr. deKernion's career in urologic oncology has involved both clinical and basic/translational research. (PX0161-0001).

Response to Finding No. 1729:
Complaint Counsel has no specific response.

1730. He co-authored the first book on urologic oncology and has co-authored 133 chapters since. (PX0161-0002; deKernion, Tr. 3042).

Response to Finding No. 1730:
Complaint Counsel has no specific response.

1731. His research has involved both basic laboratory research and clinical research publishing 228 papers to date in peer-reviewed journals and many other invited manuscripts. (PX0161-0002; deKernion, Tr. 3043).

Response to Finding No. 1731:
Complaint Counsel has no specific response.

1732. For 6 years Dr. deKernion was the associate editor of the Journal of Urology and has been a reviewer for approximately 20 other peer-reviewed journals. (deKernion, Tr. 3041; PX0161-0002).

Response to Finding No. 1732:
Complaint Counsel has no specific response.

1733. Dr. deKernion served on a number of national committees and was a founding member of the Society of Urologic Oncology. (PX0161-0002).

Response to Finding No. 1733:
Complaint Counsel has no specific response.

1734. Dr. deKernion was elected as a trustee of the American Board of Urology, and numerous committees of national urological societies. (PX0161-0002).

Response to Finding No. 1734:
Complaint Counsel has no specific response.

1735. Dr. deKernion was appointed to the National Cancer Advisory board by President Bush. (deKernion, Tr. 3040).

Response to Finding No. 1735:
Complaint Counsel has no specific response.

1736. At the National Cancer Institute, Dr. deKernion was a member of the NCI Clinical Trials Advocacy Committee and the SPORE Leadership Committee. (PX0161-0002).

Response to Finding No. 1736:
Complaint Counsel has no specific response.

1737. Dr. deKernion served as the chair of the Department of Defense prostate cancer integration and research panel. (deKernion, Tr. 3040).

Response to Finding No. 1737:
Complaint Counsel has no specific response.

1738. Among the awards and prizes that he has received are the Jonsson Prize for Research awarded by the Jonsson Cancer Foundation and the Hugh Hampton Young Award of the American Urological Association. (deKernion, Tr. 3043; PX0161-0014).

Response to Finding No. 1738:
Complaint Counsel has no specific response.

2. Summary of Dr. deKernion's Opinions

(a) POM's In Vitro and Animal Studies Showed That the Challenged Products Inhibited the Growth Of Prostate Cancer Cells and Actually Killed Them

1739. In addition to the publications attached to Dr. deKernion's expert report upon which he relied, Dr. deKernion has also extensively relied upon his education, years of experience and knowledge of developments in the field of urology and prostate health, including the promotion of prostate heath and treatment of prostate cancer in forming his opinions on Respondents' prostate health research. (PX0351 (deKernion, Dep. at 26); PX0351a02-0001; PX0351a04-0001-PX0351a04-0002; PX0351a05-0001; PX0161).

Response to Finding No. 1739:
Complaint Counsel has no specific response.

1740. Dr. deKernion testified that Respondents' *in vitro* and animal studies showed that pomegranate juice inhibited the growth of prostate cancer cells and actually killed them. (deKernion, Tr. 3044-45, 3120; PX0351 (deKernion, Dep. at 110).

Response to Finding No. 1740:
The proposed finding is incomplete as Dr. deKernion also testified at his deposition that he "can't prove that it can kill the cell" in humans. (PX0351 (deKernion, Dep. at 110)).

1741. Dr. deKernion testified that while we cannot always extrapolate from *in vitro* and animal results to what the results would be in humans, these pre-clinical studies indicated a strong likelihood that, in humans, pomegranate juice would at least inhibit the growth of prostate cancer cells. (deKernion, Tr. 3063; PX0161-0011-0012).

Response to Finding No. 1741:
The proposed finding mischaracterizes Dr. deKernion's trial testimony. Dr. deKernion testified that even where the *in vitro* and animal evidence is strong and shows that an

agent's mechanism of action works, this evidence does not prove that the agent works in humans. (deKernion, Tr. 3063-64).

1742. Dr. deKernion, noted that Respondents animal studies were on human prostate tissue inserted in the animals and were not merely a study of animal glands. (deKernion, Tr. 3049).

Response to Finding No. 1742:
Complaint Counsel has no specific response.

(b) PSA Doubling Time Is a Valid Surrogate Marker for Prostate Cancer Recurrence and Death

1743. Dr. deKernion opined in his expert report as well as during deposition and trial testimony on the validity of PSA doubling time as a surrogate marker in clinical trials. (PX0161; PX0351; deKernion, Tr. 3039-3127).

Response to Finding No. 1743:
Complaint Counsel has no specific response except to note that Dr. deKernion also testified that PSADT is not accepted by experts in the field of prostate cancer as a surrogate for clinical benefit in prostate cancer treatment trials. (*See* CCFF ¶ 978).

1744. He 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).

Response to Finding No. 1744:
Complaint Counsel has no specific response except to note that although both Respondents' and Complaint Counsel's experts agree that PSADT has value as a prognostic tool, they recognize that there are no studies demonstrating that an agent which modulates PSADT changes the natural history of prostate cancer by delaying the development of metastases or death from the disease. (*See* CCFF ¶¶ 980-83).

1745. He testified that there are different risk profiles based on the length of the PSA doubling time, with less than 3 months in the highest risk and those of 12 to 15 months and above in a lower risk category. (PX0351 (deKernion, Dep. at 96); deKernion, Tr. 3084-85).

Response to Finding No. 1745:
Complaint Counsel agrees. (*See also* CCFF ¶¶ 981-82).

1746. Dr. deKernion stated that PSA doubling time is clearly a useful marker in determining risk or outcome in patients following prostate cancer treatment. (deKernion, Tr. 3055).

Response to Finding No. 1746:
The proposed finding is incomplete in that Dr. deKernion testified that PSADT is a marker for predicting outcome and an indicator of recurrence. (deKernion, Tr. 3055).

1747. Dr. deKernion testified that given the understanding of PSA doubling time in predicting risk of clinical recurrence and to some extent survival, it is not only permissible and logical to use changes in PSADT as indicative of an intervention's effectiveness regarding prostate tumor behavior, but it is particularly compelling when coupled with the previous science, including in vivo, and in vitro, using POM and adjudging its usefulness as to prostate health. (PX0161-0007, 0011-0012).

Response to Finding No. 1747:
The proposed finding mischaracterizes Dr. deKernion's testimony in that he did not opine as such in his report. However, Dr. deKernion did state 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" and that "it [is] unclear if this will ultimately result in improved survival." (PX0161 (deKernion, Report at 0011-12)).

1748. If 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. (PX0161-0007, 0011-0012).

Response to Finding No. 1748:
The proposed finding mischaracterizes the cited evidence. In addition, Complaint Counsel notes that the statistically significant changes observed in the Pantuck and Carducci studies were a *within-group* analysis, which has much less scientific value than a *between-group* analysis. And without a placebo group, it is not possible to know whether the same change in PSADT would have been observed in this patient group if it had never received POM. (*See* CCFF ¶¶ 778, 1003-05).

1749. Dr. Heber also opined that PSA doubling time was a valid surrogate for prostate cancer recurrence and death and that this was now widely recognized by doctors in the field. (Heber, Tr. 1996-97).

Response to Finding No. 1749:
Complaint Counsel has no specific response except to note that Dr. Heber is not an expert in the clinical treatment of prostate cancer. (CCFF ¶¶ 728, 1008, 1043).

1750. 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)).

Response to Finding No. 1750:
Complaint Counsel objects to the deposition testimony cited in the proposed finding as non-designated testimony. Without waiving this objection, Complaint Counsel states that Dr. Heber is neither a urologist nor an expert in the clinical treatment of prostate cancer. (CCFF ¶¶ 728, 1008, 1043).

1751. Dr. Heber testified that PSA doubling time is a, "very important clinically utilized marker of clinical status." (CX1352 (Heber, Dep. at 314)).

Response to Finding No. 1751:
Complaint Counsel objects to the deposition testimony cited in the proposed finding as non-designated testimony. Without waiving this objection, Complaint Counsel states that Dr. Heber is neither a urologist nor an expert in the clinical treatment of prostate cancer. (CCFF ¶¶ 728, 1008, 1043).

1752. Dr. Liker testified that most experts believe that there is a relationship between PSA going up and the progression of prostate cancer. (CX1350 (Liker, Dep. at 175)).

Response to Finding No. 1752:
Complaint Counsel has no specific response except to note that Dr. Heber is neither a urologist nor an expert in the clinical treatment of prostate cancer. (CCFF ¶¶ 728, 1008, 1043).

1753. 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)).

Response to Finding No. 1753:
Complaint Counsel objects to the deposition testimony cited in the proposed finding as non-designated testimony. Without waiving this objection, Complaint Counsel states that Dr. Heber is neither a urologist nor an expert in the clinical treatment of prostate cancer. (CCFF ¶¶ 728, 1008, 1043).

1754. 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)).

Response to Finding No. 1754:
Complaint Counsel objects to the deposition testimony cited in the proposed finding as non-designated testimony. Without waiving this objection, Complaint Counsel states that Dr. Heber is neither a urologist nor an expert in the clinical treatment of prostate cancer. (CCFF ¶¶ 728, 1008, 1043).

1755. 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).

Response to Finding No. 1755:
Complaint Counsel does not disagree that Dr. Heber testified as such but notes that he is neither a urologist nor an expert in the clinical treatment of prostate cancer. (CCFF ¶¶ 728, 1008, 1043). In addition, Complaint Counsel notes that although both Respondents' and Complaint Counsel's experts agree that PSADT has value as a prognostic tool, experts in the field do not accept it as a surrogate endpoint for prostate cancer treatment trials. (*See* CCFF ¶¶ 978, 980-81). Respondents' own medical research summary acknowledges this fact. (*See* CCFF ¶ 1045).

(c) From a Patient Care Standpoint PSA Doubling Time Is Extremely Important

1756. Dr. deKernion stated that level of comfort, quality of life, avoidance of more drastic invasive and potentially complicated treatments, all are very important and PSA doubling

time serves as a good marker in addressing these points. (PX0161-0010; deKernion Tr. 3065).

Response to Proposed Finding No. 1756:
The proposed finding is unsupported by the cited evidence in that Dr. deKernion did not state that PSA doubling time serves as a good marker for addressing the level of comfort, quality of life, or avoidance of more drastic invasive and potentially complicated treatments.

1757. 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)).

Response to Proposed Finding No. 1757:
Complaint Counsel has no specific response except to note that Dr. Pantuck also testified 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." (*See* CCFF ¶¶ 994-95).

1758. Dr. Pantuck stated that from a patient care standpoint PSA doubling time is extremely important. (CX1341 (Pantuck, Dep. at 255)).

Response to Proposed Finding No. 1758:
Complaint Counsel has no specific response except to note that Dr. Pantuck also testified 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." (*See* CCFF ¶¶ 994-95).

1759. Dr. Carducci testified that the potential benefits from a clinical or patient point of view of extending PSA doubling time include delaying more aggressive therapy and living longer. (CX1340 (Carducci, Dep. at 182)).

Response to Proposed Finding No. 1759:
Complaint Counsel has no specific response except to note that Dr. Carducci also testified that "ultimately we're going to be able to prove yes or no that if you slow a

man's doubling time, it is beneficial to him," but that it has "not been proven." (CX1340 (Carducci, Dep. at 89-90)).

(d) POM's Clinical Studies Showed, With a "High Degree of Probability" That POM and POMx Lengthened PSA Doubling Time and Thus at Least Deferred Death from Prostate Cancer

1760. The fact that the Carducci and Pantuck studies were published and survived the peer review process is significant evidence that the research was scientifically valid. (Eastham, Tr. 1224).

Response to Finding No. 1760:
The proposed find is unsupported by the cited evidence. Dr. Eastham testified that the purpose of peer review is to ensure scientific validity without any reference to the Carducci and Pantuck studies. Moreover, Dr. Pantuck's article was rejected by the first journal to which it was submitted and was published by a second journal only after he edited it in response to criticism by peer reviewers. (*See* CCFF ¶ 990). In addition, to date, only the abstract for the Carducci study has been presented. (*See* CCFF ¶ 1013).

1761. 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. (deKernion, Tr. 3057).

Response to Finding No. 1761:
Complaint Counsel has no specific response.

1762. 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. (deKernion, Tr. 3057).

Response to Finding No. 1762:
Complaint Counsel has no specific response.

1763. 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).

Response to Finding No. 1763:

Complaint Counsel has no specific response except to note that, without a placebo-control group, it is impossible to know whether the same change in PSADT would have been observed in this patient group even if it never received the POM Products. (*See* CCFF ¶¶ 1002-05, 1023). In addition, the lack of a dose response in the Carducci Dose Study is an indication of non-efficacy. (*See* CCFF ¶ 1025).

1764. Dr. deKernion testified that in each of the Dr. Pantuck and Dr. Carducci studies the control was the previous doubling time prior to treatment. (deKernion, Tr. 3058).

Response to Finding No. 1764:
Complaint Counsel has no specific response.

1765. The researchers measured the doubling time before patients took POM Juice or POMx and then measured doubling time afterwards comparing one to the other. (deKernion, Tr. 3058).

Response to Finding No. 1765:
Complaint Counsel has no specific response except to note that *within-group* analysis, where a researcher compares the treatment group participants' "before" data to their "after" data, has much less scientific value. (*See* CCFF ¶ 778).

1766. This was done in lieu of a separate placebo group. (deKernion, Tr. 3058).

Response to Finding No. 1766:
Complaint counsel has no specific response except to note that: 1) Dr. Pantuck testified that the greatest limitation of the Pantuck Phase II Prostate Cancer Study (2006) was the lack of a blinded control arm; 2) Dr. Carducci testified that he wanted to include a placebo arm in his study but Respondents denied his request; and 3) Dr. Carducci testified that without a placebo, he cannot be sure that the effect of PSADT observed in the Carducci Dose Study is attributable to POMx. (*See* CCFF ¶¶ 996-98; 1014-16, 1018).

1767. 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).

Response to Finding No. 1767:

Complaint Counsel has no specific response except to note that without a placebo group there is no way to eliminate confounding factors that may have impacted PSADT – such as changes in diet, exercise, or the reduction of stress. (*See* CCFF ¶¶ 1004-05).

1768. 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. (deKernion, Tr. 3059-60; PX0351 (deKernion, Dep. at 97-99); PX0161- 0007).

Response to Finding No. 1768:
Complaint Counsel has no specific response except to note that Dr. deKernion also testified 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 it is impossible to control for confounding factors. (*See* CCFF ¶¶ 1004-05).

1769. 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).

Response to Finding No. 1769:
Complaint Counsel has no specific response except to note that there are randomized controlled studies in which the patients similar to those studied in the Pantuck Phase II Prostate Cancer Study (2006) received an intervention and both the treatment and placebo groups experienced a lengthening of PSADT treatment suggesting a possible placebo effect. (*See* CCFF ¶¶ 996-98, 1007).

1770. Dr. deKernion testified that patients in a placebo-group often want and sometimes seek the treatment being tested. (deKernion, Tr. 3083).

Response to Finding No. 1770:
The proposed finding is incomplete in that Dr. deKernion also testified that it would have been ethical to use a placebo in the Pantuck Phase II Prostate Cancer Study (2006).

1771. Dr. Heber also testified that one of the reasons that there was no placebo group was the difficulty in recruiting prostate cancer patients for a placebo arm, after being aware of the benefits of pomegranate juice. (PX0353 (Heber, Dep. at 155-156)).

Response to Finding No. 1771:
Complaint Counsel has no specific response except to note that conducting a study with a placebo control group is possible and

(*See* also CCFF ¶ 1026-29).

1772. Dr. deKernion testified 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).

Response to Finding No. 1772:
Complaint Counsel has no specific response except to note that Dr. deKernion agreed with Complaint Counsel's experts that modulating PSADT has not been proven to delay the development of metastases or death from prostate cancer. (*See* CCFF ¶ 983).

1773. 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).

Response to Finding No. 1773:
The proposed finding mischaracterizes Dr. deKernion's testimony in that he did not state 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.

1774. Dr. deKernion 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).

Response to Finding No. 1774:

Complaint Counsel has no specific response except to note that Dr. deKernion also testified that the POM Products have not been proven to prevent prostate cancer or prolong their lives. (*See* CCFF ¶ 1041).

1775. Dr. Heber testified 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).

Response to Finding No. 1775:
Complaint Counsel has no specific response except to note that Dr. Heber is not an expert in the clinical treatment of prostate cancer. (CCFF ¶¶ 1008, 1043).

1776. 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).

Response to Finding No. 1776:
Complaint Counsel has no specific response except to note that: 1) Dr. Heber is not an expert in the clinical treatment of prostate cancer; and 2) Complaint Counsel's and Respondents' prostate cancer experts agreed that there are no studies demonstrating that modulating PSADT changes the natural history of the prostate cancer by delaying the development of metastases or death from the disease. (*See* CCFF ¶¶ 983, 1008, 1043).

(e) The Evidence Is Compelling That POM Promotes Prostate Health and May Help Prevent Prostate Cancer, Including for Healthy Undiagnosed Persons

1777. 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).

Response to Finding No. 1777:
Complaint Counsel has no specific response except to note that Dr. deKernion also testified that: 1) even where the *in vitro* and animal evidence is strong and shows that an agent's mechanism of action works, this evidence does not prove that the agent works in

humans; and 2) there are no clinical studies proving that the POM Products prevent or reduce the risk of prostate cancer. (*See* CCFF ¶ 1038).

1778. 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)).

Response to Finding No. 1778:
Complaint Counsel has no specific response except to note that Dr. deKernion testified that there are no clinical studies proving that the POM Products prevent or reduce the risk of prostate cancer. (*See* CCFF ¶ 1038).

1779. 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).

Response to Finding No. 1779:
Complaint Counsel has no specific response except to note that Respondents have not conducted a prevention clinical study on prostate cancer and they themselves acknowledge that they have "no data on prostate cancer prevention, prior to radiation or prostatectomy." (*See* CCFF ¶ 1010).

1780. 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).

Response to Finding No. 1780:
Complaint Counsel has no specific response except to note that Dr. deKernion also testified that there are no clinical studies proving that the POM Products prevent or reduce the risk of prostate cancer. (*See* CCFF ¶ 1038).

1781. 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).

Response to Finding No. 1781:

Complaint Counsel objects to the proposed finding as outside the scope of Dr. Miller's designated testimony. *See* Response to Finding 721.

1782. Dr. Heber stated that he would not exclude from the realm of possibility that, based on what we have scientifically, that pomegranate, ellagitannins in a supplement or juice form could contribute to the prevention of prostate cancer. (CX1352 (Heber, Dep. at 329)).

Response to Finding No. 1782:
Complaint Counsel objects to the deposition testimony cited in the proposed finding as non-designated testimony. Without waiving this objection, Complaint Counsel notes that Respondents have not conducted a prevention clinical study on prostate cancer and they themselves acknowledge that they have "no data on prostate cancer prevention, prior to radiation or prostatectomy." (*See* CCFF ¶ 1010).

1783. 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).

Response to Finding No. 1783:
The proposed finding is incomplete and mischaracterizes Dr. Heber's factual testimony as providing opinion testimony. Dr. Heber testified that "I think that there was a consensus [at POM's scientific advisory board meetings] 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. 2155-56). Complaint Counsel presented rebuttal testimony from Dr. Kantoff, Chief of the Genitourinary Oncology Division at the Dana-Farber Cancer Institute at Harvard Medical School, who contradicted Dr. Heber's testimony. Dr. Kantoff testified that he attended those 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." (*See* CCFF ¶ 1042).

(f) RCTs Are Not Necessary in the Context of a Food Like Pomegranate Juice

1784. 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. (deKernion, Tr. 3060).

Response to Finding No. 1784:
Complaint Counsel has no specific response except to note that Dr. Eastham opined that even safe products can have negative effects. Dr. Eastham testified that his opinion is "based on experience that we have with Vitamin E and selenium. They're innocuous substances. . . . When the studies were done, they didn't work and they did cause problems, so . . . it's a leap of faith to make a claim that something is innocuous when it hasn't been very well-studied in the scientific realm." (Eastham Tr. 1329; *see also* CCFF ¶ 1106 (stating the SELECT trial stopped early because of increased incidence of prostate cancer in men taking Vitamin E)).

1785. 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, just to mention a few), genetic predisposition, racial and ethnic factors, benign prostatic hypertrophy, and other factors that might have an effect on carcinogenesis of prostate cancer. (PX0206-0014).

Response to Finding No. 1785:
Complaint Counsel has no specific response.

1786. Dr. Miller stated that, "based on the solid nonclinical data, there should be no need to conduct two randomized well controlled trials to publicize that drinking POM Wonderful might decrease one's risk of developing prostate cancer. Such a statement is in the public's best interest and empowers individuals to take control of their own health by drinking and eating healthful foods, engaging in healthy activities, and avoiding potentially or known harmful ones." (PX0206-0013).

Response to Finding No. 1786:
Complaint Counsel does not disagree that Dr. Miller opined as such, but disagrees with his conclusions and notes that he has never designed clinical research protocols for foods

and has never been involved in designing clinical trials to prevent cancer in healthy people. (Miller, Tr. 2218).

1787. 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. (Miller, Tr. 2201).

Response to Finding No. 1787:
Complaint Counsel does not disagree Dr. Miller testified as such, but disagrees with his conclusion. Experts agree that to substantiate a claim that a food or dietary supplement is effective in preventing or reducing the risk of prostate cancer, experts in the field of prostate cancer would require at least one RCT involving an appropriate sample population and endpoint. (CCFF ¶ 974).

1788. 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)).

Response to Finding No. 1788:
The proposed finding is irrelevant. This case has to do with commercial advertising for the purpose of selling Respondents' products directly to the public, not the clinical practice of physicians following the standard of care.

1789. 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 he makes recommendations to patients about whether they should have radiation or surgery. (CX1341 (Pantuck, Dep. at 267-268)).

Response to Finding No. 1789:
The proposed finding is irrelevant. This case has to do with commercial advertising for the purpose of selling Respondents' products directly to the public, not the surgical practice of physicians following the standard of care.

1790. In clinical practice Dr. Pantuck guessed that significantly less than 50 percent of his clinical decisions are based on results of randomized placebo controlled Phase III studies as there are very few in urology that have been done. (CX1341 (Pantuck, Dep. at 276)).

Response to Finding No. 1790:
The proposed finding is irrelevant. This case has to do with commercial advertising for the purpose of selling Respondents' products directly to the public, not the clinical practice of physicians following the standard of care.

1791. Dr. Pantuck stated that clinicians remove kidneys without a randomized placebo controlled Phase III trial showing the benefits of nephrectomy. (CX1341 (Pantuck, Dep. at 276-277)).

Response to Finding No. 1791:
The proposed finding is irrelevant. This case has to do with commercial advertising for the purpose of selling Respondents' products directly to the public, not the surgical practice of physicians following the standard of care.

1792. Dr. Pantuck opined that clinicians base recommendations on the best estimates of the safety and benefits of treatments that are available at the time. (CX1341 (Pantuck, Dep. at 277)).

Response to Finding No. 1792:
The proposed finding is irrelevant. This case has to do with commercial advertising for the purpose of selling Respondents' products directly to the public, not the clinical practice of physicians following the standard of care.

(g) Clinicians Currently Recommend Pomegranate Juice Consumption as an Adjunct to Traditional Medical Care for Some Categories of Patients with Prostate Cancer

1793. 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. (deKernion, Tr. 3104; PX0161-0012).

Response to Finding No. 1793:
Complaint Counsel has no specific response except to note that the POM Products are not the only thing Dr. deKernion recommends to his prostate cancer patients and that he emphasizes to his patients that the POM Products have not been proven to prevent prostate cancer or prolong their lives. (*See* CCFF ¶ 1041).

1794. 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. (PX0161-0011-0012).

Response to Finding No. 1794:
Complaint Counsel has no specific response except to note that Dr. deKernion also stated that it is unclear whether POM will ultimately result in improved survival. (PX0161-0012).

1795. 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. (PX0351 (deKernion, Dep. at 83)).

Response to Finding No. 1795:
Complaint Counsel has no specific response except to note even safe products may have negative effects. Dr. Eastham testified that his opinion is "based on experience that we have with Vitamin E and selenium. They're innocuous substances. . . . When the studies were done, they didn't work and they did cause problems, so . . . it's a leap of faith to make a claim that something is innocuous when it hasn't been very well-studied in the scientific realm." (Eastham, Tr. 1329). *See also* Responses to Findings 201 and 1033.

1796. Dr. Pantuck testified that there are categories of patients that he recommends pomegranate juice. (CX1341 (Pantuck, Dep. at 269-271)).

Response to Finding No. 1796:
The proposed finding is incomplete in that Dr. Pantuck testified that it is reasonable to discuss pomegranate juice with patients like those he studied in the Pantuck Phase II Prostate Cancer Study (2006) – 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. (*See* ¶ CCFF 1040).

1797. Dr. Pantuck also testified that he is aware of doctors who have discussed the findings of his research with their patients. (CX1341 (Pantuck, Dep. at 268)).

Response to Finding No. 1797:
Complaint Counsel has no specific response.

1798. Dr. Pantuck, himself, consumes POM Wonderful pomegranate juice a few times a week. (CX1341 (Pantuck, Dep. at 264)).

Response to Finding No. 1798:
Complaint Counsel has no specific response.

1799. Dr. deKernion, testified that he consumes pomegranate extract. (deKernion, Tr. 3117).

Response to Finding No. 1799:
Complaint Counsel has no specific response.

1800. Dr. Heber testified that he informs prostate cancer patients about the research on pomegranate juice and pomegranate extract. (CX1352 (Heber, Dep. at 239)).

Response to Finding No. 1800:
Complaint Counsel has no specific response.

1801. 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).

Response to Finding No. 1801:
Complaint Counsel objects to the proposed finding as outside the scope of Dr. Miller's designated testimony. *See* Response to Finding 721.

(h) Premiere Hospitals in America Reference Information about the Health Benefits of the Pomegranate and Prostate Health in Their Publications and Websites

1802. The University of Texas MD Anderson Cancer Center, ranked by U.S. News & World Report as the best cancer hospital in America includes pomegranates in its" Glossary of Caner Terms." (U.S. News & World Report, *Best Hospitals Rankings*, *available at* http://health.usnews.com/best-hospitals/rankings/cancer (last visited Jan. 3, 2012)).

Response to Finding No. 1802:
The proposed finding is unsupported because the evidence cited is not in the record, in violation of the Court's Order on Post-Trial Briefs.

1803. MD Anderson Cancer Center defines pomegranate as "Punica granatum. A subtropical shrub or tree. Juice from the fruit may contain substances that decrease or slow the rise of prostate-specific antigen (PSA) levels. It is being studied for its ability to delay or prevent

recurrent prostate cancer." (MD Anderson Cancer Center, Glossary of Cancer Terms, P, *available at* http://www.mdanderson.org/patient-and-cancer-information/cancer-information/glossary-of-cancer-terms/p.html (last visited Jan. 3, 2012)).

Response to Finding No. 1803:
The proposed finding is unsupported because the evidence cited is not in the record, in violation of the Court's Order on Post-Trial Briefs.

1804. Inside Integrative Medicine a newsletter published by MD Anderson Cancer Center's Integrative Medicine Center too has cited the "Anticancer Effects of Pomegranate" stating that it may have preventative effects against prostate cancer. (MD Cancer Center, Inside Integrative Medicine (February/March 2010), *available at* http://www.mdanderson.org/publications/inside-integrative-medicine/issues/issue-15-febmarch2-010.pdf (last visited Jan. 3, 2012)).

Response to Finding No. 1804:
The proposed finding is unsupported because the evidence cited is not in the record, in violation of the Court's Order on Post-Trial Briefs.

1805. Memorial Sloan-Kettering Cancer Center in New York, is ranked second on U.S. News and World Reports list of best cancer hospitals. (U.S. News & World Report, *Best Hospitals Rankings*, *available at* http://health.usnews.com/health-news/best-hospitals/articles/2011/07/18/best-hospitals-2011-12-the-honor-roll (last visited Jan. 3, 2012)).

Response to Finding No. 1805:
The proposed finding is unsupported because the evidence cited is not in the record, in violation of the Court's Order on Post-Trial Briefs.

1806. Memorial Sloan-Kettering Cancer Center is also the hospital of Complaint Counsel's prostate expert Dr. James Eastham. (Eastham Tr. 1207).

Response to Finding No. 1806:
Complaint Counsel does not disagree except to clarify that Memorial Sloan-Kettering Cancer Center is Dr. Eastham's employer.

1807. On the website of Memorial Sloan-Kettering Cancer Center, information about the pomegranate is included on their Cancer Care Integrative Medicine web page. (Memorial Sloan-Kettering Cancer Center, Pomegranate, *available at* http://www.mskcc.org/cancer-care/herb/pomegranate (last visited Jan. 3, 2012)).

Response to Finding No. 1807:

The proposed finding is unsupported because the evidence cited is not in the record, in violation of the Court's Order on Post-Trial Briefs.

1808. The webpage includes a clinical summary of the pomegranate stating that pomegranate juice has been shown to "suppress inflammatory cell signaling, inhibit prostate tumor grown, and lower serum PSA levels." (Memorial Sloan-Kettering Cancer Center, Pomegranate, *available at* http://www.mskcc.org/cancer-care/herb/pomegranate (last visited Jan. 3, 2012)).

Response to Finding No. 1808:
The proposed finding is unsupported because the evidence cited is not in the record, in violation of the Court's Order on Post-Trial Briefs.

1809. The clinical summary also states that pomegranate juice was "found to benefit patients with carotid artery stenosis, in those with hypertension, hyperlipdemia, mild to moderate erectile dysfunction." (Memorial Sloan-Kettering Cancer Center, Pomegranate, *available at* http://www.mskcc.org/cancer-care/herb/pomegranate (last visited Jan. 3, 2012)).

Response to Finding No. 1809:
The proposed finding is unsupported because the evidence cited is not in the record, in violation of the Court's Order on Post-Trial Briefs.

1810. The webpage cites many POM sponsored studies including the Pantuck (prostate) study. (Memorial Sloan-Kettering Cancer Center, Pomegranate, *available at* http://www.mskcc.org/cancer-care/herb/pomegranate (last visited Jan. 3, 2012)).

Response to Finding No. 1810:
The proposed finding is unsupported because the evidence cited is not in the record, in violation of the Court's Order on Post-Trial Briefs.

1811. Johns Hopkins Hospital in Baltimore, Maryland is consistently ranked at the top or near the top of hospitals in America. U.S. News & World Report currently ranks Johns Hopkins as the number one overall hospital in America and as the third best cancer hospital in the country. (U.S. News & World Report, *Best Hospitals Rankings*, *available at* http://health.usnews.com/health-news/best-hospitals/articles/2011/07/18/best-hospitals-2011-12-the-honor-roll (last visited Jan. 3, 2012)).

Response to Finding No. 1811:
The proposed finding is unsupported because the evidence cited is not in the record, in violation of the Court's Order on Post-Trial Briefs.

1812. On the Johns Hopkins Prostate Cancer webpage for the Sidney Kimmel Comprehensive Cancer Center under the section New Treatments and Research, information about pomegranate research is provided under the heading, "Alternative Medicine/Natural Product Therapies." (New Treatments and Research: The Johns Hopkins Kimmel Cancer Center, *available at* (http://www.hopkinsmedicine.org/kimmel_cancer_center/types_cancer/prostate_cancer/new_treatments.html) (last visited Jan. 3, 2012)).

Response to Finding No. 1812:
The proposed finding is unsupported because the evidence cited is not in the record, in violation of the Court's Order on Post-Trial Briefs.

1813. Dr. Carducci's study on pomegranate extract which slowed PSA doubling time by more than six months in men with rising PSA levels following treatment for prostate cancer is cited. (New Treatments and Research: The Johns Hopkins Kimmel Cancer Center, *available at* (http://www.hopkinsmedicine.org/kimmel_cancer_center/types_cancer/prostate_cancer/new_treatments.html) (last visited Jan. 3, 2012)).

Response to Finding No. 1813:
The proposed finding is unsupported because the evidence cited is not in the record, in violation of the Court's Order on Post-Trial Briefs.

1814. The May 29, 2008 Johns Hopkins Health Alert Newsletter notes that pomegranates and pomegranate juice has been found to cause prostate cancer cells to "self-destruct." (Johns Hopkins Health Alerts, *Prostate Disorder Special Report: Simple Steps to Protect Yourself Against Prostate Cancer*, *available at* http://www.johnshopkinshealthalerts.com/reports/prostate_disorders/2016-1.html (last visited Jan. 3, 2012)).

Response to Finding No. 1814:
The proposed finding is unsupported because the evidence cited is not in the record, in violation of the Court's Order on Post-Trial Briefs.

1815. The May 29, 2008 Johns Hopkins Health Alert Newsletter further states that, "among men with prostate cancer, daily glasses of pomegranate juice have slowed the increase in PSA levels after treatment." (Johns Hopkins Health Alerts, *Prostate Disorder Special Report: Simple Steps to Protect Yourself Against Prostate Cancer*, *available at* http://www.johnshopkinshealthalerts.com/reports/prostate_disorders/2016-1.html (last visited Jan. 3, 2012)).

Response to Finding No. 1815:

The proposed finding is unsupported because the evidence cited is not in the record, in violation of the Court's Order on Post-Trial Briefs.

1816. The Mayo Clinic in Rochester, Minnesota, is according to U.S. News & World Report the third best hospital in America.(U.S. News & World Report, *Best Hospitals Rankings*, *available at* http://health.usnews.com/health-news/best-hospitals/articles/2011/07/18/best-hospitals-2011-12-the-honor-roll (last visited Jan. 3, 2012)).

Response to Finding No. 1816:
The proposed finding is unsupported because the evidence cited is not in the record, in violation of the Court's Order on Post-Trial Briefs.

1817. On the expert answers portion of the Mayo Clinic website the question is posed whether pomegranate juice is a cure for prostate cancer. (Mayo Clinic, Pomegranate juice: A cure for prostate cancer? *available at* http://www.mayoclinic.com/health/pomegranate-juice/AN01477 (last visited Jan. 3, 2012)).

Response to Finding No. 1817:
The proposed finding is unsupported because the evidence cited is not in the record, in violation of the Court's Order on Post-Trial Briefs.

1818. In response to whether pomegranate juice is a cure for prostate cancer, Mayo Clinic urologist Dr. Erik Castle, responds by stating that, "some research suggests that drinking pomegranate juice may slow the progression of prostate cancer." (Mayo Clinic, Pomegranate juice: A cure for prostate cancer?, *available at* http://www.mayoclinic.com/health/pomegranate-juice/AN01477 (last visited Jan. 3, 2012)).

Response to Finding No. 1818:
The proposed finding is unsupported because the evidence cited is not in the record, in violation of the Court's Order on Post-Trial Briefs.

1819. In response to whether pomegranate juice is a cure for prostate cancer, Mayo Clinic urologist Dr. Erik Castle cites the POM sponsored Allan Pantuck study where PSA doubling time was extended after drinking pomegranate juice. (Mayo Clinic, Pomegranate juice: A cure for prostate cancer? *available at* http://www.mayoclinic.com/health/pomegranate-juice/AN01477 (last visited Jan. 3, 2012)).

Response to Finding No. 1819:

The proposed finding is unsupported because the evidence cited is not in the record, in violation of the Court's Order on Post-Trial Briefs.

1820. In response to whether pomegranate juice is a cure for prostate cancer, Mayo Clinic urologist Dr. Erik Castle, states that, "a longer PSA doubling time indicates cancer may be progressing less rapidly." (Mayo Clinic, Pomegranate juice: A cure for prostate cancer? *available at* http://www.mayoclinic.com/health/pomegranate-juice/AN01477 (last visited Jan. 3, 2012)).

Response to Finding No. 1820:
The proposed finding is unsupported because the evidence cited is not in the record, in violation of the Court's Order on Post-Trial Briefs.

G. Complaint Counsel's Expert Offered Opinions That Are Insufficient to Undermine Respondents' Showing of Substantiation

1. Dr. Eastham's Positions Are Extreme

1821. Dr. James Eastham testified that RCT studies are required for health claims. (Eastham, Tr. 1327-30).

Response to Finding No. 1821:
Complaint Counsel has no specific response except to clarify that Dr. Eastham opined that RCTs are necessary to substantiate a claim that a food or dietary supplement prevents, reduces the risk of, or treats prostate cancer. (*See* CCFF ¶ 977).

1822. He testified that studies of disease prevention should involve 10,000 to 30,000 mean and that such studies are "incredibly expensive" and in the range of $600 million. (Eastham, Tr.1328).

Response to Finding No. 1822:
The proposed finding is incomplete in that Dr. Eastham also testified that: 1) the size of the study depends upon "the statistics of the study and what claims in terms of benefit that are projected"; and 2) "cost shouldn't necessarily change the bar of the scientific effort . . . just because something is expensive and difficult to do doesn't mean that that relieves someone from the burden of proof." (Eastham, Tr. 1328-29).

1823. Dr. Eastham testified that even if a product is safe and might create a benefit, like fruit juice, he would still require an expensive randomized control trial before he would consider it. (Eastham, Tr. 1329-31).

Response to Finding No. 1823:
The proposed finding is incomplete in that Dr. Eastham also testified that his opinion is "based on experience that we have with Vitamin E and selenium. They're innocuous substances. . . . When the studies were done, they didn't work and they did cause problems, so . . . it's a leap of faith to make a claim that something is innocuous when it hasn't been very well-studied in the scientific realm." (Eastham, Tr. 1329).

1824. Dr. Eastham has performed over 200 radical prostatectomies per year for a number years without a randomized control trial proving a benefit. (Eastham, Tr.1331-32).

Response to Finding No. 1824:
The proposed finding is irrelevant. This case has to do with commercial advertising for the purpose of selling Respondents' products directly to the public, not the surgical practice of physicians following the standard of care for the treatment of prostate cancer.

1825. He performed 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. (Eastham Tr. 1331-32).

Response to Finding No. 1825:
The proposed finding is irrelevant. This case has to do with commercial advertising for the purpose of selling Respondents' products directly to the public, not the surgical practice of physicians following the standard of care for the treatment of prostate cancer.

1826. Pomegranate juice consumption on the other hand has none of these side effects. (PX0352 (Goldstein, Dep. at 44); CX1341 (Pantuck, Dep. at 270).

Response to Finding No. 1826:
Complaint Counsel has no specific response except to note that the proposed finding implies that POM Juice is scientifically proven to be a substitute treatment for prostate cancer. However, Dr. Pantuck testified that POM Juice is not the standard of care. (*See* CCFF ¶ 1039).

1827. Dr. Eastham conceded that he cut out hundreds of prostates despite all those risks and without RCT substantiation, yet he would not consider pomegranate juice unless supported by RCTs. (Eastham, Tr. 1332).

Response to Finding No. 1827:
The proposed finding is irrelevant. This case has to do with commercial advertising for the purpose of selling Respondents' products directly to the public, not the surgical practice of physicians following the standard of care for the treatment of prostate cancer.

2. Dr. Eastham Agrees That the Pantuck and Carducci Studies Are Good Well Conducted Studies

1828. Dr. Pantuck's study was a Phase II study. Dr. Eastham agreed that the Pantuck study as a Phase II study could not be blinded. He agrees that blinding is not important in such a study. (Eastham, Tr. 1327).

Response to Finding No. 1828:
The proposed finding is incomplete in that Dr. Eastham also testified that although it was not possible to blind the Pantuck Phase II Prostate Cancer Study (2006) because it was a single-arm study, it is possible to design a study with a comparison substance or placebo which can be blinded.

1829. Dr. Eastham admits that the Carducci and Pantuck studies were well-designed, good studies. (Eastham, Tr. 1339).

Response to Finding No. 1829:
The proposed finding is incomplete in that Dr. Eastham also testified that "[w]hile they're well-designed, the flaw in the study is using PSA doubling time." (Eastham, Tr. 1339).

1830. They were well designed in how they selected patients, how they did their statistics and calculations. (Eastham, Tr. 1339).

Response to Finding No. 1830:
The proposed finding is incomplete in that Dr. Eastham also testified that "[w]hile they're well-designed, the flaw in the study is using PSA doubling time." (Eastham, Tr. 1339).

3. Dr. Eastham Incorrectly Asserts That Changes in PSA Doubling Time as a Surrogate For Progression or Death from Prostate Cancer Are Not Accepted

1831. In his testimony, Dr. Eastham stated that no one accepts modulation of or change in PSADT as a surrogate for progression or death from prostate cancer. (Eastham, Tr. 1340-41).

Response to Finding No. 1831:
Complaint Counsel does not disagree that Dr. Eastham testified as such.

1832. He testified that at baseline, PSADT is a prognostic marker – a predictor of clinical progression and death but does not know when after baseline it stops being a predictor. (Eastham, Tr.1342-44).

Response to Finding No. 1832:
The proposed finding mischaracterizes Dr. Eastham's testimony in that he did not say that he "does not know when after baseline it stops being a predictor." Dr. Eastham testified that "if one intervenes, then the PSA kinetics typically change. That change in PSA kinetics . . . hasn't been well studied to see how that impacts a clinically meaningful endpoint." (Eastham, Tr. 1344-45).

1833. Dr. Eastham could not say when or why it stopped being predictive. (Eastham, Tr.1344-45).

Response to Finding No. 1833:
Complaint Counsel has no specific response except to note that in response to the question "Then does it stop being an accurate predictor of survival or death a month after baseline?" Dr. Eastham responded: "We don't know. It hasn't been well-studied . . . ." (Eastham, Tr. 1344).

1834. Dr. Eastham insisted that no one would propose that changes in PSA doubling time are a prognostic factor. However Dr. deKernion and Dr. Heber did. Which is consistent with many articles (further illustrated below) that have used PSA doubling time as a surrogate and predictor of disease and death. (Eastham, Tr. 1345).

Response to Finding No. 1834:
The first sentence of the proposed finding is incomplete in that Dr. Eastham testified that PSADT is prognostic at the time of biochemical recurrence, but once an intervention is

introduced the PSA kinetics change and those changes have not been well-studied enough to know how it impacts a clinically meaningful endpoint such as death. Therefore, to his knowledge as an expert in the field of prostate cancer, no one would accept changes or modulation in PSA doubling time as a prognostic factor. (Eastham, Tr. 1344-45). Notably, Respondents' researchers Dr. Pantuck and Dr. Carducci confirmed Dr. Eastham's opinion. (*See* CCFF ¶ 994 (Pantuck stating nobody has ever shown conclusively that changes in PSA kinetics arising from therapeutic intervention is meaningful); CX1340 (Carducci, Dep. at 89-90) (stating that slowing PSADT has not yet been proven to be beneficial)). Complaint Counsel has no specific response to the first sentence of the proposed finding. The second and third sentences of the proposed finding are unsupported by the cited evidence.

1835. Complaint counsel's expert, Dr. Meir Stampfer opined that PSA doubling time was a "predictor of disease and mortality" and that, if the extension of PSA doubling time is true, it would substantially prolong lives. (Stampfer, Tr. 869, 873).

Response to Finding No. 1835:

The proposed finding mischaracterizes Dr. Stampfer's testimony in that he stated that PSADT is an "imperfect predictor of mortality, but it does predict, yes." (Stampfer, Tr. 869). In addition, the proposed finding is incomplete. While Dr. Stampfer testified that extending PSADT could prolong lives if proven true, he stated that "it's a pity that they didn't include a proper control group." (Stampfer, Tr. 873). Moreover, Dr. Stampfer opined in his report that "it is unknown if PSADT predicts overall survival in prostate cancer patients throughout its range." (CX1293 (Stampfer, Report at 0026)).

1836. Complaint counsel's expert, Dr. Sacks also testified that if something is considered a surrogate for a particular illness or death (as is PSA doubling time), it necessarily follow that changes in that surrogate predict the likelihood of illness or death. (Sacks, Tr. 1613).

Response to Finding No. 1836:

The proposed finding mischaracterizes Dr. Sacks' testimony in that he gave his opinion in response to a question about cholesterol as a surrogate and not PSADT. As Respondents' expert admits, there are no studies demonstrating that an agent which modulates PSADT changes the natural history of prostate cancer by delaying development of metastatic disease or death from the disease. (*See* CCFF ¶ 983).

1837. Dr. Eastham testified that he would not use the word "surrogate" for PSA doubling time but used it in his article, "Prostate-specific antigen doubling time as a prognostic marker in prostate cancer" published in Nature Clinical Practice October 2005. (PX0178; Eastham, Tr. 1342).

Response to Finding No. 1837:
Complaint Counsel does not disagree except to note that Dr. Eastham also testified that "'surrogate' is probably an overstatement" and that he would say that "PSA doubling time is one of the prognostic factors that is used to assess risk when a man has recurrence of prostate cancer." (Eastham, Tr. 1342-43).

1838. In his article, Dr. Eastham wrote 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." (emphasis added) (PX0178-0001).

Response to Finding No. 1838:
Complaint Counsel does not disagree that the article states as such but notes that the article does not contradict the fact that: 1) there are no studies demonstrating that *modulating* PSADT (as the POM Products appeared to do in the Pantuck and Carducci studies) changes the natural history of prostate cancer by delaying the development of metastases or death from disease; and 2) PSADT has not been accepted by experts in the field of prostate cancer as a surrogate endpoint for survival in prostate cancer treatment clinical trials. (CCFF ¶¶ 978-83, 994-95; *see also* CX1340 (Carducci, Dep. at 89-90) (stating that slowing PSADT has not yet been proven to be beneficial)).

1839. 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).

Response to Finding No. 1839:
Complaint Counsel has no specific response except to note that none of the cited studies demonstrate that *modulating* PSADT (as the POM Products appeared to do in the Pantuck and Carducci studies) changes the natural history of prostate cancer by delaying the development of metastases or death from disease. (*See* CCFF ¶ 982).

1840. 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).

Response to Finding No. 1840:
Complaint Counsel does not disagree except to note that Dr. Eastham also wrote that "[c]ombined with other known clinical and pathologic parameters, the PSADT is an effective tool to assess the risk after biochemical failure and to counsel men regarding the probability of clinical progression." (PX0178-0009). Moreover, nothing in this article contradicts Dr. Eastham's opinion that: 1) PSADT is not accepted by experts in the field as a surrogate endpoint in prostate cancer clinical studies evaluating an agent's efficacy for the treatment of prostate cancer; and 2) there are no studies demonstrating that modulating PSADT changes the natural course of the disease. (*See* CCFF ¶¶ 978, 983).

4. A Number of Published Studies Have Demonstrated the Now Widespread Acceptance of PSA Doubling Time as a Valid Surrogate and Predictor of Disease and Death

1841. In a study entitled, "Does PSADT After Radical Prostatectomy Correlate With Overall Survival?" Dr. Anna Teeter and her colleagues wrote in the January 2011 edition of the Journal of Urology of the "widespread acceptance" that PSADT after radical prostatectomy predicts prostate cancer mortality and that this has been "well established" and that PSADT is "a powerful predictor of overall survival." (PX0167).

Response to Finding No. 1841:

The proposed finding mischaracterizes the cited evidence by taking the statement "a powerful predictor of overall survival" out of context. The article states that PSADT is a "powerful predictor of [overall survival] and [prostate cancer specific mortality] among this older cohort with a high prevalence of tobacco use and medical comorbidities." (PX0167-0004). Complaint Counsel also notes that both Complaint Counsel's and Respondents' experts agree that PSADT has prognostic value. (*See* CCFF ¶¶ 980-82). This study is part of the body of research which supports the use of PSADT as a predictor of clinical progression in men with biochemical recurrence after initial therapy for prostate cancer. This study does not refute the fact that PSADT has not been accepted by experts in the field of prostate cancer as a surrogate endpoint in prostate cancer clinical studies evaluating an agent's efficacy for the treatment of prostate cancer. (*See* CCFF ¶ 978).

1842. In the Teeter study the researchers examined the correlation between prostate-specific antigen doubling time and overall survival among men undergoing radical prostatectomy. The authors concluded that a PSADT of less than three months was associated with poorer overall survival than a PSADT of equal to or greater than 15 months. (PX0167).

Response to Finding No. 1842:

Complaint Counsel has no specific response except to note that both Complaint Counsel's and Respondents' experts agree that PSADT has prognostic value. (*See* CCFF ¶¶ 980-82). This study is part of the body of research which supports the use of PSADT as a predictor of clinical progression in men with biochemical recurrence after initial therapy for prostate cancer. This study does not refute the fact that PSADT has not been accepted by experts in the field of prostate cancer as a surrogate endpoint in prostate cancer clinical studies evaluating an agent's efficacy for the treatment of prostate cancer. (*See* CCFF ¶ 978).

1843. The authors also concluded that their study validated previous findings that PSADT is a "useful tool for identifying men at increased risk of all-cause mortality early in their disease course." (PX0167).

Response to Finding No. 1843:

Complaint Counsel does not disagree that this study contains this statement but notes that both Complaint Counsel's and Respondents' experts agree that PSADT has prognostic value. (*See* CCFF ¶¶ 980-82). This study is part of the body of research which supports the use of PSADT as a predictor of clinical progression in men with biochemical recurrence after initial therapy for prostate cancer. This study does not refute the fact that PSADT has not been accepted by experts in the field of prostate cancer as a surrogate endpoint in prostate cancer clinical studies evaluating an agent's efficacy for the treatment of prostate cancer. (*See* CCFF ¶ 978).

1844. Dr. Tollefson and colleagues wrote in the April 2007 issue of Mayo Clinic Proceedings in a study entitled, "Stratification of Patient Risk Based on Prostate-Specific Antigen Doubling Time after Radical Retropublic Prostatectomy" that PSADT was "a highly significant and reliable test" to determine the likelihood of disease recurrence and death, an "excellent indicator of clinical disease recurrence" and the only significant factor that predicts clinical progression." (PX0166)(emphasis added).

Response to Finding No. 1844:

The proposed finding mischaracterizes the study by taking the statement "a highly significant and reliable test" out of context. The article states that "[PSADT] has been investigated as a highly significant and reliable tool to distinguish patients destined to have prolonged or innocuous PSA levels after definitive therapy from those who are at great risk for clinical disease recurrence and death." (PX0166-0001). Complaint Counsel also notes that both Complaint Counsel's and Respondents' experts agree that PSADT has prognostic value. (*See* CCFF ¶¶ 980-82). This study is part of the body of research which supports the use of PSADT as a predictor of clinical progression in men with biochemical recurrence after initial therapy for prostate cancer. This study does not

refute the fact that PSADT has not been accepted by experts in the field of prostate cancer as a surrogate endpoint in prostate cancer clinical studies evaluating an agent's efficacy for the treatment of prostate cancer. (*See* CCFF ¶ 978).

1845. In the Tollefson study, researchers sought to "assess the risk of local recurrence, systemic progression, and death from cancer among patients who experience biochemical relapse after radical retropubic prostatectomy and to stratify those patients by prostate-specific antigen doubling time." (PX0166).

Response to Finding No. 1845:
Complaint Counsel does not disagree that this study states as such except to note that both Complaint Counsel's and Respondents' experts agree that PSADT has prognostic value. (*See* CCFF ¶¶ 980-82). This study is part of the body of research which supports the use of PSADT as a predictor of clinical progression in with men biochemical recurrence after initial therapy for prostate cancer. This study does not refute the fact that PSADT has not been accepted by experts in the field of prostate cancer as a surrogate endpoint in prostate cancer clinical studies evaluating an agent's efficacy for the treatment of prostate cancer. (*See* CCFF ¶ 978).

1846. The researchers concluded that, "prostate-specific antigen doubling time is an independent predictor of clinical disease recurrence and mortality after surgical biochemical failure." (PX0166).

Response to Finding No. 1846:
See Response to Finding 1845.

1847. In a study entitled, "Risk of Prostate Cancer-Specific Mortality Following Biochemical Recurrence After Radical Prostatectomy" Dr. Freedland and colleagues used PSADT to "define risk factors for prostate cancer death following radical prostatectomy and to develop tables to risk stratify for prostate cancer-specific survival." (PX0165).

Response to Finding No. 1847:
Complaint Counsel does not disagree that this study states as such except to note that both Complaint Counsel's and Respondents' experts agree that PSADT has prognostic value. (*See* CCFF ¶¶ 980-82). This study is part of the body of research which supports

the use of PSADT as a predictor of clinical progression in men with biochemical recurrence after initial therapy for prostate cancer. This study does not refute the fact that PSADT has not been accepted by experts in the field of prostate cancer as a surrogate endpoint in prostate cancer clinical studies evaluating an agent's efficacy for the treatment of prostate cancer. (*See* CCFF ¶ 978).

1848. Dr. Freedland et al., found that patients with a PSADT in less than 3 months had a median survival of 6 years. Patients with a PSADT in less than 3 months, biochemical recurrence 3 years or less after surgery, and a pathological Gleason score of 8-10 has a median survival of 3 years. Patients with a PSADT of 15 or more months and a biochemical recurrence more than 3 years after surgery had a 100% cause–specific survival. (PX0165).

Response to Finding No. 1848:
Complaint Counsel has no specific response except to note that both Complaint Counsel's and Respondents' experts agree that PSADT has prognostic value. (*See* CCFF ¶¶ 980-82). This study is part of the body of research which supports the use of PSADT as a predictor of clinical progression in men with biochemical recurrence after initial therapy for prostate cancer. This study does not refute the fact that PSADT has not been accepted by experts in the field of prostate cancer as a surrogate endpoint in prostate cancer clinical studies evaluating an agent's efficacy for the treatment of prostate cancer. (*See* CCFF ¶ 978).

1849. The researchers found that clinical parameters such as PSADT can help risk stratify patients for prostate cancer-specific mortality following biochemical recurrence after radical prostatectomy. (PX0165).

Response to Finding No. 1849:
See Response to Finding 1848.

1850. In a study entitled, "Recurrence Patterns After Radical Retropubic Prostatectomy: Clinical Usefulness of Prostate Specific Antigen Doubling Times and Log Slope Prostate Speicfic Antigen" published in the October 1997 edition of the Journal of Urology, Drs. Patel, deKernion, et al. studied the correlation between prostate specific antigen doubling time and clinical recurrence in patients with detectable PSA after radical retropubic prostatectomy. (PX0162).

Response to Finding No. 1850:
Complaint Counsel has no specific response except to note that both Complaint Counsel's and Respondents' experts agree that PSADT has prognostic value. (*See* CCFF ¶¶ 980-82). This study is part of the body of research which supports the use of PSADT as a predictor of clinical progression in men with biochemical recurrence after initial therapy for prostate cancer. This study does not refute the fact that PSADT has not been accepted by experts in the field of prostate cancer as a surrogate endpoint in prostate cancer clinical studies evaluating an agent's efficacy for the treatment of prostate cancer. (*See* CCFF ¶ 978).

1851. The researchers concluded that, after PSA became detectable PSA doubling time was a better indicator of the risk and time to clinical recurrence after radical retropubic prostatectomy than other factors including preoperative PSA. (PX0162).

Response to Finding No. 1851:
See Response to Finding 1850.

5. Dr. Eastham's Opinions Do Not Rebut Respondents Pre-Clinical, and Clinical Research Showing a Benefit for Pomegranates and Prostate Health

1852. Dr. Eastham's opinions on PSA doubling time were impeached by his own article. (PX0178).

Response to Finding No. 1852:
The proposed finding is not supported by the cited evidence. Dr. Eastham testified that 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. (*See* CCFF ¶¶ 980-81). His testimony is consistent with the conclusions of his article that PSADT is an important prognostic marker in men with biochemical failure after initial local therapy for prostate cancer. (PX0178-0009). This study does not refute the fact that PSADT has not been accepted by experts in the field of prostate cancer as a surrogate endpoint in prostate cancer

clinical studies evaluating an agent's efficacy for the treatment of prostate cancer. (*See* CCFF ¶ 978).

1853. Dr. Eastham himself has performed over 200 radical prostatectomies per year for a number of years when no RCT had been done showing that the operation provided a benefit for the treatment of prostate cancer. (Eastham, Tr. 1331; PX0358 (Eastham, Dep. at 154-155).

Response to Finding No. 1853:
The proposed finding is irrelevant. This case has to do with commercial advertising for the purpose of selling Respondents' products directly to the public, not the surgical practice of physicians following the standard of care for the treatment of prostate cancer.

1854. Dr. Eastham testified that Dr. Pantuck's study was a well-designed Phase II study and that in the grouping of patients that were examined, PSA doubling time was prolonged. (PX0358 (Eastham, Dep. at 88)).

Response to Finding No. 1854:
The proposed finding mischaracterizes Dr. Eastham's opinion. At trial, Dr. Eastham also testified that "[w]hile they're well-designed, the flaw in the study is using PSA doubling time." (Eastham, Tr. 1339).

H. In Addition to the Science, Research, and Expert Testimony Discussed Above, Respondents Offered Into Evidence Additional Research That Provides Substantiation for the Challenged Products

1. Research Not Sponsored by POM Wonderful, But on Similar Extracts, Supports Findings That the Challenged Products Support Prostate Health

1855. In a study by Malik, et al., *Pomegranate Fruit Juice for Chemoprevention and Chemotherapy of Prostate Cancer*, Proc. Natl. Acad. Sci. USA, 2005 Oct 11; 102(41): 14813-8, pomegranate fruit extract was shown to have an effect on prostate cancer cells. (PX0173).

Response to Finding No. 1855:
Complaint Counsel has no specific response except to note that: 1) animal and *in vitro* studies do not prove that an agent works in humans; and 2) data from RCTs provide the

best evidence of a causal relationship between a nutrient and a disease outcome in humans. (*See* CCFF ¶¶ 763-71).

1856. In the Malik study, pomegranate fruit extract with acetone and water (Fruit Juice Extract or FJE) known to be rich in pomegranate ellagitannins similar to POM Wonderful juice, POMx, and POMx Liquid were shown to have potent prostate cancer reducing effects when consumed by mice implanted with androgen- sensitive CWR22Rvl cells. (PX0173).

Response to Finding No. 1856:
See Response to Finding 1855.

1857. The research showed significant inhibition in tumor growth concomitant with a significant decrease in serum prostate-specific antigen levels. (PX0173).

Response to Finding No. 1857:
See Response to Finding 1855.

1858. FJE (pomegranate ellagitannins) consumption resulted in a significant drop in PSA levels or doubling time in direct relationship to prostate cancer tumor volume. (PX0173).

Response to Finding No. 1858:
See Response to Finding 1855.

1859. FJE (pomegranate ellagitannins) inhibited PSA, a marker for prostate cancer progression. (PX0173).

Response to Finding No. 1859:
See Response to Finding 1855.

1860. Also, in vitro results demonstrated that FJE (10-100 ug/ml) treatment of highly aggressive human prostate cancer PC3 cells resulted in a dose dependent inhibition of cell growth/cell viability and induction of apoptosis. (PX0173).

Response to Finding No. 1860:
See Response to Finding 1855.

1861. Also, FJE decreased PSA expression in human prostate cancer cells. (PX0173).

Response to Finding No. 1861:
See Response to Finding 1855.

1862. The researchers concluded that "the fruit pomegranate and its associated antioxidants may possess a strong potential for development as a chemopreventive and possible therapeutic agent against CaP (prostate cancer)." (PX0173).

Response to Finding No. 1862:
See Response to Finding 1855.

1863. In a study by, Albrecht M, Jiang W, Kumi-Diaka J, et al., *Pomegranate extracts potently suppress proliferation, xenograft growth, and invasion of human prostate cancer cells*. J Med Food 7: 274-283, 2004, pomegranate extract was shown to have anti-tumor activity. (PX0207).

Response to Finding No. 1863:
Complaint Counsel has no specific response except to note that: 1) animal and *in vitro* studies do not prove that an agent works in humans; and 2) data from RCTs provide the best evidence of a causal relationship between a nutrient and a disease outcome in humans. (*See* CCFF ¶¶ 763-71).

1864. In this study, pomegranate juice and pericarp (extract from peel) polyphenols were studied on human prostate cancer cell xenograft growth (in vivo) and the proliferation, cell cycle distribution, apoptosis, and gene expression (in vitro). (PX0207).

Response to Finding No. 1864:
See Response to Finding 1863.

1865. The juice and pericarp polyphenols demonstrated similar and significant anti- tumor activity against human cancer cells (LNCaP, PC-3 and DU 145). (PX0207).

Response to Finding No. 1865:
See Response to Finding 1863.

1866. Pericarp polyphenols demonstrated potent inhibition of PC-3 xenograft growth in mice. (PX0207).

Response to Finding No. 1866:
See Response to Finding 1863.

1867. The researchers concluded that pomegranate juice and extract have similar anti-cancer effects. (PX0207).

Response to Finding No. 1867:
The proposed finding is unsupported by the cited evidence in that "pomegranate juice" was not tested.

1868. Respondents have also offered into evidence further research not sponsored by POM Wonderful supporting the Challenged Products and prostate health. (PX0382).

Response to Finding No. 1868:
Complaint Counsel has no specific response except to note that PX0382 is a compendium of more than 450 articles, including numerous animal and *in vitro* studies, studies that have been previously cited and discussed above, studies on diseases other than prostate cancer, and studies on agents other than pomegranate. Without expert testimony verifying the relevance of these studies, it is not possible to determine whether they support "the Challenged Products and prostate health."

2. Additional Research Contributing to the Total Body Of Science Supporting the Challenged Products and Prostate Health

1869. Seeram NP, Aronson WJ, Zhang Y, Henning SM, Moro A, Lee R, Sartippour M, Harris DM, Rettig M, Suchard MA, Pantuck AJ, Belldegrun A, and Heber D, *Pomegranate Ellagitannin-Derived Metabolites Inhibit Prostate Cancer Growth and Localize to the Mouse Prostate Gland*, J. Agric. Food Chem.2007, 55, 7732-7737. (PX0069).

Response to Finding No. 1869:
Complaint Counsel has no specific response except to note its disagreement with Respondents' characterization of this study as additional research. This study has been previously cited and discussed above. *See* Responses to Findings 1641-44.

1870. Rettig MB, Heber D, An J, Seeram NP, Rao JY, Liu H, Klatt T, Belldegrun A, Moro A, Henning SM, Mo D, Aronson WJ, and Pantuck A, *Pomegranate extract inhibits androgen-independent prostate cancer growth through a nuclear factor-κB-dependent mechanism*, Molecular Cancer Therapy 7 (9): 2662-2671 (2008). (PX0070).

Response to Finding No. 1870:
Complaint Counsel has no specific response except to note its disagreement with Respondents' characterization of this study as additional research. This study has been previously cited and discussed above. *See* Responses to Findings 1618-27.

1871. Sartippour MR, Seeram NP, Rao JY, Moro A, Harris DM, Henning SM, Firouzi A, Rettig MB, Aronson WJ, Pantuck AJ, and Heber D, *Ellagitannin-rich pomegranate extract inhibits angiogenesis in prostate cancer in vitro and in vivo*, International Journal of Oncology 32: 475-480, 2008. (PX0071).

Response to Finding No. 1871:

Complaint Counsel has no specific response except to note its disagreement with Respondents' characterization of this study as additional research. This study has been previously cited and discussed above. *See* Responses to Findings 1654-58.

1872. Koyama, et al., *Pomegranate Extract Induces Apoptosis in Human Prostate Cancer Cells by Modulation of the IGF-IGFBP Axis*, Growth Horm IGF Res. 2010 Feb; 20(1): 55-62. (PX0183).

Response to Finding No. 1872:
Complaint Counsel has no specific response except to note that: 1) animal and *in vitro* studies do not prove that an agent works in humans; and 2) data from RCTs provide the best evidence of a causal relationship between a nutrient and a disease outcome in humans. (*See* CCFF ¶¶ 763-71).

1873. Agensys, *Investigation of the Effect of Pomegranate Juice (PJC) on Human Prostate Cancer* (Unpublished Study Results, 2001) (PX065).

Response to Finding No. 1873:
Complaint Counsel has no specific response except to note its disagreement with Respondents' characterization of this study as additional research. This study has been previously cited and discussed above. *See* Responses to Findings 1638-40.

1874. Agensys, *Investigation of the Effect of Pomegranate Juice (PJC) on Human Prostate Cance*r, Final Power Point Presentation (2003) (PX0066).

Response to Finding No. 1874:
Complaint Counsel has no specific response except to note its disagreement with Respondents' characterization of this study as additional research. This study has been previously cited and discussed above. *See* Responses to Findings 1638-40.

1875. Agensys, *PJC Reduces Subcutaneous Growth of Prostate Tumors* (11/20/2001) (PX0067)

Response to Finding No. 1875:
Complaint Counsel has no specific response except to note its disagreement with Respondents' characterization of this study as additional research. This study has been previously cited and discussed above. *See* Responses to Findings 1638-40.

1876. Hong MY, Seeram NP, and Heber D, *Pomegranate polyphenols down-regulate expression of androgen synthesizing genes in human prostate cancer cells overexpressing the androgen receptor*, Journal of Nutritional Biochemistry 19 (2008) 848-855. (PX0068).

Response to Finding No. 1876:
Complaint Counsel has no specific response except to note its disagreement with Respondents' characterization of this study as additional research. This study has been previously cited and discussed above. *See* Responses to Findings 1645-49.

1877. Carducci MA, 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 (unpublished clinical study report, 2007) (PX0063).

Response to Finding No. 1877:
Complaint Counsel has no specific response except to note its disagreement with Respondents' characterization of this study as additional research. This study has been previously cited and discussed above. *See* Responses to Findings 1696-1700.

1878. Beer, et al., Double-Blinded Randomized Study of High-Dose Calcitriol Plus Docetaxel in Androgen-Independent Prostate Cancer: A Report From the ASCENT Investigators, J. Clin. Oncol. 2007 Feb 20; 25(6): 669-74 (PX0186).

Response to Finding No. 1878:
Complaint Counsel has no specific response except to note that the cited article does not examine the effect of the POM Products on prostate cancer.

1879. Andriole, et al., Treatment With Finasteride Following Radical Prostatectomy for Prostate Cancer, Urology, March 1995, Volume 45, Number 3. (PX0177).

Response to Finding No. 1879:
Complaint Counsel has no specific response except to note that the cited article does not examine the effect of the POM Products on prostate cancer.

1880. Carducci, et al., A Phase II Study of Pomegranate Extract for Men with Rising Prostate-Specific Antigen Following Primary Therapy, J. Clin. Oncol. 29: 2011 (suppl 7; abstr 11). (PX0175).

Response to Finding No. 1880:

Complaint Counsel has no specific response except to note its disagreement with Respondents' characterization of this study as additional research. This study has been previously cited and discussed above. *See* Responses to Findings 1696-1700.

1881. Carmody, et al., A dietary Intervention for Recurrent Prostate Cancer after Definitive Primary Treatment: Results of a Randomized Pilot Trial, Urology 2008 December; 72(6): 1324-8. (PX0168).

Response to Finding No. 1881:
Complaint Counsel has no specific response except to note that the cited article does not examine the effect of the POM Products on prostate cancer.

1882. deNigris et al., Beneficial Effects of Antioxidants and L-arginine on Oxidation-Sensitive Gene Expression and Endothelial NO Synthase Activity at Sites of Disturbed Shear Stress, PNAS 2003 100: 1420-1425. (PX0174).

Response to Finding No. 1882:
Complaint Counsel has no specific response except to note that 1) animal and *in vitro* studies do not prove that an agent works in humans; and 2) data from RCTs provide the best evidence of a causal relationship between a nutrient and a disease outcome in humans. (*See* CCFF ¶¶ 763-71).

1883. Freedland, et al., Risk of Prostate Cancer-Specific Mortality Following Biochemical Recurrence After Radical Prostatectomy (Abstract), JAMA, 2005; 294(4): 433-439. (PX0165).

Response to Finding No. 1883:
Complaint Counsel has no specific response except to note its disagreement with Respondents' characterization of this study as additional research. This study has been previously cited and discussed above. *See* Responses to Findings 1847-49.

1884. Giovacchini, et al., PSA Doubling Time for Prediction of [(11)C]choline PET/CT Findings in Prostate Cancer Patients with Biochemical Failure after Radical Rrostatectomy (Abstract), Eur. J. Nucl. Med. Mol. Imaging, 2010 June; 37(6): 1106-16. (PX0164).

Response to Finding No. 1884:

Complaint Counsel has no specific response except to note that both Complaint Counsel's and Respondents' experts agree that PSADT has prognostic value. (*See* CCFF ¶¶ 980-82). This study is part of the body of research which supports the use of PSADT as a predictor of clinical progression in men with biochemical recurrence after initial therapy for prostate cancer. This is not a clinical study evaluating an agent's efficacy for the treatment of prostate cancer.

1885. Leung, et al., Exercise Alters the IGF Axis In Vivo and Increases P54 Protein in Prostate Tumor Cells In Vitro, J. Appl. Physiol. 96: 450-454, 2004; 10.1152/japplphysiol.00871.203 (PX0176).

Response to Finding No. 1885:
Complaint Counsel has no specific response except to note that the cited article does not examine the effect of the POM Products on prostate cancer.

1886. Pantuck AJ, Leppert JT, Zomorodian N, Aronson W, Hong J, Bardnard RJ, Seeram N, Liker H, Wang J, Elashoff R, Heber D, Aviram M, Ignarro L, Belldegrun A, Phase II Study of Pomegranate Juice for Men with Rising Prostate-Specific Antigen following Surgery or Radiation for Prostate Cancer, Clin. Cancer Research 12 (13): 4018-4026 (2006). (PX0060).

Response to Finding No. 1886:
Complaint Counsel has no specific response except to note its disagreement with Respondents' characterization of this study as additional research. This study has been previously cited and discussed above. *See* Responses to Findings 1661-64, 1670-73.

1887. Pantuck AJ, Zomorodian N, Rettig M, Aronson WJ, Heber D, Belldegrun AS, Long Term Follow Up of Phase 2 Study of Pomegranate Juice for Men with Prostate Cancer Shows Durable Prolongation of PSA Doubling Time, J. of Urology Vol. 181 No. 4, Supplement (2009). (PX0061).

Response to Finding No. 1887:
Complaint Counsel has no specific response except to note its disagreement with Respondents' characterization of this study as additional research. This study has been previously cited and discussed above. *See* Responses to Findings 1676-81.

1888. Patel, et al., Recurrence Patterns After Radical Retropubic Prostatectomy: Clinical Usefulness of Prostate Specific Antigen Doubling Times and Log Slope Prostate Specific Antigen, Journal of Urology, Vol. 158, 1441-1445, October 1997. (PX0162).

Response to Finding No. 1888:
Complaint Counsel has no specific response except to note its disagreement with Respondents' characterization of this study as additional research. This study has been previously cited and discussed above. *See* Responses to Findings 1850-51.

1889. Pound, et al., Natural History of Progression After PSA Elevation Following Radical Prostatectomy (Abstract), JAMA 1999; 281(17): 1591-1597. (PX0163).

Response to Finding No. 1889:
Complaint Counsel's and Respondents' experts agree that PSADT has prognostic value. (*See* CCFF ¶¶ 980-82). This study is part of the body of research which supports the use of PSADT as a predictor of clinical progression in men with biochemical recurrence after initial therapy for prostate cancer. This is not a clinical study evaluating an agent's efficacy for the treatment of prostate cancer.

1890. Schroder, et al., Randomized, Double-Blind, Placebo-Controlled Crossover Study in Men with Prostate Cancer and Rising PSA: Effectiveness of a Dietary Supplement, Eur. Urol. 2005 December; 48(6): 922-30. (PX0169).

Response to Finding No. 1890:
Complaint Counsel has no specific response except to note that the cited article does not examine the effect of the POM Products on prostate cancer.

1891. Smith MR, et al., Rosiglitazone versus Placebo for Men with Prostate Cancer and a Rising Serum Prostate Specific Antigen after Radical Prostatectomy and/or Radiation Therapy, Cancer, 2004 October 1; 101(7): 1569-74. (PX0172).

Response to Finding No. 1891:
Complaint Counsel has no specific response except to note that this randomized, double-blind, placebo-controlled study examined the effect of an agent on PSADT in a population of men similar to the patients studied in the Pantuck Phase II Prostate Cancer Study. Men in both the placebo and treatment groups experienced a lengthening of

PSADT suggesting a possible placebo effect. The authors concluded 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." (*See* CCFF ¶¶ 996-98). This study supports Complaint Counsel's experts' opinion that without a placebo, it is not possible to determine whether POM Juice and POMx had an effect on PSADT in the Pantuck and Carducci studies. (*See* CCFF ¶¶ 1003-04, 1023).

1892. Teeter, et al., Does PSADT after Prostatectomy Correlate with Overall Survival?—A Report from the SEARCH Database Group, Urology. 2011 January; 77(1): 149-53. (PX0167).

Response to Finding No. 1892:
Complaint Counsel has no specific response except to note its disagreement with Respondents' characterization of this study as additional research. This study has been previously cited and discussed above. *See* Responses to Findings 1841-43.

1893. Tollefson, et al., Stratification of Patient Risk Based on Prostate-Specific Antigen Doubling Time after Tadical Retropubic Prostatectomy (Abstract), Mayo Clin. Proc. 2007 Apr; 82(4): 422-7. (PX0166).

Response to Finding No. 1893:
Complaint Counsel has no specific response except to note its disagreement with Respondents' characterization of this study as additional research. This study has been previously cited and discussed above. *See* Responses to Findings 1844-46.

1894. Trapasso, et al, The Incidence and Significance of Detectable Levles of Serum Prostate Specific Antigen After Radical Prostatectomy, Journal of Urology, Vol. 152, 1821-1825, November 1994. (PX0171).

Response to Finding No. 1894:
Complaint Counsel's and Respondents' experts agree that PSADT has prognostic value. (*See* CCFF ¶¶ 980-82). This study is part of the body of research which supports the use of PSADT as a predictor of clinical progression in men with biochemical recurrence after

initial therapy for prostate cancer. This is not a clinical study evaluating an agent's efficacy for the treatment of prostate cancer.

1895. Zhang, et al., Effect of Lycopene on Androgen Receptor and Prostate-Specific Antigen Velocity, Chin. Med J. (Engl) 2010 August; 123(16): 2231-6. (PX0170).

Response to Finding No. 1895:
Complaint Counsel has no specific response except to note that the cited article does not examine the effect of the POM Products on prostate cancer.

1896. Benchikh El Fegoun, et al., PSA and Follow-up after Treatment of Prostate Cancer, Prog. Urol. 2008 Mar; 18(3): 137-44. (PX0187).

Response to Finding No. 1896:
Complaint Counsel's and Respondents' experts agree that PSADT has prognostic value. (*See* CCFF ¶¶ 980-82). This study is part of the body of research which supports the use of PSADT as a predictor of clinical progression in men with biochemical recurrence after initial therapy for prostate cancer. This is not a clinical study evaluating an agent's efficacy for the treatment of prostate cancer.

1897. Danella, et al., Detectable Prostate Specific Antigen Levels Following Radical Prostatectomy: Relationship of Doubling Time to Clinical Outcome, Presented at the American Urological Association 88th Annual Meeting, San Antonio, Texas, May 1993. (PX0180).

Response to Finding No. 1897:
Complaint Counsel's and Respondents' experts agree that PSADT has prognostic value. (*See* CCFF ¶¶ 980-82). This study is part of the body of research which supports the use of PSADT as a predictor of clinical progression in men with biochemical recurrence after initial therapy for prostate cancer. This is not a clinical study evaluating an agent's efficacy for the treatment of prostate cancer.

1898. Eastham, Prostate Specific Antigen Doubling Time as a Prognostic Marker in Prostate Cancer, Nat. Clin. Pract. Urol. 2005 Oct: 2(10): 482-91. (PX0178).

Response to Finding No. 1898:

Complaint Counsel has no specific response except to note its disagreement with Respondents' characterization of this study as additional research. This study has been previously cited and discussed above. *See* Responses to Findings 1837-40, 1852.

1899. Finley, et al., The Natural History of Ultrasensitive PSA Following Radical Prostatectomy, Unpublished. (PX0179).

Response to Finding No. 1899:
Complaint Counsel's and Respondents' experts agree that PSADT has prognostic value. (*See* CCFF ¶¶ 980-982). This study is part of the body of research which supports the use of PSADT as a predictor of clinical progression in men with biochemical recurrence after initial therapy for prostate cancer. This is not a clinical study evaluating an agent's efficacy for the treatment of prostate cancer.

1900. Oudard, et al., Prostate Specific Antigen Doubling Time before Onset of Chemotherapy as a Predictor of Survival for Hormone-refractory Prostate Cancer Patients, Ann Oncol. 2007 Nov; 18(11): 1828-33. (PX0181).

Response to Finding No. 1900:
Complaint Counsel's and Respondents' experts agree that PSADT has prognostic value. (*See* CCFF ¶¶ 980-82). This study is part of the body of research which supports the use of PSADT as a predictor of clinical progression in men with biochemical recurrence after initial therapy for prostate cancer. This is not a clinical study evaluating an agent's efficacy for the treatment of prostate cancer.

1901. Petrylak, et al., Evaluation of Prostate-Specific Antigen Declines for Surrogacy in Patients Treated on SWOG 99-16, J. Natl Cancer Inst. Volume 98 Issue 8: pp. 516-521. (PX0185).

Response to Finding No. 1901:
Complaint Counsel has no specific response except to note that Complaint Counsel's and Respondents' experts agree that PSADT is not accepted by experts in the field of prostate cancer as a surrogate endpoint for clinical trials evaluating an agent's efficacy for the treatment of prostate cancer. (*See* CCFF ¶ 978). This study attempts to validate PSADT

as a surrogate endpoint for prostate cancer treatment trials and concludes that future clinical trials are needed. (PX0185-0001). This is not a clinical study evaluating an agent's efficacy for the treatment of prostate cancer.

1902. Roberts, et al., PSA Doubling Time as a Predictor of Clinical Progression after Biochemical Failure Following Radical Prostatectomy for Prostate Cancer, Mayo Clin. Proc. 2001 Jun; 76(6): 576-81. (PX0188).

Response to Finding No. 1902:
Complaint Counsel's and Respondents' experts agree that PSADT has prognostic value. (*See* CCFF ¶¶ 980-82). This study is part of the body of research which supports the use of PSADT as a predictor of clinical progression in men with biochemical recurrence after initial therapy for prostate cancer. This is not a clinical study evaluating an agent's efficacy for the treatment of prostate cancer.

1903. Trock, et al., Prostate Cancer-Specific Survival Following Salvage Radiotherapy vs Observation in Men with Biochemical Recurrence after Radical Prostatectomy, JAMA 2008; Jun 18; 299(23): 2760-9. (PX0182).

Response to Finding No. 1903:
Complaint Counsel's and Respondents' experts agree that PSADT has prognostic value. (*See* CCFF ¶¶ 980-82). This study is part of the body of research which supports the use of PSADT as a predictor of clinical progression in men with biochemical recurrence after initial therapy for prostate cancer. This is not a clinical study evaluating an agent's efficacy for the treatment of prostate cancer.

I. Researchers Communicated to Respondents the Prostate Health Benefits of the Challenged Products

1904. Doctors reviewing the results of basic and animal studies done on prostate health represented to Respondent Stewart Resnick that the results were the best they had ever seen. (S. Resnick, Tr. 1734, 1736).

Response to Finding No. 1904:
The proposed finding mischaracterizes Mr. Resnick's testimony and is incomplete in that he testified that "[*O*]*ne* of the doctors who worked on the in vitro and the [animal] study .

. . came to me and said, 'We should do this on humans. This is the best result I've ever seen." (S. Resnick, Tr. 1734 (emphasis added)).

1905. Many different medical doctors assured Respondent Stewart Resnick that PSA doubling time was an acceptable endpoint in prostate cancer studies and a placebo was not necessary. (S. Resnick, Tr. at 1732-1733; CX1360 (S. Resnick, Dep. at 225-226); CX1376 (S. Resnick, Ocean Spray Dep. at 237-238)).

Response to Finding No. 1905:
Complaint Counsel has no specific response except to note that 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 and that the lack of a placebo control group was a significant weakness in their prostate cancer studies. (*See* CCFF ¶¶ 995-96, 1014-16, 1044-54).

1906. Dr. Harley Liker told Respondents that Pantuck's Phase II study proves that pomegranate juice slows down the progression PSA. (CX1350 (Liker, Dep. at 174-175)).

Response to Finding No. 1906:
The proposed finding mischaracterizes Dr. Liker's testimony in that he did not state that he told Respondents that Pantuck's Phase II study proves that pomegranate juice slows down the progression of PSA.

1907. In a January 2007 email, Dr. Heber stated to Mark Dreher, "The prolongation of PSA doubling time is considered clinically significant by urologists and is being confirmed in large multicenter trials." (PX0494).

Response to Finding No. 1907:
Complaint Counsel has no specific response except to note that Dr. Heber is neither a urologist nor an expert in the clinical treatment of prostate cancer. (*See* CCFF ¶¶ 1008, 1043).

1908. Dr. David Heber has shared his view with Dr. Liker that POM products could contribute to the prevention of prostate cancer. (CX1350 (Liker, Dep. at 174)).

Response to Finding No. 1908:

Complaint Counsel has no specific response except to note that: 1) there are no clinical studies on the ability of the POM Products to prevent the development of prostate cancer in healthy men; 2) Respondents' expert Dr. deKernion testified that there is no clinical study proving that the POM Products prevent or reduce the risk of prostate cancer; and 3) Respondents have admitted that they have "no data on prostate cancer prevention, prior to radiation or prostatectomy." (*See* CCFF ¶¶ 1000, 1010, 1017-18, 1022, 1026, 1037-38, 1047).

1909. In a January 2007 email, Dr. Heber stated to Mark Dreher, "The prolongation of PSA doubling time is considered clinically significant by urologists and is being confirmed in large multicenter trials." (PX0494).

Response to Finding No. 1909:
See Response to Finding 1907.

1910. In a January 2007, Dr. Heber stated to Mark Dreher that there was justification for the statement that "pomegranate extract promotes prostate health." (PX0494).

Response to Finding No. 1910:
Complaint Counsel does not disagree that Dr. Heber stated as such but notes that Dr. Heber is not an expert in the clinical treatment of prostate cancer. (CCFF ¶¶ 728, 1008, 1043).

1911. Dr. Heber attended meetings with Respondents about prostate cancer research attended by Allan Pantuck, Phil Kantoff, and Michael Carducci. (Heber, Tr. 2157-58).

Response to Finding No. 1911:
Complaint Counsel agrees.

1912. Dr. Heber testified that at meetings with Respondents about prostate cancer research there was a discussion of the scientific data which included comments to Respondents that the Challenged Products, considering the studies done to date, could help prevent prostate cancer. (Heber, Tr. 2157-58).

Response to Finding No. 1912:
The proposed finding mischaracterizes Dr. Heber's testimony in that he testified that he was unable to "answer [the] question as stated" when Complaint Counsel asked whether

anyone made a comment to Mr. Resnick that the POM Products could prevent prostate cancer.

1913. Dr. Heber testified that there was enthusiasm from everyone including Dr. Phillip Kantoff of Harvard Medical School. (Heber, Tr. 2157-58).

Response to Finding No. 1913:
Complaint Counsel agrees that Dr. Heber testified as such, but his testimony is not credible. Complaint Counsel called Dr. Philip Kantoff, Chief of the Genitourinary Oncology Division at the Dana-Farber Cancer Institute at Harvard Medical School, as a rebuttal witness to contradict Dr. Heber's testimony. Dr. Kantoff testified that he attended POM's scientific advisory board meetings with Dr. Heber and that he told the group assembled that although the date was "very encouraging . . . more work needs to be done in order to demonstrate that [POM Products] have effectiveness." (*See* CCFF ¶ 1042).

1914. Dr. Heber stated that ultimately there, "was substantial agreement on the body of evidence there that it could help to prevent in the correct setting." (Heber, Tr. 2157-58).

Response to Finding No. 1914:
Complaint Counsel agrees that Dr. Heber testified as such, but his testimony is not credible. Complaint Counsel called Dr. Philip Kantoff, Chief of the Genitourinary Oncology Division at the Dana-Farber Cancer Institute at Harvard Medical School, as a rebuttal witness to contradict Dr. Heber's testimony. Dr. Kantoff testified that he attended POM's scientific advisory board meetings with Dr. Heber and that he told the group assembled that although the date was "very encouraging . . . more work needs to be done in order to demonstrate that [POM Products] have effectiveness." (*See* CCFF ¶ 1042).

1915. Dr. Heber further testified that prevent would not mean absolutely prevent nor a substitute for a pharmaceutical prevention. (Heber, Tr. 2157-58).

Response to Finding No. 1915:
Complaint Counsel does not disagree that Dr. Heber testified as such.

1916. Researchers looking at prostate health benefits have also made public remarks that the research shows a benefit. (PX0428_0001).

Response to Finding No. 1916:
Complaint Counsel has no specific response.

1917. For example, Dr. Pantuck has publicly made positive remarks about the findings in his research done for Respondents. (PX0428_0001).

Response to Finding No. 1917:
Complaint Counsel has no specific response.

1918. 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)).

Response to Finding No. 1918:
Complaint Counsel has no specific response except to note that Dr. Pantuck also stated:

"This is not a cure, but we may be able to change the way prostate cancer grows."

(PX0428_0001). In addition, Dr. Pantuck testified that the current level of scientific evidence would not support a public health statement that everyone should drink pomegranate juice and that pomegranate juice is not the standard of care for prostate cancer. (*See* CCFF ¶ 1039).

J. Summary of Prostate Health Claims Supported By the Evidence

1919. Research on the Challenged Products has gone through the rigorous peer review process by respected journals, performed by thought leading researchers and performed at prestigious institutions. (Liker, Tr. 1887-1888; CX1352 (Heber Dep. at 268-269; CX1340 (Carducci, Dep. at 176).

Response to Finding No. 1919:
Complaint Counsel has no specific response except to note that only research selected by Respondents has gone through the peer review process. (*See e.g.,* CCFF ¶¶ 862-63; 895-

98, 913-14, 946-48 (examples of Respondents refusing or delaying publication of research)).

1920. 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).

Response to Finding No. 1920:
The proposed finding mischaracterizes the record as a whole for the health benefits at issue in this matter. Respondents' research is inadequate to substantiate the prostate cancer claims challenged by Complaint Counsel. (*See* CCFF ¶ 1037). Moreover, Respondents' expert Dr. deKernion did not dispute that there are no clinical studies, research and/or trials proving these claimed benefits. (*See* CCFF ¶ 1038).

1921. 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. (PX0161; PX0353 (Heber Dep. at 84-85); deKernion Tr. 3126; PX0351 (deKernion, Dep. at 41-42); Heber, Tr. 2012).

Response to Finding No. 1921:
See Response to Finding 1920.

1922. Competent and reliable scientific evidence supports the conclusion that 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 the Challenged Products inhibit the clinical development of prostate cancer cells in men who have not been diagnosed. (deKernion, Tr. 3126; PX0351 (deKernion, Dep. at 76-77); PX0206 at 12; Heber, Tr. 2156).

Response to Finding No. 1922:
The proposed finding is unsupported by the record as a whole in that: 1) there are no clinical studies on the ability of the POM Products to prevent the development of prostate cancer in healthy men; 2) Respondents' expert Dr. deKernion testified that there is no clinical study proving that the POM Products prevent or reduce the risk of prostate cancer; and 3) Respondents have admitted that they have "no data on prostate cancer

prevention, prior to radiation or prostatectomy." (*See* CCFF ¶¶ 1000, 1010, 1017-18, 1022, 1026, 1038, 1047).

XVI. RESPONDENTS' ERECTILE HEALTH CLAIMS ARE SUBSTANTIATED

A. Respondents' Erectile Health Claims Are Substantiated

1923. It is "[w]ithout a question" that competent and reliable scientific evidence demonstrates that pomegranate juice in its various forms (including POM Juice, POMx, and POM Pills) provides a positive benefit to erectile health and erectile function. (Goldstein, Tr. 2605; PX0189-0014; PX0149-0006-0007; Burnett, Tr. 2255-56; PX0349 (Burnett, Dep. at 103, 116-118, 137; Heber, Tr. 2012).

Response to Finding No. 1923:
The proposed finding is incomplete and mischaracterizes the evidence. Neither Dr. Burnett nor Dr. Goldstein believe that drinking eight ounces of POM Juice daily treats erectile dysfunction in humans. (CCFF ¶¶ 1088-90). Dr. Burnett and Dr. Heber did not conclude that pomegranate juice's efficacy has been demonstrated, but rather limited their conclusion to a "likely" effect on erectile function. (Burnett, Tr. 2255; Heber, Tr. 2012). Moreover, Dr. Burnett and Dr. Goldstein testified that they did not offer any opinions regarding POMx Pills or POMx Liquid. (CCFF ¶¶ 750, 754).

1924. The mechanism by which this fruit promotes erectile health and function is via its potent antioxidant components and its impact on nitric oxide ("NO"), which is of "paramount importance" to good erectile health and function and is the key molecule that governs penile erections. (PX0149-0004-0006; Burnett, Tr. 2249-51, 2276; PX0190-0006; Melman, Tr. 1169; PX0189-0011).

Response to Finding No. 1924:
The proposed finding is incorrect and incomplete. The mechanism by which pomegranate juice purportedly affects erectile function or erectile health has not been proven. (Burnett, Tr. 2255 (noting that pomegranate juice has a "likely beneficial effect on erectile function"); PX0189-0008 (describing the "hypothetical mechanism" of how pomegranate juice consumption promotes erectile health)). Moreover, pomegranate juice is not a whole fruit. (CCFF ¶¶ 124-26).

1925. Additionally, because pomegranate juice is a fruit and not a pharmaceutical drug, physicians who treat patients concerned with erectile health would not hold pomegranate juice to the standards of safety and efficacy traditionally required by the FDA for approval of a pharmaceutical (i.e., performance of a large, randomized, double-blind, placebo controlled clinical trial ("RCT")) before recommending pomegranate juice to their patients. (PX0149; PX0189; Heber, Tr. 2182).

Response to Finding No. 1925:
The proposed finding is incorrect because pomegranate juice is not a whole fruit. (CCFF ¶¶ 124-26). Furthermore, experts would require RCTs if pomegranate juice were being recommended to consumers as an effective way to treat, prevent, or reduce the risk of erectile dysfunction. (CCFF ¶¶ 1055, 1102, 1108).

B. POM's Advertising Claims Regarding Erectile Health

1926. Complaint Counsel's Complaint identifies four purported advertisements for the Challenged Products in which Respondents allegedly made health-benefit claims regarding erectile dysfunction. (CX1426_0027, 0031-0035).

Response to Finding No. 1926:
Complaint Counsel has no specific response, except to note that Complaint Counsel also challenges the promotional piece in CX0128 as making false establishment claims and unsubstantiated efficacy claims regarding erectile dysfunction. (*See* CCFF Appendix A).

1927. Paragraph 9.A and Ex. A of the Complaint identify a POM Wonderful juice bottle "hangtag" that incorporates (in pertinent part) the following text:

> 100% PURE POMEGRANATE JUICE
>
> It's 100% pure! It's heroically healthy! It's The Antioxidant Superpower, POM 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!

Response to Finding No. 1927:
Complaint Counsel has no specific response; the Complaint speaks for itself.

1928. Paragraph 9.D and Ex. E-1 of the Complaint identify a *screen capture* from Respondents' pomegranatetruth.com website, which allegedly contained (in pertinent part) the following text as of April 28, 2009:

Backed by science.

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 the studies featured patients who drank POM Wonderful 100% Pomegranate Juice, not any other brands**. . . . Read more.

Response to Finding No. 1928:
This proposed finding is incomplete and mischaracterizes the evidence, as it does not reflect the entire Exhibit E-1 to the Complaint (CX0473, April 2009, "Pomegranate Truth").

1929. Paragraph 9.G and Ex. F of the Complaint identify a *Newsweek* article consisting of an *interview* of Respondent Lynda Resnick. Paragraph 9.G of the Complaint selectively quotes the following language from the interview, ignoring the several preceding pages in which Mrs. Resnick discusses the economy, politics, and business philosophy:

* * *

Should I take vitamins?

I don't know your family history. How's your father?

He's in good health. Had a bout of prostate cancer, but that's–

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?

Twenty-six.

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!

Response to Finding No. 1929:
This proposed finding mischaracterizes the evidence, as Paragraph 9 clearly states that the cited materials "contain the following representations or statements, among others," and Exhibit F to the Complaint is the entire document.

1930. Paragraph 9.H and Ex. E-2 of the Complaint identify a *screen capture* from Respondents' pomwonderful.com "POM Truth – Backed by Science" web page, which allegedly contained (in pertinent part) the following text as of April 29, 2009:

> **Backed by Science**
>
> Only POM Wonderful products are backed by $32 million in medical research. Actually, we are the only pomegranate juice backed by any medical research at all.
>
> There has been a lot of talk lately about the role of pomegranates in promoting heart health, prostate health and proper erectile function. . . .
>
> * * *
>
> **Erectile Function**
>
> 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 [sic] of POM Wonderful 100% Pomegranate Juice daily for four weeks were 50% more likely to experience improved erections**.

Response to Finding No. 1930:
This proposed finding is incomplete and mischaracterizes the evidence, as it does not reflect the entire Exhibit E-2 to the Complaint (CX0473, April 2009, "POM Wonderful Health Benefits").

1931. In addition to advertisements identified in their Complaint, Complaint Counsel also identified in discovery a print ad for POMx capsules, which contains (in pertinent part) the following text regarding erectile function:

> **$32 million in research.**
>
> **We're not just playing doctor.**

> 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.
>
> **Is that POMx in your pocket?**
>
> Our POMx pills are made from the same pomegranates we use to make our POM 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[1, 2, 3]
>
> [1]pompills.com/research. [2]These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease. [3]53 men with mild/moderate erectile dysfunction drank 8oz. 100% pomegranate juice daily for one month.

Response to Finding No. 1931:

This proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel states that in addition to CX1426 Exh. A/CX0475, CX1426 Exh. E-1/CX0473 (Pomegranate Truth website capture), CX1426 Exh. E-2/CX0473 (POM Wonderful Health Benefits website capture), and CX1426 Exh. F/CX0473 (Mrs. Resnick interview on Newsweek.com), it is also challenging CX0351 ("Only Antioxidant Supplement Rated X" print ad), CX0355 ("Only Antioxidant Supplement Rated X" print ad), CX0473 (POMWonderful.com Community Site and POMPills.com website captures), and CX0128 (June 2006 press release) as making false establishment claims and unsubstantiated efficacy claims regarding erectile

dysfunction. (*See* Complaint Counsel's Findings of Fact, Section V.D – V.F and Appendix A).

1932. Based on these representations, Complaint Counsel alleges, that Respondents "have represented, expressly or by implication, that clinical studies, research, and/or trials prove that: [¶] A. Drinking eight ounces of POM Juice daily prevents or reduces the risk of erectile dysfunction; and [¶] B. Drinking eight ounces of POM Juice daily treats erectile dysfunction." (CX1426_0019).

Response to Finding No. 1932:
Complaint Counsel has no specific response. The Complaint speaks for itself.

C. Respondents Deny Complaint Counsel's Allegations That Their Advertisements Are False and Misleading

1933. Respondents deny Complaint Counsel's allegations that their advertising and promotional materials make the claim that: "A. Drinking eight ounces of POM Juice daily prevents or reduces the risk of erectile dysfunction; and B. Drinking eight ounces of POM Juice daily treats erectile dysfunction." (PX0364-0005).

Response to Finding No. 1933:
Complaint Counsel agrees that Respondents made this assertion, but Complaint Counsel disagrees with this conclusion.

1934. Respondents dispute Complaint Counsel's allegations or characterizations regarding Respondents' science and aver there is substantial scientific research indicating the health benefit of their products and substantiating their advertising and promotional materials. (PX0364-0005).

Response to Finding No. 1934:
Complaint Counsel agrees that Respondents made this assertion, but Complaint Counsel disagrees with this conclusion.

1935. Respondents deny Complaint Counsel's allegations that their advertising and promotional materials make the claim that "A. Drinking eight ounces of POM Juice daily prevents or reduces the risk of erectile dysfunction; and B. Drinking eight ounces of POM Juice daily treats erectile dysfunction." (PX0364-0005).

Response to Finding No. 1935:
Complaint Counsel agrees that Respondents made this assertion, but Complaint Counsel disagrees with this conclusion.

D. Substantiation for Respondents' Erectile Health Claims

1. Competent and Reliable Scientific Evidence Supports The Conclusion That The Consumption of Pomegranate Juice Has Positive Effects On Erectile Function

(a) *In Vitro* and *In Vivo* Studies on the Challenged Products Specifically

(1) Dr. Aviram and Colleagues Found that Pomegranate Juice Had Potent Anitatherogenic Effects in Humans and Atherosclerotic Mice That May be Attributable to its Antioxidative Properties

1936. Dr. Aviram, is a distinguished professor of biochemistry and researcher at the Technion Faculty of Medicine and the Rambam Medical Center in Haifa, Israel, and head of the Lipid Research Laboratory. (PX0004; CX1358 (Aviram, Dep. at 7-8)).

Response to Finding No. 1936:
Complaint Counsel has no specific response.

1937. Complaint Counsel's designated erectile function expert, Arnold Melman, described Technion Institute in Haifa, Israel as a "terrific" institution. (Melman, Tr. 1168).

Response to Finding No. 1937:
Complaint Counsel has no specific response.

1938. For over 30 years, Dr. Aviram's major research focused on antioxidants in general, and on its dietary role in cardiovascular disease. (CX1358 (Aviram, Dep. at 5)).

Response to Finding No. 1938:
Complaint Counsel has no specific response.

1939. Dr. Aviram's 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*, reported that dietary supplementation with nutrients rich in antioxidants was associated with inhibition of atherosclerosis. (PX0189-0012; PX0004).

Response to Finding No. 1939:
Complaint Counsel has no specific response.

1940. 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. (PX0189-0012; PX0004).

Response to Finding No. 1940:
Complaint Counsel has no specific response.

1941. Dr. Aviram and colleagues found that in humans, pomegranate juice consumption decreased low-density lipoprotein ("LDL") susceptibility to aggregation and retention and increased an high-density lipoprotein ("HDL") associated esterase that can protect against lipid peroxidation. (PX0189-0012; PX0004).

Response to Finding No. 1941:
Complaint Counsel has no specific response.

1942. Similar positive anti atherosclerosis effects were seen in the E-deficient mice. (PX0189-0012; PX0004).

Response to Finding No. 1942:
Complaint Counsel has no specific response.

1943. Dr. Aviram and colleagues concluded that pomegranate juice had potent antiatherogenic effects in humans (and atherosclerotic mice) that may be attributable to its antioxidative properties. (PX0189-0012; PX0004).

Response to Finding No. 1943:
Complaint Counsel has no specific response.

1944. Dr. Goldstein noted that Dr. Aviram's study is "a very fascinating and very important piece of information." (PX0352 (Goldstein, Dep. at 127)).

Response to Finding No. 1944:
Complaint Counsel has no specific response, except to note that Dr. Goldstein described

Dr. Aviram's study as "a fascinating and very important piece of information." (PX0352

(Goldstein, Dep. at 127)).

(2) Dr. Azadzoi and Colleagues Found That Pomegranate Juice Possesses Potent Antioxidants, and That Long Term Intake of Pomegranate Juice Increased Intracavernosal Blood Flow, Improved Erectile Responses, Improved Smooth Muscle Relaxation, and Decreased Erectile Tissue Fibrosis

1945. Dr. Azadzoi is a distinguished research professor of urology and pathology at the Boston University School of Medicine and Director of Urology Research at the Veterans Affairs Boston Healthcare System. (PX0051).

Response to Finding No. 1945:
Complaint Counsel has no specific response.

1946. Dr. Azadzoi, along with Dr. Goldstein developed an atherosclerotic animal model for erectile dysfunction. (Goldstein, Tr. 2595).

Response to Finding No. 1946:
Complaint Counsel has no specific response.

1947. Dr. Azadzoi has published extensively on studies using atherosclerotic animal models with erectile dysfunction. (Goldstein, Tr. 2595).

Response to Finding No. 1947:
Complaint Counsel has no specific response.

1948. Dr. Azadzoi's Study entitled *Oxidative stress in arteriogenic erectile dysfunction: Prophylactic role of antioxidants*, studied the anti-oxidant properties of various fruit juices, such as orange juice, blueberry juice, and cranberry juice, and other known antioxidant beverages such as green tea and red wine, and reported that pomegranate juice possessed the highest free radical scavenging capacity. (PX0189-0011-0012; PX0051; PX0352 (Goldstein, Dep. at 123-124); Goldstein, Tr. 2595).

Response to Finding No. 1948:
Complaint Counsel has no specific response.

1949. Dr. Azadzoi and colleagues examined that effect of various antioxidant beverages on atherogenic erectile dysfunction in rabbits that demonstrated decreased intracavernous blood flow, erectile dysfunction, loss of smooth muscle relaxation, decreased endothelial nitric oxide synthase, and neuronal nitric oxide synthase, diffuse cavernosal fibrosis and increased cavernous levels of the oxidative product isoprostane 8 – epi – prostaglandin F 2 alpha. (PX0189-0011-0012; PX0051).

Response to Finding No. 1949:
The proposed finding is incorrect because Dr. Azadzoi examined the effect of pomegranate juice only on arteriogenic erectile dysfunction in rabbits. (PX0051).

1950. Animal studies are very informative as it can characterize what's going on at the human level. (PX0349 (Burnett, Dep. at 111); PX0352 (Goldstein, Dep. at 122-124); Goldstein, Tr. 2644). Work from animal studies have some potential for benefit of a therapy at the human level. (PX0349 (Burnett, Dep. at 112); Burnett, Tr. 2262-63).

Response to Finding No. 1950:
The proposed finding is incomplete. Dr. Burnett testified that "animal studies are very informative to the extent that some of the basic physiology is there." (PX0349 (Burnett, Dep. at 111)). While animal studies can be preliminary research, both Complaint

Counsel's and Respondents' experts testified that animal studies alone are insufficient to support a claim that a product is efficacious in humans. (CCFF ¶ 764; *see also* ¶ 1073).

1951. Dr. Azadzoi and colleagues found that long term pomegranate juice intake increased intracavernosal blood flow, improved erectile responses, improved smooth muscle relaxation, and decreased erectile tissue fibrosis. (PX0189-0011-0012; PX0051; PX0352 (Goldstein, Dep. at 123); Goldstein, Tr. 2595-97).

Response to Finding No. 1951:
Complaint Counsel has no specific response.

1952. Dr. Azadzoi and colleagues concluded that arteriogenic erectile dysfunction accumulates oxidative products in erectile tissues and that oxidative stress is an important pathophysiologic factor of erectile dysfunction. (PX0189-0011-0012; PX0051).

Response to Finding No. 1952:
The proposed finding is incorrect. Dr. Azadzoi's article stated that "[o]xidative stress *may be* of great importance in the pathophysiology of arteriogenic ED." (PX0051-0001) (emphasis added).

1953. Dr. Azadzoi and colleagues found antioxidant therapy may be useful as a prophylactic for preventing smooth muscle dysfunction and fibrosis in erectile dysfunction. (PX0189-0011-0012; PX0051).

Response to Finding No. 1953:
Complaint Counsel has no specific response.

(3) Dr. de Nigris and Colleagues Showed that Polyphenolic Antioxidants Contained in Pomegranate Juice Can Contribute to the Reduction of Oxidative Stress and Atherogenesis Both *In Vitro* in Cultured Human Coronary Endothelial Cells and *In Vivo* in Hypercholesterolemic Mice

1954. Dr. de Nigris, of the Department of General Pathology and Excellence Research Center on Cardiovascular Diseases of the 1st School of Medicine at the II University of Naples, Italy, and colleagues, including Dr. Louis Ignarro, evaluated the effects of intervention with pomegranate juice on oxidation-sensitive genes and endothelial nitric oxide synthase expression induced by high shear stress *in vitro* and *in vivo*. (PX0059). The study was entitled *Beneficial effects of pomegranate juice on oxidation-sensitive genes and endothelial nitric oxide synthase activity at sites of perturbed shear stress*. (PX0059).

Response to Finding No. 1954:

Complaint Counsel has no specific response, except to note that Dr. de Nigris worked at the Departments of General Pathology, Medicine, Human Pathology, and Clinical Pathology, School of Medicine, University of Naples, Italy.

1955. Cultured human coronary artery endothelial cells exposed to high shear stress *in vitro* and hypercholesterolemic mice were used in the study. (PX0059).

Response to Finding No. 1955:
Complaint Counsel has no specific response.

1956. Dr. de Nigris and colleagues found that pomegranate juice concentrate reduced the activation of redox-sensetive genes and increased endothelial nitric oxide synthase expression in cultured human coronary artery endothelial cells and hypercholesterolemic mice. (PX0059; Burnett, Tr. 2290).

Response to Finding No. 1956:
Complaint Counsel has no specific response, except to note that Dr. de Nigris' article specifies that the effects were seen in the "atherosclerosis-prone areas of the hypercholesterolemic mice." (PX0059-0001).

1957. Dr. de Nigris and colleagues also found that oral administration of pomegranate juice to hypercholesterolemic mice at various stages of disease reduced significantly the progression of atherosclerosis. (PX0059).

Response to Finding No. 1957:
Complaint Counsel has no specific response.

1958. This study indicates that polyphenolic antioxidants contained in pomegranate juice can contribute to the reduction of oxidative stress and atherogenesis. (PX0059; Burnett, Tr. 2290).

Response to Finding No. 1958:
Complaint Counsel agrees that Dr. Burnett stated this about the study, but disagrees with the implied conclusion. For example, Dr. Burnett did not review the Davidson Study (CCFF ¶ 1081) where a large RCT on humans had null results regarding atherogenesis, erectile dysfunction, and various biomarkers related to heart health. (CCFF ¶¶ 882-84, 1080). The Davidson study states that the antioxidant mechanism in relation to cardiovascular disease may be wrong. (CX1199_0006). Furthermore, numerous RCTs

conducted by Respondents' showed no change in measures of oxidative stress and inflammation. (CCFF ¶¶ 825, 884, 915, 933).

(4) Dr. de Nigris and Colleagues Found that Prolonged Supplementation with Pomegranate Fruit Extract or Pomegranate Juice Can Largely Correct the Perturbed Shear Stress-Induced Proatherogenic Di4sequilibrium by Increasing Endothelial Nitric Oxide Synthase and cGMP and Decreasing Redox-Sensitive Transcription Factors Both *In Vitro* in Cultured Human Coronary Endothelial Cells and *In Vivo* in Hypercholesterolemic Mice

1959. In a 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 her esteemed colleagues showed that atherosclerosis is enhanced in arterial segments exposed to perturbed shear stress as a result of increased expression of oxidation-sensitive responsive genes. (PX0189-0010-0011; PX0056).

Response to Finding No. 1959:
Complaint Counsel has no specific response.

1960. The authors studied the effect of pomegranate fruit extract and pomegranate juice antioxidant activity on reduction of oxidative stress and atherogenesis during disturbed shear stress flow using cultured human coronary artery endothelial cells. (PX0189-0010-0011; PX0056).

Response to Finding No. 1960:
Complaint Counsel has no specific response.

1961. Their study showed that pomegranate fruit extract and pomegranate juice reduced the activation of oxidation-sensitive genes and increased endothelial nitric oxide synthase expression. (PX0189-0010-0011; PX0056).

Response to Finding No. 1961:
Complaint Counsel has no specific response.

1962. Their study also showed that pomegranate fruit extract and pomegranate juice increased cyclic GMP levels. (PX0189-0010-0011; PX0056).

Response to Finding No. 1962:
Complaint Counsel has no specific response.

1963. Their study further showed that administration of pomegranate juice reduced the progression of atherosclerosis in hypercholesterolemic mice. (PX0189-0010-0011; PX0056).

Response to Finding No. 1963:
Complaint Counsel has no specific response.

1964. The authors concluded that the proatherogenic effects of perturbed shear stress can be reversed with chronic administration of pomegranate fruit extract. (PX0189-0010-0011; PX0056).

Response to Finding No. 1964:
Complaint Counsel agrees that this was the authors' conclusion, but the proposed finding is incomplete. The authors also stated in this in vivo and in vitro study that some large clinical trials for different antioxidants have failed to show any beneficial effect in terms of preventing major cardiovascular events. (PX0056-0008). One reason possible is that the models used in experimental studies may not precisely reflect the disease in humans. (PX0056-0008. (*See also* Response to Finding 1958).

(5) Nobel-Prize-Winner Dr. Louis Ignarro Found that Pomegranate Juice Possesses Potent Antioxidant Activity that Results in Marked Protection of Nitric Oxide Against Oxidative Destruction in Vascular Endothelial Cells

1965. Nobel-prize-winner Dr. Louis Ignarro for his discoveries concerning nitric oxide, conducted an *in vitro* study, entitled *Pomegranate juice protects nitric oxide against oxidative destruction and enhances the biological actions of nitric oxide*, to evaluate pomegranate juice's capacity to protect nitric oxide against oxidative destruction. (PX0189-0011; PX0058; Goldstein, Tr. 2593-95; Heber, Tr. 1995-96; Burnett, Tr. 2252-53).

Response to Finding No. 1965:
Complaint Counsel has no specific response.

1966. Dr. Ignarro found that pomegranate juice was found to possess more antioxidant activity than grape juice, blueberry juice, red wine, and ascorbic acid. (PX0189-0011; PX0058).

Response to Finding No. 1966:
Complaint Counsel has no specific response.

1967. Based on a series of studies that were performed on vascular endothelial cells, Dr. Ignarro concluded that pomegranate juice possesses potent antioxidant activity that results in marked protection of nitric oxide against oxidative destruction, thereby augmenting the biologic actions of nitric oxide. (PX0189-0011; PX0058).

Response to Finding No. 1967:
Complaint Counsel has no specific response.

1968. Dr. Goldstein testified that the "Ignarro study is another part of the sequence of evidence that supports that a nutraceutical, specifically pomegranate juice, has incredible vascular-sparing properties that ultimately, when you follow this path leads to the improvement of erectile function in men with erectile health issues." (PX0352 (Goldstein, Dep. at 133)).

Response to Finding No. 1968:
Complaint Counsel agreed that this was in part Dr. Goldstein's testimony, but the proposed finding is incomplete because Dr. Goldstein said that "'you have to study humans to make statements about humans.'" (CCFF ¶ 764).

1969. Complaint Counsel's erectile health expert, Dr. Arnold Melman, recognizes that Dr. Ignarro is highly respected. (Melman, Tr. 1167).

Response to Finding No. 1969:
Complaint Counsel has no specific response, except to note that the court recognized Dr. Melman as an expert in urology as it relates to the treatment, prevention, and reduction of risk of erectile dysfunction; and in clinical testing involving erectile dysfunction. (CCFF ¶ 720).

1970. Dr. Melman also agrees that UCLA School of Medicine, where Dr. Ignarro is a professor in molecular and medical pharmacology, has a good reputation. (Melman, Tr. 1168; PX0058; Goldstein, Tr. 2593-94).

Response to Finding No. 1970:
Complaint Counsel has no specific response.

(b) Clinical Trial

(1) Dr. Padma-Nathan's Study is Clinically Significant in That it Suggests a Likely Beneficial Effect of Pomegranate Juice on Erectile Tissue Physiology and Health and Supports the Conclusion That The Positive Results in The Basic Science Are Borne Out in Human Function

1971. Dr. Padma Nathan received the first fellowship from the American Foundation for Urologic Disease that was awarded in the area of erectile dysfunction. The prestigious fellowship is awarded to two urologists annually. His work involved two years of basic lab and in vitro scientific research in smooth muscle pharmacology cosponsored by the

Department of Urology and the Department of Cardiology at Boston University. (CX1338 (Padma-Nathan, Dep. at 32-33)).

Response to Finding No. 1971:
Complaint Counsel has no specific response.

1972. Dr. Padma-Nathan is a man of repute in the field of urology. (Heber, Tr. 2000).

Response to Finding No. 1972:
Complaint Counsel has no specific response.

1973. Dr. Padma-Nathan and colleagues performed a randomized, double-blind, placebo-controlled cross-over design trial of Wonderful variety pomegranate juice versus placebo. (PX0189-0012-0013; CX0908; Goldstein, Tr. 2598).

Response to Finding No. 1973:
Complaint Counsel has no specific response.

1974. The study, entitled *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*, was published in the International Journal of Impotence Research in 2007, a very reputable journal. (Hereinafter referred to as the "*Forest/Padma-Nathan RCT Study*"). (PX0189-0012-0013; CX0908; CX1337 (Forest, Dep. at 225)).

Response to Finding No. 1974:
Complaint Counsel has no specific response.

1975. Dr. Goldstein, Respondent's expert, indicated that as editor in chief of the International Journal of Impotence Research, the *Forest/Padma-Nathan RCT Study* "is the first and only nutraceutical clinical trial that is randomized and double-blind that [he has] ever come across in [the] field." (Goldstein, Tr. 2598).

Response to Finding No. 1975:
Complaint Counsel has no specific response.

1976. The *Forest/Padma-Nathan RCT Study* engaged 53 completed subjects with mild-to-moderate erectile dysfunction who underwent two four-week treatment periods separated by a two-week washout. (PX0189-0012-0013; CX0908).

Response to Finding No. 1976:
Complaint Counsel has no specific response, except to note that participants received a different beverage during the two twenty-eight-day treatment periods. (CCFF ¶ 1065).

1977. The *Forest/Padma-Nathan RCT Study* had all the same scientific rigors of any study, including drug studies. (CX1337 (Forest, Dep. at 220-221); CX1338 (Padma-Nathan, Dep. at 195-197)).

Response to Finding No. 1977:
The proposed finding mischaracterizes the evidence and is incomplete. Dr. Padma-Nathan considered the Forest/Padma-Nathan RCT Study "a scientifically rigorous study," and agreed that the level of scientific rigor used "rises to the level almost like a drug in some ways." (CX1338 (Padma-Nathan Dep. at 196-97)). Dr. Padma-Nathan further testified that the Forest/Padma-Nathan RCT Study was a pilot study, underpowered, and relied on a non-validated measure as its primary measure. (CCFF ¶¶ 1057, 1060-61, 1064, 1066-67, 1071).

1978. Such a scientifically rigorous study is almost unheard of in the food industry. (CX1338 (Padma-Nathan, Dep. at 196); Goldstein, Tr. 2601-02, 2613-14)).

Response to Finding No. 1978:
The proposed finding is unsupported by the cited evidence. Dr. Padma-Nathan is a fact witness and his opinion is irrelevant, and Dr. Goldstein was not qualified as an expert in the field of nutrition. (CCFF ¶ 753).

1979. A total of 42 subjects demonstrated improved Global Assessment Question (GAQ) scores, 25 after drinking pomegranate juice. (PX0189-0012-0013; CX0908).

Response to Finding No. 1979:
Complaint Counsel has no specific response, except to note that the GAQ, a nonvalidated measure, did not have statistically significant results. (CCFF ¶¶ 1069, 1077).

1980. In the pomegranate juice–placebo sequence, 56% demonstrated improvement of GAQ score versus 33% in placebo. (PX0189-0012-0013; CX0908).

Response to Finding No. 1980:
Complaint Counsel has no specific response, except to note that the GAQ, a nonvalidated measure, did not have statistically significant results. (CCFF ¶¶ 1069, 1077).

1981. In the placebo—pomegranate juice sequence, 38% versus 29% reported improvement in GAQ score. (PX0189-0012-0013; CX0908).

Response to Finding No. 1981:
Complaint Counsel has no specific response, except to note that the GAQ, a nonvalidated measure, did not have statistically significant results. (CCFF ¶¶ 1069, 1077).

1982. 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. (PX0189-0012-0013; CX0908; Heber, Tr. 1978; Goldstein, Tr. 2598).

Response to Finding No. 1982:
The proposed finding of fact is incomplete. The 0.058 p value was achieved using the GAQ, a non-validated measure. (CCFF ¶¶ 1060-61, 1077).

1983. This means the study had a 94%, rather than 95%, probability of being valid and not the result of chance. (Heber, Tr. 1978; Goldstein, Tr. 2599; Burnett, Tr. 2305).

Response to Finding No. 1983:
Complaint Counsel agrees that experts explained that this is what the statistic means, but disagrees this is what the Forest/Padma-Nathan RCT Study means. The GAQ was a non-validated measure. Experts in the erectile dysfunction field require the use of a validated measure like the IIEF because such a measure ensures "reliability, responsiveness, and discriminant and predictive validity." (CCFF ¶¶ 1057-58).

1984. Dr. Goldstein testified that choosing a significance level is technically an arbitrary task, and although a p-value of 0.050 was agreed upon in the *Forest/Padma-Nathan RCT Study*, "in specific situations a different value could be utilized." (Goldstein, Tr. 2598-99).

Response to Finding No. 1984:
The proposed finding of fact mischaracterizes the evidence. Dr. Goldstein described the 0.05 significance level as a "choice . . . something that appears to be an agreeable point." (Goldstein, Tr. 2599).

1985. Overall, the GAQ scores demonstrated that pomegranate juice drinkers enjoyed a nearly 50% better improvement in erections over placebo drinkers. (CX0908-0003; PX0352 (Goldstein, Dep. at 109, 144); CX1338 (Padma-Nathan, Dep. at 191-192)).

Response to Finding No. 1985:

Complaint Counsel does not disagree that this is in part Dr. Padma-Nathan and Dr. Goldstein's testimony, but the proposed finding is incomplete because the GAQ, a nonvalidated measure, did not have statistically significant results. (CCFF ¶¶ 1069, 1077).

1986. Although the p-value was a few thousandths of a percentage point shy of an arbitrary 95% threshold, the study has major clinical significance in showing a benefit from pomegranate juice on erectile tissue physiology and health, and supporting the conclusion that the positive results in the basic science are borne out in human function. (PX0189-0013; PX0149-0006; CX0908; Heber, Tr. 1979, 2001; Goldstein, Tr. 2598-99; PX0352 (Goldstein, Dep. at 108-109); Burnett, Tr. 2256; PX0349 (Burnett, Dep. at 138-139); CX1350 (Liker, Dep. at 190-191)).

Response to Finding No. 1986:
The proposed finding is incomplete because the Forest/Padma-Nathan RCT Study's results were not clinically significant in showing that POM Juice treated, prevented, or reduced the risk of erectile dysfunction in humans (CCFF ¶¶ 782, 1055, 1060, 1078) and did not show that the findings from basic science research were reflected in humans as related to treatment of erectile dysfunction. (CCFF ¶¶ 1069, 1072-73, 1076-77, 1086, 1088-1090). Moreover, neither Dr. Heber nor Dr. Liker are urologists or qualified as experts in erectile dysfunction. (CCFF ¶¶ 728; Liker, Tr. 1873).

1987. The *Forest/Padma-Nathan RCT Study* also demonstrates pomegranate juice is "a potential treatment for ED." (PX0349 (Burnett, Dep. at 142)).

Response to Finding No. 1987:
Complaint Counsel has no specific response, except to note that Dr. Burnett testified that the Forest/Padma-Nathan RCT Study did not allow the conclusion that pomegranate juice treats erectile dysfunction. (PX0349 (Burnett, Dep. at 142)).

(c) Testing On The Mechanisms Of Action Generally

1988. In addition to studies specifically evaluating the Challenged Products, a significant body of scientific literature supports the validity of the mechanisms of action by which pomegranate juice promotes erectile function. (PX0352 (Goldstein, Dep. at 100-101)).

Response to Finding No. 1988:
The proposed finding is unsupported by the cited evidence. The cited transcript page identifies studies included with Dr. Goldstein's report, but does not discuss what, if anything, these studies show.

1989. Clinical trials demonstrate that the Mediterranean Diet, with which pomegranate juice consumption is consistent, promotes healthy erectile function. (PX0189-0013; PX0190).

Response to Finding No. 1989:
The proposed finding mischaracterizes the evidence. The cited study by Dr. Katherine Esposito, *Dietary Factors, Mediterranean Diet and Erectile Dysfunction*, noted that "[t]he major limitation remains the paucity of studies that have assessed the role of dietary factors and of Mediterranean diet on ED. . . . More studie[s] are needed to have a clearer view of all factors that may play a role in the association between diet and ED." (PX0190-0006).

1990. For example, Dr. Esposito's study entitled "Dietary Factors, Mediterranean Diet and Erectile Dysfunction" showed that the adoption of the Mediterranean diet 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. (PX0190; Goldstein, Tr. 2641-42; PX0352 (Goldstein, Dep. at 134-135); PX0189-0013).

Response to Finding No. 1990:
The proposed finding is unsupported by the cited evidence. The two year study in Dr. Esposito's article of obese men with erectile dysfunction involved an intensive weight loss program with both diet and exercise changes. (PX0190-0004). Dr. Esposito's article neither stated that the obese men in the treatment group specifically adopted the Mediterranean diet nor concluded that the dietary changes alone caused the improvement in erectile dysfunction. (PX0190-0004).

1991. Significant scientific evidence and published studies also exists to support the general proposition that antioxidants "have the ability to improve the erectile function of those people that take the antioxidant." (Goldstein, Tr. 2604-2605; PX0352 (Goldstein, Dep. at 100-104)). Some of that evidence includes the following studies:

- Javier Angulo, PhD, et al., *The novel antioxidant, AC3056 (2,6-di-t-butyl-4-((Dimethyl-4-Methoxyphenylsilyl)Methyloxy)Phenol), reverses erectile dysfunction in diabetic rats and improves NO-mediated responses in penile tissue from diabetic men*, J. Sex. Med. (2009); 6:373-387. (PX0352 (Goldstein, Dep. at 100));

- Alessandra Barassi, MD, *et al.*, *Oxidative stress and antioxidant status in patients with erectile dysfunction*, J. Sex. Med. (2009); 6:2820-2825. (PX0352 (Goldstein, Dep. at 100));

- Sekar Suresh, PhD, *et al.*, *Effect of mucuna pruriens (Linn.) on oxidative stress-induced structural alteration of corpus cavernosum in streptozotocin-induced diabetic rat*, J. Sex. Med. (PX0352 (Goldstein, Dep. at 100-101));

- Rita C. Tostes, PhD, *et al.*, *Cigarette smoking and erectile dysfunction: focus on NO bioavailability and ROS generation*, J. Sex. Med. (2008); 5:1284-1295. (PX0352 (Goldstein, Dep. at 101));

- Enzo Vicari, MD, *et al.*, *Endothelial antioxidant administration ameliorates the erectile response to PDE5 regardless of the extension of the atherosclerotic process*, J. Sex. Med. (2010); 7:1247-1253. (PX0352 (Goldstein, Dep. at 81-82, 100)).

Response to Finding No. 1991:
The proposed finding is unsupported by the cited evidence. Dr. Goldstein stated that several studies have been published showing that antioxidant therapies have the ability to improve erectile function, but he did not testify whether this evidence was "significant." The cited transcript pages from Dr. Goldstein's deposition identified studies supplementing his expert report, but does not discuss what, if anything, these studies show.

E. Tools For Evaluating Erectile Function

1. The GAQ

1992. The global assessment questionnaire ("GAQ") is a single question designed to assess the individual self-evaluation of the study treatment (e.g., pomegranate juice consumption versus placebo consumption) effect on the patient's sexual health concern. (PX0189-0009).

Response to Finding No. 1992:
Complaint Counsel has no specific response.

1993. The GAQ is a yes/no question. (Goldstein, Tr. 2603).

Response to Finding No. 1993:
Complaint Counsel has no specific response.

1994. The GAQ is a very easy evaluation and written for a high school educated person to understand. (Goldstein, Tr. 2603; CX1337 (Forest, Dep. at 151-152)).

Response to Finding No. 1994:
Complaint Counsel has no specific response.

1995. The GAQ is informative. (Burnett, Tr. 2294; PX0349 (Burnett, Dep. at 131-132)).

Response to Finding No. 1995:
The proposed finding is incomplete. Both Respondents' and Complaint Counsel's experts testified that the GAQ, a non-validated measure, is not alone a sufficient measure to evaluate whether a product is efficacious in treating erectile dysfunction. (CCFF ¶¶ 1060-61, 1067).

1996. The GAQ is widely used. (Goldstein, Tr. 2602, 2603; Burnett, Tr. 2304; PX0349 (Burnett, Dep. at 127)).

Response to Finding No. 1996:
Complaint Counsel has no specific response.

1997. The GAQ is valuable to use in clinical studies. (Burnett, Tr. 2294).

Response to Finding No. 1997:
Complaint Counsel has no specific response, but *see also* Response to Finding 1995 above.

1998. The GAQ is commonly accepted as a standardized instrument among those conducting erectile dysfunction research. (CX1337 (Forest, Dep. at 79)).

Response to Finding No. 1998:
Complaint Counsel does not disagree that this was in part Mr. Forest's testimony, but the proposed finding is incomplete. Both Respondents' and Complaint Counsel's experts testified that the GAQ is not a validated measure for showing whether a product treats erectile dysfunction. (CCFF ¶¶ 1057, 1060-61, 1067).

1999. The GAQ is used on all sexual medicine trials. (Goldstein, Tr. 2603; PX0352 (Goldstein, Dep. at 57)).

Response to Finding No. 1999:
Complaint Counsel has no specific response.

2000. The GAQ was used by Pfizer in testing sildenafil (Viagra). (Burnett, Tr. 2304; Goldstein, Tr. 2602).

Response to Finding No. 2000:
Complaint Counsel has no specific response.

2001. The GAQ was also used in every vardenafil (Levitra) and tadalafil (Cialis) trial. (Goldstein, Tr. 2602; PX0352 (Goldstein, Dep. at 57)).

Response to Finding No. 2001:
Complaint Counsel has no specific response, except to note that the cited evidence does not identify the drug names of the brands Levitra or Cialis. (Goldstein, Tr. 2591; PX0352 (Goldstein, Dep. at 57)).

2002. The GAQ is a very "acceptable," informative," and "valuable" tool to use for testing pomegranate juice. (Burnett, Tr. 2294, 2304).

Response to Finding No. 2002:
The proposed finding is incomplete. Experts would not consider the GAQ, by itself, to be a sufficient endpoint in a clinical study evaluating a treatment for erectile dysfunction (CCFF ¶¶ 1060-61).

2. The IIEF

2003. The International Index of Erectile Function ("IIEF") is a 15 question psychometrically validated instrument designed to assess a man's overall erectile and sexual function via the individual domains of erectile function, orgasmic function, sexual desire, intercourse satisfaction and overall satisfaction. (PX0189-0009).

Response to Finding No. 2003:
Complaint Counsel does not disagree.

2004. Although validated, the IIEF also has its deficiencies as it requires patient recall and involves patients' subjective interpretation of their erection physiology. (Burnett, Tr. 2294).

Response to Finding No. 2004:

Complaint Counsel does not disagree that this was in part Dr. Burnett's testimony, but the proposed finding is incomplete. Dr. Burnett also opined that the IIEF "may be the best we have short of doing objective studies . . . ." (Burnett, Tr. 2294). Furthermore, Dr. Goldstein has 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.'" (CCFF ¶ 1059).

2005. The IIEF was designed for evaluating pharmaceuticals, not natural botanical products. (Goldstein, Tr. 2604).

Response to Finding No. 2005:
Complaint Counsel has no specific response.

2006. The erectile function domain relates only to erectile performance and does not evaluate orgasm or ejaculation. (Goldstein, Tr. 2604).

Response to Finding No. 2006:
Complaint Counsel has no specific response.

F. Respondents' Experts Confirm That Respondents' Substantiation Constitutes Competent and Reliable Scientific Evidence

1. Qualifications of Respondents Proffered Experts

(a) Arthur L. Burnett, M.D.

2007. Dr. Burnett is a Doctor of Medicine and obtained his medical degree in 1988 from the Johns Hopkins University School of Medicine in Baltimore, Maryland. (PX0149-0001).

Response to Finding No. 2007:
Complaint Counsel has no specific response.

2008. From 1988 to 1993, he completed an internship in general surgery and residencies in general surgery and urology at the Johns Hopkins Hospital. From 1993 to 1996, he completed fellowships in urology and reconstructive urology & urodynamics also at the Johns Hopkins Hospital. (PX0149-0001; Burnett, Tr. 2240-41).

Response to Finding No. 2008:
Complaint Counsel has no specific response.

2009. Dr. Burnett completed a master's degree in business administration with a concentration in medical services management in 2009 from the Johns Hopkins University Carey Business School. (PX0149-0001).

Response to Finding No. 2009:
Complaint Counsel has no specific response.

2010. Dr. Burnett is board certified in urology and is a practicing urological surgeon specializing in sexual medicine, major pelvic reconstruction, voiding dysfunction, female urology, and prostate cancer. (PX0149-0001).

Response to Finding No. 2010:
Complaint Counsel has no specific response.

2011. He has treated between 10,000 and 15,000 patients for erectile dysfunction ("ED"). (Burnett, Tr. 2244).

Response to Finding No. 2011:
Complaint Counsel has no specific response, except to note that Dr. Burnett testified that he sees about 10 to 15 patients per week with erectile dysfunction and has been doing so for more than 20 years. (Burnett, Tr. 2244).

2012. Dr. Burnett is also the Patrick C. Walsh Professor of Urology within the faculty of the Department of Urology at the Johns Hopkins University School of Medicine/Johns Hopkins Hospital in Baltimore, Maryland. (PX0149-0001; Burnett, Tr. 2241; PX0349 (Burnett, Dep. at 19)).

Response to Finding No. 2012:
Complaint Counsel has no specific response.

2013. Dr. Burnett also holds a faculty appointment in the Cellular and Molecular Medicine Training Program of the Johns Hopkins University School of Medicine. (PX0149-0001; PX0349 (Burnett, Dep. at 20)).

Response to Finding No. 2013:
Complaint Counsel has no specific response.

2014. Dr. Burnett also 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. (PX0149-0001; Burnett, Tr. 2241; PX0349 (Burnett, Dep. at 19)).

Response to Finding No. 2014:
Complaint Counsel has no specific response.

2015. Dr. Burnett has had a number of visiting professorships in urology nationally and internationally. (Burnett, Tr. 2241-42).

Response to Finding No. 2015:
Complaint Counsel has no specific response.

2016. Dr. Burnett has served in many journal editorial capacities including as an Assistant Editor of The Journal of Urology; Co-Editor-in-Chief of The Journal of Andrology; Reviews and Associate Editor of The Journal of Sexual Medicine, and Administrative Editor of Practical Reviews in Urology. (PX0149-0002-0003; Burnett, Tr. 2242).

Response to Finding No. 2016:
Complaint Counsel has no specific response.

2017. Dr. Burnett has authored and published over 180 original peer-reviewed articles and 40 book chapters, along with numerous editorials, books and reviews relating to his biomedical research and clinical activities. His work has appeared in many prominent journals, including *Science, Nature Medicine, Proceedings of the National Academy of Sciences, The Journal of Urology, Urology, The Journal of Andrology, and The Journal of Sexual Medicine*. (PX0149-0003; Burnett, Tr. 2243).

Response to Finding No. 2017:
Complaint Counsel has no specific response.

2018. Dr. Burnett has received multiple investigator-initiated research awards at federal, foundation sponsored and industry-related levels. (PX0149-0003). He has continuously been funded by the National Institutes of Health since 1998 holding project titles such as "Nitric Oxide Regulatory System in the Penis" and "Endothelial Nitric Oxide Synthase Regulatory Mechanisms in Penile Vascular Function", which have enabled his research group to advance the science of erection disorders related to nitric oxide biology. (PX0149-0003; Burnett, Tr. 2243).

Response to Finding No. 2018:
Complaint Counsel has no specific response.

2019. Dr. Burnett's research on nitric oxide ("NO") is world renowned. (PX0149-0003).

Response to Finding No. 2019:
Complaint Counsel has no specific response.

2020. Dr. Burnett's lab was 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)). 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. (PX0149-0005).

Response to Finding No. 2020:

Complaint Counsel has no specific response.

2021. 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. (PX0149-0005).

Response to Finding No. 2021:
Complaint Counsel has no specific response.

2022. Dr. Burnett's lab also refined the understanding of PDE5 (type 5 phosphodiesterases) 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. (PX0149-0005; PX0349 (Burnett, Dep. at 89)).

Response to Finding No. 2022:
Complaint Counsel has no specific response.

2023. 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). (PX0149-0005).

Response to Finding No. 2023:
Complaint Counsel has no specific response.

2024. Complaint Counsel's purported erectile health expert, Dr. Melman, recognizes "[t]hat Dr. Burnett of Johns Hopkins is a man highly respected in his field." (Melman, Tr. 1166).

Response to Finding No. 2024:
Complaint Counsel has no specific response, except to note that the court recognized Dr. Melman as an expert in urology as it relates to the treatment, prevention, and reduction of risk of erectile dysfunction; and in clinical testing involving erectile dysfunction. (CCFF ¶ 720). Dr. Burnett testified that he considered Dr. Melman to be an expert in the erectile dysfunction field and highly respected among urologists. (Burnett, Tr. 2299).

(b) Irwin Goldstein, M.D.

2025. Dr. Goldstein is a sexual medicine physician and has been practicing medicine since 1976. (PX0189-0001; PX0352 (Goldstein, Dep. at 14)).

Response to Finding No. 2025:

Complaint Counsel has no specific response.

2026. Dr. Goldstein has been involved in sexual medicine clinical practice, clinical research and basic science research since 1980. (PX0189-0002).

Response to Finding No. 2026:
Complaint Counsel has no specific response.

2027. Dr. Goldstein obtained his medical degree in 1975 from McGill University in Montreal, Quebec, Canada. (PX0149-0001).

Response to Finding No. 2027:
The proposed finding is unsupported by the cited evidence.

2028. From 1975-1976, Dr. Goldstein completed an internship at the Royal Victoria Hospital in Montreal, Canada. (PX0149-0001).

Response to Finding No. 2028:
The proposed finding is unsupported by the cited evidence.

2029. From 1976-1977, Dr. Goldstein completed a first year surgical residency at the Boston University School of Medicine at University Hospital in Boston. (PX0149-0001).

Response to Finding No. 2029:
The proposed finding is unsupported by the cited evidence.

2030. From 1977-1980, Dr. Goldstein completed a urology residency at the Boston University School of Medicine at University Hospital in Boston. (PX0149-0001).

Response to Finding No. 2030:
The proposed finding is unsupported by the cited evidence.

2031. From 1981-1984, Dr. Goldstein completed a Urology Fellowship and was awarded the Clinical Investigator Award from the NIAMDDK which allowed him to do research in the field of sexual medicine. (PX0189-0001; Goldstein, Tr. 2588-89).

Response to Finding No. 2031:
Complaint Counsel has no specific response.

2032. Dr. Goldstein has been certified by the American Board of Urology since 1982. (PX0189-0001).

Response to Finding No. 2032:
Complaint Counsel has no specific response.

2033. Dr. Goldstein was Professor of Urology and Professor of Gynecology at the Boston University School of Medicine from 1990-2005 and 2002-2005, respectively. (PX0189-0001).

Response to Finding No. 2033:
Complaint Counsel has no specific response.

2034. Dr. Goldstein was the Director/Co-Director of the Laboratory for Sexual Medicine Research at the Boston University School of Medicine from 1981-2005. (PX0189-0002).

Response to Finding No. 2034:
Complaint Counsel has no specific response.

2035. From 2002-2005, Dr. Goldstein also served as Director of the Institute for Sexual Medicine at the Boston University School of Medicine. (PX0189-0001).

Response to Finding No. 2035:
Complaint Counsel has no specific response.

2036. Since 2007, Dr. Goldstein has served as the Director of San Diego Sexual Medicine, APC and as the Director of Sexual Medicine at Alvarado Hospital, San Diego, California. (PX0189-0001; PX0352 (Goldstein, Dep. at 11))

Response to Finding No. 2036:
Complaint Counsel has no specific response.

2037. Dr. Goldstein also serves as Clinical Professor of Surgery, University of California, San Diego, and has held this position since 2007. (PX0189-0001; PX0352 (Goldstein, Dep. at 11)).

Response to Finding No. 2037:
Complaint Counsel has no specific response.

2038. In his clinical practice, Dr. Goldstein manages male and female patients with varying types of sexual health complaints, including numerous male patients who have had normal erectile function and desired enhanced sexual performance due to issues of sexual confidence, erection quality and better sexual performance, and also numerous men with erectile dysfunction who have had limited responses to traditional first-line therapies such as phosphodiesterase type 5 inhibitors ("PDE5 inhibitors" or "PDE5i"s), including Viagra, and who do not wish to consider invasive or mechanical treatments for their erectile health complaint. (PX0189-0001-0002; PX0352 (Goldstein, Dep. at 13)).

Response to Finding No. 2038:
Complaint Counsel has no specific response.

2039. Dr. Goldstein also established the first sexual medicine clinic in a Veterans Administration Hospital in the United States. (Goldstein, Tr. 2591).

Response to Finding No. 2039:
Complaint Counsel has no specific response.

2040. 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).

Response to Finding No. 2040:
Complaint Counsel has no specific response.

2041. Dr. Goldstein was part of the original advisory board to Pfizer that engaged in a very extensive drug development plan that developed sildenafil (Viagra). (Goldstein, Tr. 2590-91).

Response to Finding No. 2041:
Complaint Counsel has no specific response.

2042. Dr. Goldstein was also on the advisory boards of Bayer and Eli Lilly for the development of vardenafil (Levitra) and tadalafil (Cialis), respectively. (Goldstein, Tr. 2591).

Response to Finding No. 2042:
Complaint Counsel has no specific response, except to note that the cited evidence does not identify the drug name or manufacturers of the brands Levitra or Cialis. (Goldstein, Tr. 2591).

2043. 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).

Response to Finding No. 2043:
Complaint Counsel has no specific response.

2044. Dr. Goldstein has published over 250 original peer-reviewed manuscripts in male and female sexual medicine. (PX0189-0002-0003).

Response to Finding No. 2044:
Complaint Counsel has no specific response.

2045. Complaint Counsel's designated erectile-health expert, Dr. Melman, also recognizes Dr. Goldstein as "highly regarded" in the field. (Melman, Tr. 1166-67).

Response to Finding No. 2045:

Complaint Counsel has no specific response, except to note that the court recognized Dr. Melman as an expert in urology as it relates to the treatment, prevention, and reduction of risk of erectile dysfunction; and in clinical testing involving erectile dysfunction. (CCFF ¶ 720).

2046. In addition to the publications attached to Exhibit 3 of Drs. Goldstein and Burnett's expert reports upon which they relied upon, both experts have also extensively relied upon their education, years of experience and knowledge of developments in the field of urology and sexual medicine, including the promotion of erectile heath and treatment of erectile dysfunction. (PX0149-0004; PX0349 (Burnett, Dep. at 21-22); PX0189-0005; PX0352 (Goldstein, Dep. at 10)).

Response to Finding No. 2046:
Complaint Counsel has no specific response.

2. Opinions

(a) Erectile Health and Erectile Dysfunction

2047. Erectile health is having a healthy erectile mechanism. (PX0189-0008).

Response to Finding No. 2047:
Complaint Counsel has no specific response.

2048. Erectile health is promoted when the male practices strategies that encourage endothelial health. (PX0352 (Goldstein, Dep. at 148); PX0189-0008).

Response to Finding No. 2048:
Complaint Counsel has no specific response.

2049. Erectile health is distinguished from erectile dysfunction. (PX0189-0008).

Response to Finding No. 2049:
Complaint Counsel agrees.

2050. Erectile dysfunction, which has a clinical connotation, is very different from the concept of something that has a potential beneficial effect on erectile tissue function and health. (Burnett, Tr. 2256-57).

Response to Finding No. 2050:
Complaint Counsel has no specific response.

2051. Erectile dysfunction is the consistent or persistent inability to obtain and/or sustain an erection adequate for sexual intercourse. (PX0189-0008-0009).

Response to Finding No. 2051:
Complaint Counsel does not disagree.

2052. Erectile dysfunction has been estimated to affect up to 30 million men in the United States. (PX0189-0008-0009).

Response to Finding No. 2052:
Complaint Counsel has no specific response.

2053. The most common cause of erectile dysfunction is cardiovascular disease. (PX0189-0009).

Response to Finding No. 2053:
Complaint Counsel has no specific response.

2054. "Subjects with ED seem to have a vascular mechanism similar to that seen in atherosclerosis [] and therefore, a diagnosis of ED may be seen as a sentinel event that should prompt investigation for coronary heart disease (CHD) in asymptomatic men." (PX0190-0002).

Response to Finding No. 2054:
Complaint Counsel has no specific response.

2055. Cardiovascular disease is strongly associated with endothelial cell dysfunction. (PX0189-0009).

Response to Finding No. 2055:
Complaint Counsel has no specific response.

2056. Endothelial cell dysfunction may act to adversely affect the structure and function of the critical arterial inflow mechanism, the critical expandability of the erectile tissue and the critical integrity of the veno-occlusive mechanism. (PX0189-0009).

Response to Finding No. 2056:
Complaint Counsel has no specific response.

2057. Risk factors for cardiovascular disease, erectile dysfunction and endothelial dysfunction are shared and include such concerns as hypertension, diabetes, hypercholesterolemia, obesity, aging, and metabolic syndrome. (PX0189-0008).

Response to Finding No. 2057:
The proposed finding is unsupported by the cited evidence. The cited evidence discusses the relationship between erectile health and endothelial dysfunction, but does not directly identify these risk factors for cardiovascular disease or erectile dysfunction.

2058. Health care providers may recommend to a patient with a sexual health concern prophylactic strategies that encourage the long-term health of the erectile mechanism. (PX0189-0008).

Response to Finding No. 2058:
Complaint Counsel has no specific response.

2059. The erectile mechanism is largely dependent on the health, integrity, structure and function of the arterial vascular and corporal erectile tissue systems. (PX0189-0008).

Response to Finding No. 2059:
Complaint Counsel has no specific response.

2060. Erectile health is promoted, in particular, when the man practices strategies that encourage endothelial health, such as exercise, use of the Mediterranean diet, and use of endothelial-healthy medications (such as aspirin, statins, and PDE5-inhibitors). (PX0189-0008; PX0190).

Response to Finding No. 2060:
Complaint Counsel has no specific response.

(b) Physiology of Human Penile Erection

2061. The penis consists of two corpora cavernosa or erectile chambers and a corpus spongiosum or erectile tissue surrounding the urethra. The corpora cavernosa erectile tissue are contained by a thick and strong fibrous lining called the tunica albuginea that stretches to some extent during penile erection but also acts as a container to provide axial rigidity to the erect penis. (PX0189-0006; Burnett, Tr. 2245).

Response to Finding No. 2061:
Complaint Counsel has no specific response.

2062. The erectile tissue includes numerous interconnecting lacunar spaces that fill with blood during erection, and are lined by vascular endothelial cells. The lacunar spaces are surrounded by vascular smooth muscle and connective tissue such as collagen and elastin. (PX0189-0006).

Response to Finding No. 2062:
Complaint Counsel has no specific response.

2063. Arterial blood enters the corpora cavernosa via the right and left cavernosal arteries. There are numerous small regulatory arteries off the cavernosal artery called helicine arterioles that open into the lacunar spaces. At the peripheral edge of the erectile tissue, underneath the tunica albuginea, there are small veins called sub-tunical venules that drain blood from the peripheral lacunar spaces through the tunica into draining veins at the side of the penis to eventually return blood back to the heart. (PX0189-0006; Burnett, Tr. 2245-46).

Response to Finding No. 2063:
Complaint Counsel has no specific response.

2064. In the flaccid state, smooth muscle in the helicine arterioles and surrounding the lacunar spaces are contracted allowing only small amounts of blood to enter the erectile chambers. Relaxation of the vascular smooth muscle of the corpora cavernosa leads to penile erection. Dilation of the helicine arterioles increases perfusion of high pressure arterial blood into the lacunar spaces. Relaxation of the smooth muscle surrounding the lacunar spaces results in engorgement of the erectile tissue and expansion of the erectile tissue against the tunca albuginea. This erectile tissue expansion results in compression of the sub-tunical venules that restricts blood outflow from the corporal erectile chambers. This venous trapping mechanism is the corporal veno-occlusive mechanism. Due to the hydraulic nature of increasing blood inflow and perfusion pressure and restricting blood outflow, there is an increase in intracavernosal pressure to a value approximating the mean systemic arterial blood pressure. The containment of pressure within the tunica albuginea leads to axial rigidity and penile hardness that enables functional penile penetration. (PX0189-0006-0007; Burnett, Tr. 2246-48).

Response to Finding No. 2064:
Complaint Counsel has no specific response.

(c) The Role of Nitric Oxide In Human Penile Erection

2065. Nitric oxide ("NO") was proclaimed "molecule of the year". (Heber, Tr. 1970).

Response to Finding No. 2065:
Complaint Counsel has no specific response.

2066. NO has a beneficial effect on blood flow. (Heber, Tr. 1969, 2140; Burnett, Tr. 2250).

Response to Finding No. 2066:
Complaint Counsel has no specific response.

2067. Blood vessels and the flow of blood to the penis are important to erectile function. (Melman, Tr. 1169).

Response to Finding No. 2067:
Complaint Counsel has no specific response.

2068. NO is "known to be of paramount importance in the maintenance of good erectile function" and is the key molecule that governs penile erection. (PX0149-0004; Burnett, Tr. 2249-50, 2276; PX0190-0006).

Response to Finding No. 2068:
Complaint Counsel has no specific response, except to note that many types of cells and molecules, in addition to nitric oxide, participate in the erection process. (CCFF ¶ 1084).

2069. Complaint Counsel's own erectile expert, Dr. Melman, testified that NO employs a critical role in the erectile process. (Melman, Tr. 1169).

Response to Finding No. 2069:
Complaint Counsel does not disagree.

2070. The physiologic mechanism of penile erection involves release of NO in the corpus cavernsosum during sexual stimulation. (PX0149-0004-0005; PX0189-0007).

Response to Finding No. 2070:
Complaint Counsel has no specific response.

2071. The NO is released from shear stress off the endothelial cells in the lacunar spaces within the corpora cavernosa and from autonomic nerves that innervate the erectile tissue and are activated during sexual stimulation. (PX0189-0007; Burnett, Tr. 2248-49; PX0349 (Burnett, Dep. at 88-90)).

Response to Finding No. 2071:
Complaint Counsel has no specific response.

2072. Upon its synthesis and release from their cellular sources, NO diffuses to neighboring vascular and trabecular smooth muscle cells lining the lacunar spaces. (PX0149-0004-0005; PX0189-0007; PX0349 (Burnett, Dep. at 87-90)).

Response to Finding No. 2072:
Complaint Counsel has no specific response.

2073. The NO activates the enzyme guanylate cyclase within the vascular smooth muscle cells that results in increased levels of cyclic guanosine monophosphate (cGMP), an effector of smooth muscle relaxation via protein kinase G (PKG) actions. (PX0149-0004-0005; PX0189-0007; PX0349 (Burnett, Dep. at 87-90)).

Response to Finding No. 2073:
Complaint Counsel has no specific response.

2074. NO, cGMP and PKG mediates the relaxation of the cavernous smooth muscle and vasodilation of blood vessels. (PX0149-0004; PX0189-0007).

Response to Finding No. 2074:
Complaint Counsel has no specific response.

2075. Persistent smooth muscle relaxation leads to tissue engorgement within the corpora cavernosa and penile erection. (PX0189-0007).

Response to Finding No. 2075:
Complaint Counsel has no specific response.

2076. Cyclic guanosine monophosphate is hydrolyzed by the phosphodiesterases, predominantly type 5 ("PDE5"), to inactive 5'-GMP, terminating penile erection. (PX0149-0004-0005; PX0349 (Burnett, Dep. at 92-93)).

Response to Finding No. 2076:
Complaint Counsel has no specific response.

2077. PDE5 inhibitors such as sildenafil (Viagra), vardenafil (Levitra) and tadalafil (Cialis) inhibit PDE5, thereby augmenting cGMP levels. (PX0149-0004-0005; PX0349 (Burnett, Dep. at 93)).

Response to Finding No. 2077:
Complaint Counsel has no specific response.

2078. Endothelial nitric oxide function is fundamental to the vascular process. (Burnett, Tr. 2290).

Response to Finding No. 2078:
Complaint Counsel has no specific response, except to note that Dr. Burnett was referring to the vascular process of penile erection. (Burnett, Tr. 2290).

2079. The vascular function of vessels in various parts of the body behave similarly. (Burnett, Tr. 2290).

Response to Finding No. 2079:
Complaint Counsel has no specific response.

(d) Pomegranate Juice Enhances The Production and Preservation of Nitric Oxide

2080. Oxidative stress molecules in the body, which are produced by various kinds of conditions of inflammatory change, disease states, etc., have deleterious effects throughout the body in the vasculature and in the penis that actually counter-effect the body's nitric oxide regulatory mechanism, not just for transient effects to bring about erection, but also to maintain the wellness of the erectile tissue. (PX0349 (Burnett, Dep. at 90); Burnett, Tr. 2251; Goldstein, Tr. 2604-05; PX0190-0006).

Response to Finding No. 2080:
Complaint Counsel has no specific response.

2081. Antioxidants are well known to enhance the biological actions of NO by virtue of their capacity to stabilize NO by protecting against the oxidative destruction of NO by oxidative stress molecules. (PX0056-0002; PX0059-0001,0004; PX0190-0006; PX0149 at ¶ 14; PX0189 at ¶¶ 13, 14; Goldstein, Tr. 2604-2605).

Response to Finding No. 2081:

Complaint Counsel has no specific response.

2082. This antioxidant effect results in much higher and more prolonged cellular concentrations of NO, leading to markedly increased biological actions of NO. (PX0056-0002; PX0059-0001, 0004; PX0149-0005-0006).

Response to Finding No. 2082:
Complaint Counsel has no specific response.

2083. Pomegranate juice possesses potent flavonoid antioxidants. (PX0149-0005-0006; Burnett, Tr. 2250-51; PX0189-0011; PX0056; PX0058; PX0051; PX0004).

Response to Finding No. 2083:
Complaint Counsel has no specific response.

2084. Dr. Aviram concluded that based on his medical research, pomegranate juice had greater antioxidant potencies than red wine, which he believed, at the time, possessed the most potent antioxidant. (CX1358 (Aviram, Dep. at 5-6)).

Response to Finding No. 2084:
Complaint Counsel has no specific response.

2085. Based on his studies, Dr. Aviram represented to Stewart Resnick that the antioxidant properties found in the pomegranate were the most powerful he had ever researched. (CX1363 (S. Resnick, Coke Dep. at 57, 66)).

Response to Finding No. 2085:
The proposed finding is based on hearsay that lacks satisfactory indicia of reliability pursuant to 16 C.F.R. § 3.43(b). The finding is not a statement by Dr. Aviram, either during a deposition, investigational hearing, prior testimony in Commission or other proceedings, or an expert report, and is instead testimony by Mr. Resnick as to what he heard Dr. Aviram say. Respondents chose not to call Dr. Aviram, who was on their Final Proposed Witness List and, therefore, reliance on this out of court statement is unfair.

2086. Dr. Louis Ignarro, a Nobel Prize winner for his work on nitric oxide, and who published an article in the New England Journal describing nitric oxide as the neurotransmitter of penile erection, also found that pomegranate juice possesses more antioxidant activity than grape juice, blueberry juice, red wine and ascorbic acid. (PX0189-0011; Goldstein, Tr. 2594-95).

Response to Finding No. 2086:
Complaint Counsel has no specific response.

2087. Not surprisingly, Dr. Ignarro found that pomegranate juice was around 5,000 times more potent than the other antioxidants he has tested. (Heber, Tr. 1967).

Response to Finding No. 2087:
Complaint Counsel has no specific response, except to note that Dr. Heber stated that Dr. Ignarro tested "pomegranate extract." (Heber, Tr. 1967).

2088. Dr. Ignarro, has tested pomegranate juice for its capacity to protect nitric oxide against oxidative destruction. (PX0189-0011; Burnett, Tr. 2253; PX0058).

Response to Finding No. 2088:
Complaint Counsel has no specific response.

2089. After a series of studies, Dr. Ignarro concluded that pomegranate juice possesses potent antioxidant activity that results in marked protection of nitric oxide against oxidative destruction thereby augmenting the biologic actions of nitric oxide. (Burnett, Tr. 2256; PX0058).

Response to Finding No. 2089:
Complaint Counsel has no specific response.

2090. Pomegranate juice enhances the production of endothelial nitric oxide formation by suppressing the oxidative stress molecules that oppose the endothelial nitric oxide synthase function. (PX0149-0005-0006; PX0349 (Burnett, Dep. at 103, 119); Burnett, Tr. 2251-54).

Response to Finding No. 2090:
Complaint Counsel has no specific response.

2091. Based on his research, Dr. Ignarro concluded that "pomegranate juice was 20 times better than any other fruit juice at increasing nitric oxide." (PX484; Burnett, Tr. 2254-55; PX0484).

Response to Finding No. 2091:
Complaint Counsel has no specific response, except to note that the document is an email from Dr. Ignarro's assistant providing a quote for use by the Resnicks attributed to Dr. Ignarro. (PX0484-0001).

2092. As a result of these findings, Dr. Ignarro told Respondents that – "It's astonishing – I've been working in this field for 20 years and I have never seen anything like it. I drink it 3 times a day without fail." (PX0484).

Response to Finding No. 2092:

Complaint Counsel has no specific response, except to note that the document is an email from Dr. Ignarro's assistant providing a quote for use by the Resnicks attributed to Dr. Ignarro. (PX0484-0001).

2093. Pomegranate juice's anti-oxidative molecular effects activate endothelial nitric oxide mechanisms in vasculature which serve potential beneficial effects on vascular blood flow and promote vascular biologic health of the penis. (PX0149-0005-0006).

Response to Finding No. 2093:
The proposed finding mischaracterizes the evidence. The cited source does not state that pomegranate juice conclusively promoted the vascular biologic health of the penis, but states that there is a "probable benefit of pomegranate juice on the vascular structures involved in penile erection." (PX0149-0005-06).

(e) Pomegranate Juice Promotes Erectile Health and Function

2094. Antioxidants play a potential role in preserving erectile tissue health. (Burnett, Tr. 2285-86; Goldstein, Tr. 2604-05).

Response to Finding No. 2094:
Complaint Counsel has no specific response.

2095. Antioxidants also play a potential role in promoting one's likelihood of preserving their erection function. (Burnett, Tr. 2285-86; Goldstein, Tr. 2604-05; PX0190-0006).

Response to Finding No. 2095:
Complaint Counsel has no specific response, except to note that nitric oxide does not alone produce erections. Likewise, having erectile dysfunction does not necessarily mean that there is a corresponding loss of nitric oxide production. (CCFF ¶ 1084).

2096. The mechanism by which consuming pomegranate juice promotes erectile health may be shown 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).

Response to Finding No. 2096:
The proposed finding is incomplete because the mechanism by which pomegranate juice affects erectile function has not been proven (PX0189-0008 (describing the "hypothetical

mechanism" of how pomegranate juice consumption promotes erectile health)), and basic research studies about antioxidants do not show that pomegranate juice is efficacious in treating, reducing the risk, or preventing erectile dysfunction in humans. (CCFF ¶¶ 763-734, 1085).

2097. The competent and reliable scientific evidence demonstrates that pomegranate juice provides a benefit to erectile health and erectile function. (Goldstein, Tr. 2605; PX0189-0014; PX0149-0006; Burnett, Tr. 2255-56; PX0349 (Burnett, Dep. at 103, 116-118, 137); Heber, Tr. 2012).

Response to Finding No. 2097:
The proposed finding mischaracterizes the evidence. Dr. Heber and Dr. Burnett testified that pomegranate juice had "likely" a benefit for erectile function. (Heber, Tr. 2012; Burnett, Tr. 2255). Moreover, Respondents' and Complaint Counsel's experts testified that pomegranate juice has not been proven to treat, prevent, or reduce the risk of erectile dysfunction. (CCFF ¶¶ 1086-90).

2098. Dr. Goldstein concluded "that competent and reliable scientific evidence exists upon which clinicians who treat men with erectile health concerns would rely in concluding that pomegranate juice promotes erectile health." (PX0189-0014).

Response to Finding No. 2098:
Complaint Counsel does not disagree that this was in part Dr. Goldstein's testimony, but the proposed finding is incomplete because Dr. Goldstein also stated that the consumption of pomegranate juice to promote erectile health was a "hypothetical mechanism." (PX0189-0008, 0013 (stating that the basic research studies suggest a "probable benefit of pomegranate juice on erectile health")). Dr. Goldstein also limited his opinion to the use of pomegranate juice in the doctor-patient relationship. (CCFF ¶¶ 1094-95).

2099. Dr. Goldstein also testified that "without a question" there is competent and reliable science showing that pomegranate juice provides a benefit to erectile function. (Goldstein, Tr. 2605).

Response to Finding No. 2099:
Complaint Counsel does not disagree that this was in part Dr. Goldstein's testimony, but the proposed finding is incomplete because Respondents' and Complaint Counsel's experts testified that POM juice has not been shown to treat, prevent, or reduce the risk of erectile dysfunction in humans (CCFF ¶¶ 1086-90), and that in vitro and animal studies cannot alone show efficacy in humans (CCFF ¶¶ 763-64). Dr. Goldstein also limited his opinion to the use of pomegranate juice in the doctor-patient relationship and not a consumer "who just goes to . . . a supermarket and just drinks pomegranate juice for no reason." (CCFF ¶¶ 1094-95).

2100. Dr. Burnett concluded "that the basic scientific and clinical evidence is sufficient to support the use of pomegranate juice as a potential benefit for vascular blood flow and the vascular health of the penis. (PX0149-0006).

Response to Finding No. 2100:
Complaint Counsel has no specific response, except to note that Dr. Burnett testified that the recommendation to use pomegranate juice for erectile health would be made by preferably a clinician, or possibly a therapist or nutritionist. (CCFF ¶¶ 1094-95; Burnett, Tr. 2288).

2101. Dr. Burnett also testified that based on POM's *in vitro* and *in vivo* studies and *Forest/Padma-Nathan RCT Study*, pomegranate juice has a likely beneficial effect on erectile function. (Burnett, Tr. 2255-56).

Response to Finding No. 2101:
Complaint Counsel does not disagree that this was in part Dr. Burnett's testimony, but the proposed finding is incomplete because Respondents' and Complaint Counsel's experts testified that POM juice has not been shown to treat, prevent, or reduce the risk of erectile dysfunction in humans (CCFF ¶¶ 1086-90), and that in vitro studies cannot alone show efficacy in humans (CCFF ¶¶ 763-64).

2102. Moreover, Dr. Burnett testified that that he thinks "there's good basic science support that pomegranate juice is a very effective agent . . . in vascular function." (PX0349 (Burnett, Dep. at 103, 116-118).

Response to Finding No. 2102:
Complaint Counsel has no specific response.

2103. Dr. Burnett further testified that the basic science only "support[s] the potential benefit at the human level to [sic] improve the physiology of erectile tissue preserving erect tissue health." (PX0349 (Burnett, Dep. at 103, 116-118).

Response to Finding No. 2103:
Complaint Counsel does not disagree that this was in part Dr. Burnett's testimony, but the proposed finding is incomplete because Respondents' and Complaint Counsel's experts testified that POM Juice has not been shown to treat, prevent, or reduce the risk of erectile dysfunction in humans (CCFF ¶¶ 1086-90), and that in vitro and animal studies cannot alone show efficacy in humans (CCFF ¶¶ 763-64).

2104. Dr. Burnett testified that he thinks "work from animal studies do [sic] have some potential for benefit of a therapy at the human level." (PX0349 (Burnett, Dep. at 112).

Response to Finding No. 2104:
Complaint Counsel does not disagree that this was in part Dr. Burnett's testimony, but the proposed finding is incomplete because Respondents' and Complaint Counsel's experts testified that POM juice has not been shown to treat, prevent, or reduce the risk of erectile dysfunction in humans (CCFF ¶¶ 1086-90), and that animal studies cannot alone show efficacy in humans (CCFF ¶ 764).

2105. Dr. Burnett further testified that the basic science only "support[s] the potential benefit at the human level to [sic] improve the physiology of erectile tissue preserving erect tissue health." (PX0349 (Burnett, Dep. at 103, 116-118).

Response to Finding No. 2105:
Complaint Counsel does not disagree that this was part of Dr. Burnett's testimony, but the proposed finding is incomplete because Respondents' and Complaint Counsel's experts testified that POM Juice has not been shown to treat, prevent, or reduce the risk

of erectile dysfunction in humans (CCFF ¶¶ 1086-90), and that in vitro and animal studies cannot alone show efficacy in humans (CCFF ¶¶ 763-64; PX0349 (Burnett, Dep. at 117-18)).

2106. Dr. Burnett testified that the in vitro and in vivo studies alone "provide powerful support for pomegranate juice, extracts and related sort of agents here and pomegranate effects here 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).

Response to Finding No. 2106:
Complaint Counsel does not disagree that this was in part Dr. Burnett's testimony, but the proposed finding is incomplete because Respondents' and Complaint Counsel's experts testified that in vitro studies cannot alone show efficacy in humans. (CCFF ¶¶ 763-64; PX0349 (Burnett, Dep. at 117-18)). Furthermore, Dr. Burnett testified that he did not offer any opinions on POMx Pills or Liquid. (CCFF ¶ 750). Dr. Burnett testified that the recommendation to use pomegranate juice for erectile health would be made by preferably a clinician, or possibly a therapist or nutritionist. (CCFF ¶¶ 1094-95; Burnett, Tr. 2288).

2107. Dr. Heber testified that there is competent and reliable science showing that pomegranate juice and its derivative are likely to lessen the risk of erectile disease and enhance erectile function. (Heber, Tr. 2012).

Response to Finding No. 2107:
Complaint Counsel does not disagree that this was in part Dr. Heber's testimony, but the proposed finding is unsupported and incorrect. Dr. Heber admitted that he is not an expert in erectile function treatment. (CCFF ¶ 728). Furthermore, Respondents' and

Complaint Counsel's experts testified that pomegranate juice has not been shown to treat, prevent, or reduce the risk of erectile dysfunction in humans. (CCFF ¶¶ 1086-90).

2108. Dr. Liker, in his deposition, stated that he, Dr. Padma-Nathan and Forest concluded that the *Forest/Padma-Nathan RCT Study* showed a clinically significant benefit to erectile health. (CX1350 (Liker, Dep. at 190-191)).

Response to Finding No. 2108:
The proposed finding is incomplete because the Forest/Padma-Nathan RCT Study stated that "'[f]urther studies are warranted to clarify the efficacy and clinical role of POM [Juice] on male ED.'" (CCFF ¶1074). Furthermore, Dr. Padma-Nathan and Mr. Forest testified that their study did not conclude that POM Juice treats, prevents, or reduces the risk of erectile dysfunction. (CCFF ¶1074). The proposed finding is also based on hearsay that lacks satisfactory indicia of reliability pursuant to 16 C.F.R. § 3.43(b). The finding is not a statement by Dr. Padma-Nathan or Mr. Forest, either during a deposition, investigational hearing, prior testimony in Commission or other proceedings, or an expert report, and is instead testimony by Dr. Liker as to what he heard Dr. Padma-Nathan or Mr. Forest say. Respondents chose not to call Dr. Padma-Nathan or Mr. Forest, who were on their Final Proposed Witness List and, therefore, reliance on these out of court statements is unfair.

2109. The *Forest/Padma-Nathan RCT Study* has major clinical significance in showing a benefit from pomegranate juice on erectile tissue physiology and health, and also supports the conclusion that the positive results in the basic science are borne out in human function. (PX0189-0013; PX0149-0006; CX0908; Heber, Tr. 1979, 2001; Goldstein, Tr. 2598-99; PX0352 (Goldstein, Dep. at 108-109); Burnett, Tr. 2256; PX0349 (Burnett, Dep. at 138-139)).

Response to Finding No. 2109:
The proposed finding is incomplete because the Forest/Padma-Nathan RCT Study's results were not clinically significant in showing that POM Juice treated erectile dysfunction in humans (CCFF ¶¶ 782, 1055, 1060, 1078) and did not show that the basic

science research findings were reflected in humans as related to the treatment of erectile dysfunction. (CCFF ¶¶ 1069, 1072, 1073, 1076-77, 1086, 1088-1090).

2110. Dr. Goldstein opined that he would recommend pomegranate juice as a management tool to promote erectile health in men who are aware that their erectile function is declining but who do not yet meet the clinical definition of ED under the IIEF and therefore do not qualify for pharmacologic treatment. (PX0189-0014-0015; PX0352 (Goldstein, Dep. at 42-45); Goldstein, Tr. 2609).

Response to Finding No. 2110:
Complaint Counsel has no specific response, except to note that such recommendation would be made in the context of the doctor-patient relationship. (CCFF ¶¶ 1094-95).

2111. The validity of the existence of this subpopulation is corroborated by the existence of a robust market for the recreational use of PDE5 inhibitors like Viagra. (PX0189-0014; PX0352 (Goldstein, Dep. at 43-44)).

Response to Finding No. 2111:
Complaint Counsel has no specific response.

2112. Dr. Goldstein also testified that men who have been diagnosed with clinical ED but who have an insufficient response to PDE5 inhibitors (like Viagra) and who are unwilling to consider invasive or mechanical therapies (such as injecting needles into the penis, inserting urethral suppositories, using vacuum pumps, or having surgically implanted prostheses), the suggestion to utilize the Mediterranean diet, which the pomegranate fruit is part of, to improve endothelial function and erectile health, is logical and rational given the risk-benefit ratio. (PX0189-0004-0005, 0014-0015; PX0352 (Goldstein, Dep. at 37-42); Goldstein, Tr. 2605, 2641; PX0190-0006-0007).

Response to Finding No. 2112:
Complaint Counsel does not disagree that this was in part Dr. Goldstein's testimony, but the proposed finding is irrelevant as to whether pomegranate fruit is part of the Mediterranean diet. This case involves pomegranate juice and POMx Pills and Liquid, which are not whole pomegranate fruit. (CCFF ¶¶ 124-26, 130, 132, 134).

2113. Improving ones erectile function may also help improving ones erectile dysfunction. (Burnett, Tr. 2303).

Response to Finding No. 2113:

Complaint Counsel has no specific response, except to note that Dr. Burnett clearly indicated that pomegranate juice has not been shown to treat, prevent, or reduce the risk of erectile dysfunction in humans. (CCFF ¶ 1088).

2114. The *Forest/Padma-Nathan RCT Study* demonstrates pomegranate juice is "a potential treatment for ED." (PX0349 (Burnett, Dep. at 137-139, 142)).

Response to Finding No. 2114:
Complaint Counsel does not disagree that this was part of Dr. Burnett's testimony, but the proposed finding is incomplete because the Forest/Padma-Nathan RCT Study also noted that "'[f]urther studies are warranted to clarify the efficacy and clinical role of POM [Juice] on male ED.'" (CCFF ¶ 1074). Respondents' and Complaint Counsel's experts testified that the Forest/Padma-Nathan RCT Study does not show that pomegranate juice treats erectile dysfunction in humans. (CCFF ¶¶ 1086-90).

2115. Dr. Heber has testified that "[t]he body of research on pomegranate juice and extract revealing how they react on the body provides support for potential health benefits for erectile dysfunction." (CX2007 (Heber, Dep. at 85)).

Response to Finding No. 2115:
The proposed finding is unsupported by the cited evidence. Dr. Heber admitted that he is not an expert in erectile function treatment. (CCFF ¶ 728).

2116. Nobel Laureate Louis Ignarro indicated that he strongly believed pomegranate juice was 40% as effective as Viagra in helping with erectile dysfunction. (CX1363 (S. Resnick, Coke Dep. at 77-78); CX1372 (S. Resnick, Tropicana Dep. at 44)).

Response to Finding No. 2116:
The proposed finding is based on hearsay that lacks satisfactory indicia of reliability pursuant to 16 C.F.R. § 3.43(b). The finding is not a statement by Dr. Ignarro, either during a deposition, investigational hearing, prior testimony in Commission or other proceedings, or an expert report, and is instead testimony by Mr. Resnick as to what he heard Dr. Ignarro say. Respondents chose not to call Dr. Ignarro, who was on their Final Proposed Witness List and, therefore, reliance on this out of court statement is unfair.

2117. Inside Integrative Medicine, a newsletter published by University of Texas MD Anderson Cancer Center, published an article entitled the "Anticancer Effects of Pomegranate" which provided that "early research also suggests that pomegranate may be beneficial as a treatment for erectile dysfunction . . . ." (MD Cancer Center, Inside Integrative Medicine (February/March 2010), available at http://www.mdanderson.org/publications/inside-integrative-medicine/issues/issue-15-febmarch2-010.pdf. (last visited Jan. 3, 2012)).

Response to Finding No. 2117:
The proposed finding is relies on non-record evidence in violation of the Court's Order on Post-Trial Briefs.

2118. On the website of Memorial Sloan-Kettering Cancer Center in New York, information about the pomegranate is included on their Cancer Care Integrative Medicine web page which provides a clinical summary of the pomegranate, stating that pomegranate juice was "found to benefit patients with carotid artery stenosis, in those with hypertension, hyperlipdemia, mild to moderate erectile dysfunction." (Memorial Sloan-Kettering Cancer Center, Pomegranate, available at http://www.mskcc.org/cancer-care/herb/pomegranate. (last visited Jan. 3, 2012)).

Response to Finding No. 2118:
The proposed finding is relies on non-record evidence in violation of the Court's Order on Post-Trial Briefs.

(f) Pomegranate Juice Reduces the Risk of ED in Some Population of Men

2119. Dr. Goldstein testified that reasonable and competent science shows that pomegranate juice reduces the risk of, or ameliorates erectile dysfunction in men caused by endothelial dysfunction or blood flow impairment or oxidative stress. (Goldstein, Tr. 2605).

Response to Finding No. 2119:
Complaint Counsel does not disagree that this was in part Dr. Goldstein's testimony, but the proposed finding is incomplete because Dr. Goldstein testified that pomegranate juice is not a treatment for erectile dysfunction in humans. (CCFF ¶¶ 1089-90).

(g) Substantiation Standard

2120. Pomegranate juice is a natural fruit with health promoting characteristics, and documented for over 5,000 years, and as a result, urologist would not require RCTs for its safety. (PX0189-0003; Goldstein, Tr. 2601-02, 2611, 2620; Miller, Tr. 2194, 2201; PX0206-0010; Heber, Tr. at 1948-1950, 2056, 2166; PX0149-0006-0007; (Burnett, Tr.

2272-2274, 2303); PX0189-0003; Goldstein, Tr. 2600- 02, 2611, 2620); deKernion, Tr. 3060; PX0025-0007).

Response to Finding No. 2120:
The proposed finding is incorrect because pomegranate juice is not itself a "natural fruit." (CCFF ¶¶ 124-26).

2121. Moreover, urologist would not require RCTs to substantiate health benefit claims for harmless pure fruit products like pomegranate juice. (PX0149-0006-0007; (Burnett, Tr. 2272, 2303); PX0189-0003; Goldstein, Tr. 2600-02, 2611, 2620).

Response to Finding No. 2121:
The proposed finding mischaracterizes the evidence because Respondents' and Complaint Counsel's experts would require RCTs before concluding that pomegranate juice treats, prevents, or reduces the risk of erectile dysfunction. (CCFF ¶¶ 783, 1055, 1089, 1102; *see also* ¶ 1073).

2122. Urologists who treat men with erectile health concerns would not require that pomegranate juice or its derivatives be subjected to RCTs before concluding that pomegranate juice has a beneficial effect on preserving erectile function. (PX0149-0006-0007; Burnett, Tr. 2272-74, 2303; PX0189-0003; Goldstein, Tr. 2600-02, 2611, 2620).

Response to Finding No. 2122:
The proposed finding mischaracterizes the evidence. Respondents' and Complaint Counsel's experts would require RCTs before concluding that pomegranate juice treats, prevents, or reduces the risk of erectile dysfunction. (CCFF ¶¶ 783, 1055, 1089, 1102; *see also* ¶ 1073). Respondents' and Complaint Counsel's experts also testified that pomegranate juice has not been shown to treat, prevent, or reduce the risk of erectile dysfunction in humans. (CCFF ¶¶ 1086-90). Dr. Burnett and Dr. Goldstein also testified that they did not offer any opinions regarding POMx Pills or POMx Liquid (CCFF ¶¶ 750, 754).

2123. Urologists who treat men with erectile health concerns would not require that pomegranate juice or derivatives be subjected to RCTs before concluding that pomegranate juice has a beneficial effect on erectile dysfunction. (Burnett, Tr. 2272-74, 2303).

Response to Finding No. 2123:
The proposed finding mischaracterizes the evidence. Respondents' and Complaint Counsel's experts would require RCTs before concluding that pomegranate juice treats, prevents, or reduces the risk of erectile dysfunction. (CCFF ¶¶ 783, 1055, 1089, 1102; *see also* ¶ 1073). Respondents' and Complaint Counsel's experts also testified that pomegranate juice has not been shown to treat, prevent, or reduce the risk of erectile dysfunction in humans. (CCFF ¶¶ 1086-90). Dr. Burnett and Dr. Goldstein also testified that they did not offer any opinions regarding POMx Pills or POMx Liquid (CCFF ¶¶ 750, 754).

2124. In the context of treating ED, "there may be a conclusion made that a therapy has a potential benefit in that treatment, even if it does not meet statistical significance." (Burnett, Tr. 2270).

Response to Finding No. 2124:
Complaint Counsel has no specific response, except to note that Dr. Burnett testified that two to three RCTs with statistically significant results are required to prove that a product treats erectile dysfunction. (CCFF ¶¶ 779, 783).

2125. A clinical treatment for ED is different than the concept of something having a potential beneficial effect on erectile tissue function and health. (PX0349 (Burnett, Dep. at 56-57)).

Response to Finding No. 2125:
Complaint Counsel has no specific response.

(h) Information Of Pomegranate Juice's Potential Erectile Health Benefits May Be Communicated to Consumers

2126. A recommendation to consider using antioxidants to benefit one's erectile health does not have to be made exclusively by a clinician or physician. (Burnett, Tr. 2288).

Response to Finding No. 2126:
The proposed finding is incomplete because 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, and Dr. Burnett testified that the

recommendation to use pomegranate juice for erectile health would be made by preferably a clinician, or possibly a therapist or nutritionist. (CCFF ¶¶ 1094-95; Burnett, Tr. 2288).

2127. Because pomegranate juice creates no material risk of harm and assuming that drinking pomegranate juice is not advocated as an alternative to following medical advice, information of pomegranate juice's likely benefit may be communicated to consumers. (PX0149-0006-0007; PX0206-0010-0011).

Response to Finding No. 2127:
The proposed finding of fact is incomplete because it does not identify the specific likely benefit that would be communicated to consumers and Dr. Goldstein testified that any recommendation of pomegranate juice to promote erectile health would be made in the context of the doctor-patient relationship only. (CCFF ¶¶ 1094-95).

2128. The *Forest/Padma-Nathan RCT Study*, which achieved a probability value of 0.058 still has 94% validity and therefore "is important information with likely benefits" that should be communicated to consumers. (Burnett, Tr. 2306).

Response to Finding No. 2127:
The proposed finding of fact is incomplete because the 0.058 p value was achieved using the GAQ, a non-validated measure (CCFF ¶¶ 1060-61, 1077) and any recommendation of pomegranate juice to promote erectile health would be made in the context of the doctor-patient relationship only according to Dr. Goldstein. (CCFF ¶¶ 1094-95). Dr. Burnett also testified that the recommendation to use pomegranate juice for erectile health would be made by preferably a clinician, or possibly a therapist or nutritionist. (Burnett, Tr. 2288).

2129. Dr. Burnett testified that "[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." (PX0349 (Burnett, Dep. at 67); PX0352 (Goldstein, Dep. at 108-109)).

Response to Finding No. 2129:

Complaint Counsel has no specific response, except to note that Dr. Burnett defined clinical significance "extremely broad" so that "[t]o the extent that it has any impact at the human level suggests clinical significance[,]" which is different than Dr. Melman's use of the phrase clinical significance. (PX0349 (Burnett, Dep. at 62); CCFF ¶ 782).

2130. When talking about consuming pomegranate juice rather than clinical treatment for ED, it is not necessary for a study to reach statistical significance in order for the study to convey important information. (Burnett, Tr. 2305).

Response to Finding No. 2130:
The proposed finding is incomplete because it does not state the purpose of consuming pomegranate juice or what information is being conveyed. Dr. Burnett also clarified that his statement about not needing RCTs pertained to when pomegranate juice was being claimed as a complimentary therapy for erectile health and not as a primary intervention for erectile dysfunction. (Burnett, Tr. 2313). When pomegranate juice is being claimed as effective in treating, preventing, or reducing the risk of erectile dysfunction, experts would require statistically significant results from at least one RCT with several investigatory sites. (CCFF ¶¶ 783, 1055, 1102).

2131. Dr. Goldstein testified that the *Forest/Padma-Nathan RCT Study* although falling short of statistical significance was nonetheless "absolutely" clinically significant. (PX0352 (Goldstein, Dep. at 108); PX0189-0013).

Response to Finding No. 2131:
Complaint Counsel does not disagree that this was in part Dr. Goldstein's testimony, but the proposed finding is incomplete because the results discussed by Dr. Goldstein relate to the GAQ, which is a non-validated measure. (CCFF ¶¶ 1060, 1077). Complaint Counsel also disagrees with the conclusion that the Forest/Padma-Nathan RCT Study was clinically significant. (CCFF ¶¶ 782, 1060, 1102).

2132. Dr. Goldstein indicated that the results showed that "there were 50 percent more people than the placebo who thought that there was erectile benefit from using this drug. And I will call that clinically significant in conjunction with the fact that there are no deaths, no

priapisms, no heart attacks, no strokes, no flushing, no nasal congestion, none of the traditional side effects seen by PDE5 inhibitors. No need for stents, drug-eluting stints, no need for surgery. No need for penile prosthetic procedures." (PX0352 (Goldstein, Dep. at 109)).

Response to Finding No. 2132:
Complaint Counsel does not disagree that this was in part Dr. Goldstein's testimony, but the proposed finding is incomplete because the results discussed by Dr. Goldstein were not statistically significant and were based on the GAQ, which is a non-validated measure. (CCFF ¶¶ 1060, 1077).

2133. Dr. Burnett believes that the current scientific and clinical evidence about pomegranate juice's potential erectile health benefits "can be put out in the public domain." (PX0349 (Burnett, Dep. at 118, 137); PX0149-0006-0007)).

Response to Finding No. 2133:
Complaint Counsel does not disagree that this was in part Dr. Burnett's testimony, but the proposed finding is incomplete because Dr. Burnett does not believe that that pomegranate juice is proven to treat, prevent, or reduce the risk of erectile dysfunction and would not endorse pomegranate juice as a primary intervention. (CCFF ¶¶ 1088, 1092). Furthermore, Dr. Goldstein testified that any recommendation to use pomegranate juice for erectile health would be made in the doctor-patient relationship. (CCFF ¶¶ 1094-95).

G. Complaint Counsel's Erectile Expert Offered Extreme Opinions That Are Insufficient to Undermine Respondents' Showing of Substantiation

1. Dr. Melman's Opinions Are Motivated by Bias

(a) Dr. Melman Is Currently Engaged In Developing His Own Erectile Dysfunction Product, Which He Hopes To Market And Make Money From, And That He Has Described As The "Fountain of Youth"

2134. Dr. Melman is the CEO and co-founder of Ion Channel Innovations, which is developing a gene-transfer therapy for erectile dysfunction called hMaxi-K. (Melman, Tr. 1148).

Response to Finding No. 2134:

Complaint Counsel has no specific response.

2135. Dr. Melman hopes to market hMaxi-K and make money from doing so. (Melman, Tr. 1153-54).

Response to Finding No. 2135:
Complaint Counsel has no specific response.

2136. Dr. Melman has 17 patents on his gene transfer therapy. (Melman, Tr. 1153).

Response to Finding No. 2136:
Complaint Counsel has no specific response.

2137. hMaxi-K is injected into the penis. (Melman, Tr. 1192).

Response to Finding No. 2137:
Complaint Counsel has no specific response.

2138. Dr. Melman convinced a patient of his, who was a school teacher, to invest one million dollars into Ion Channel Innovations. (Melman, Tr. 1159-60).

Response to Finding No. 2138:
Complaint Counsel has no specific response.

2139. Dr. Melman announced to the public, in an interview with the New York Observer, that his hMaxi-K produced spontaneous normal erections in men suffering from erectile dysfunction. (Melman, Tr. 1154).

Response to Finding No. 2139:
Complaint Counsel has no specific response.

2140. Dr. Melman also told the New York Observer reporter that the men who tried it became like they were young again. (Melman, Tr. 1154).

Response to Finding No. 2140:
Complaint Counsel has no specific response.

2141. Dr. Melman told the reporter that he was talking about "modifying the aging process." (Melman, Tr. 1155).

Response to Finding No. 2141:
Complaint Counsel has no specific response.

2142. Dr. Melman told the reporter that his product was the "the fountain of youth." (Melman, Tr. 1154 -55).

Response to Finding No. 2142:

Complaint Counsel has no specific response.

2143. Dr. Melman's public claim regarding his hMaxi-K product was based on an animal study. (Melman, Tr. 1155).

Response to Finding No. 2143:
Complaint Counsel has no specific response, except to note that Dr. Melman testified that the gene transfer therapy product was not on the market, has not been sold, and would require FDA approval before being made available to consumers. (Melman, Tr. 1151).

2144. There are severe health risks associated with gene-transfer therapy. (Melman, Tr. 1158).

Response to Finding No. 2144:
The proposed finding is incomplete because Dr. Melman testified about the health risk associated with the viral vector method for inducing the gene transfer only. (Melman, Tr. 1158).

2145. Dr. Melman acknowledged people have died and gotten very sick from gene-transfer therapy. (Melman, Tr. 1158).

Response to Finding No. 2145:
The proposed finding is incomplete because Dr. Melman testified about the health risk associated with the viral vector method for inducing the gene transfer only. (Melman, Tr. 1158).

2146. Dr. Melman admits that pomegranate juice is safe. (PX0360 (Melman, Dep. at 59, 130-131)).

Response to Finding No. 2146:
Complaint Counsel has no specific response.

2147. Nevertheless, Dr. Melman contends that "the standards . . . for substantiating a claim for fruit juice are the same as for substantiating a claim for gene transfer therapy." (Melman, Tr. 1148-49).

Response to Finding No. 2147:
The proposed finding is incomplete because Dr. Melman stated that the standards for fruit juice or gene transfer therapy are the same when a "help[s] erectile dysfunction" claim is being made. (Melman, Tr. 1149).

2148. Dr. Melman further testified that if a patient with ED was unresponsive to PDE5 inhibitors like Viagra and did not want to undergo invasive therapies, like penile injections (required by his competing hMaxi-K product), that he would still not recommend pomegranate juice and that he'd tell his patients to "stop having intercourse." (Melman, Tr. 1192-94; PX0360 (Melman, Dep. at 31)).

Response to Finding No. 2148:
The proposed finding mischaracterizes the evidence because Dr. Melman did not testify that he would "tell his patients to 'stop having intercourse,'" but stated that if patients did not want to try other forms of treatment, besides PDE-5 inhibitors, then the result would be that they "stop having intercourse." (PX0360 (Melman, Dep. at 31); Melman, Tr. 1194).

(b) Dr. Melman Always Sides With the FTC

2149. Dr. Melman has testified on behalf of the FTC on three or four prior occasions. (Melman, Tr. 1161).

Response to Finding No. 2149:
Complaint Counsel has no specific response.

2150. Dr. Melman always testified in favor of the FTC, i.e., that the respondent lacked adequate substantiation. (Melman, Tr. 1161).

Response to Finding No. 2150:
Complaint Counsel has no specific response.

2. Dr. Melman's Positions Are Extreme

(a) Dr. Melman's Position Regarding Claims That Help With Erectile Function Are Extreme

2151. Dr. Melman testified that the only kind of science to support claims to help erectile function are two double-blind placebo based randomized trials. (Melman, Tr. 1138-39).

Response to Finding No. 2151:
The proposed finding is incorrect because Dr. Melman agreed that "one must have a double-blind, placebo-based, randomized trial, and . . . done in two separate institutions at least." (Melman, Tr. 1138-39; *see also* CCFF ¶ 1055 (stating the requirement of one

well-designed, human RCT involving several investigatory sites to substantiate a claim that pomegranate juice prevents, reduces the risk, or treats erectile dysfunction)).

2152. Dr. Melman also testified that there has to be a trial done in two separate institutions. (Melman, Tr. 1138-39).

Response to Finding No. 2152:
Complaint Counsel has no specific response, except to note that Dr. Melman required at least one RCT with several investigatory sites to substantiate a claim that pomegranate juice prevents, reduces the risk, or treats erectile dysfunction. (CCFF ¶ 1055).

2153. Dr. Melman testified there must also be a large group, and the two studies must reach statistical significance. (Melman, Tr. 1139).

Response to Finding No. 2153:
The proposed finding is incorrect as to the requirement of two separate studies. Dr. Melman testified that experts require one well-designed, human RCT involving several investigatory sites to substantiate a claim that pomegranate juice prevents, reduces the risk, or treats erectile dysfunction. (CCFF ¶ 1055).

2154. Dr. Melman testified that the trials must be held in multiple locations. (Melman, Tr. 1137-39).

Response to Finding No. 2154:
The proposed finding is incorrect as to the requirement of more than one separate clinical trial. Dr. Melman requires one well-designed, human RCT involving several investigatory sites to substantiate a claim that pomegranate juice prevents, reduces the risk, or treats erectile dysfunction. (CCFF ¶ 1055).

2155. Dr. Melman testified that the men's sexual partners must also confirm the result. (Melman, Tr. 1139-40).

Response to Finding No. 2155:
Complaint Counsel does not disagree that this was in part Dr. Melman's testimony, but the proposed finding is incomplete. In studies investigating a treatment for erectile dysfunction, Dr. Melman testified that the FDA's trend is to require independent

validation by the men's partners using the partner component of the IIEF or the Treatment Satisfaction Scale, which are validated measures. A study's outcome data is stronger if both members of the couple give the same response. (Melman, Tr. 1106).

2156. Dr. Melman testified that for a study to claim any improvement in participants, the men must have reached orgasm. (Melman, Tr. 1141-43).

Response to Finding No. 2156:
The proposed finding mischaracterizes the testimony. Dr. Melman stated that a clinically significant treatment of erectile dysfunction means that a man can complete intercourse with sexual satisfaction, and according to the NIH definition, sexual satisfaction for men can include orgasm. (Melman, Tr. 1142-43; CCFF ¶¶ 782, 1055, 1060, 1078).

2157. Dr. Melman testified that for a study to claim any improvement in participants, the sexual partner must reach sexual satisfaction. (Melman, Tr. 1142-43).

Response to Finding No. 2157:
The proposed finding is incomplete. Dr. Melman testified about a claim regarding the treatment of erectile dysfunction. (Melman, Tr. 1141). In studies investigating a treatment for erectile dysfunction, Dr. Melman testified that the FDA's trend is to require independent validation by the men's partners using the partner component of the IIEF or the Treatment Satisfaction Scale, which are validated measures. A study's outcome data is stronger if both members of the couple give the same response. (Melman, Tr. 1106).

2158. Dr. Melman testified that you cannot properly make public claims that a product helps with erectile function in absence of such trials. (Melman, Tr. 1138-39).

Response to Finding No. 2158:
The proposed finding mischaracterizes Dr. Melman's position that a well-designed, human RCT involving several investigatory sites is necessary to substantiate a claim that pomegranate juice prevents, reduces the risk, or treats erectile dysfunction. (CCFF ¶ 1055).

2159. Dr. Melman agreed that, with respect to such requirements, he was applying the FDA standard for drugs being submitted to the FDA. (Melman, Tr. 1140).

Response to Finding No. 2159:
Complaint Counsel does not disagree and notes that Dr. Melman explained that his analysis was equated to what the FDA would require because he was asked by Complaint Counsel what experts in the erectile dysfunction field would require when evaluating whether eight ounces of pomegranate juice daily treats, prevents, or reduces the risk of erectile dysfunction in humans. (CCFF ¶¶ 1055-56, 1102; Melman, Tr. 1196).

2160. Dr. Melman testified that even if Dr. Burnett did a proper RCT at Johns Hopkins, who he deems to be a very distinguished man in the field, and the RCT came out positive, it is still not enough to support a public claim. (Melman, Tr. 1139).

Response to Finding No. 2160:
Complaint Counsel does not disagree that this was in part Dr. Melman's testimony, but the proposed finding is incomplete. Dr. Melman testified that he would require a well-designed, human RCT involving several investigatory sites to substantiate a claim that pomegranate juice prevents, reduces the risk, or treats erectile dysfunction. (CCFF ¶ 1055).

(b) Dr. Melman Insists Pomegranate Juice Is a Drug

2161. Dr. Melman takes the extreme position that "pomegranate juice is a drug." (PX0360 (Melman, Dep. at 17-19); Melman, Tr. 1141).

Response to Finding No. 2161:
The proposed finding mischaracterizes Dr. Melman's testimony. Dr. Melman used the word "drug," to refer to "any product with an active ingredient," including the polyphenol agents in pomegranate juice when discussing whether a product treats, prevents, or reduces the risk of erectile dysfunction. (Melman, Tr. 1140-41, 1196).

2162. He even goes so far as to suggest that water is a drug because it is composed of hydrogen and oxygen molecules. (Melman, Tr. 1141).

Response to Finding No. 2162:

The proposed finding of fact is incorrect. Dr. Melman used the word "drug," to refer to "any product with an active ingredient" and did not state that water is a drug. (Melman, Tr. 1140-41, 1196).

2163. On cross-examination, Dr. Melman testified that everything is a drug. (Melman, Tr. 1165).

Response to Finding No. 2163:
The proposed finding mischaracterizes Dr. Melman's testimony. Dr. Melman used the word "drug," to refer to "any product with an active ingredient," including the polyphenol agents in pomegranate juice, when discussing whether a product treats, prevents, or reduces the risk of erectile dysfunction. (Melman, Tr. 1140-41, 1196).

2164. Dr. Goldstein testified, however, that pomegranate juice is a nutraceutical (a naturally occurring botanical product with health-promoting characteristics) and not a drug. (PX0352 (Goldstein, Dep. at 134); PX0189-0003).

Response to Finding No. 2164:
Complaint Counsel has no specific response, except to note that PX0189 states that pomegranate juice was not a "pharmaceutical drug." (PX0189 (Goldstein, Report at 0003)).

(c) Dr. Melman Insists That If a Study Doesn't Show Statistical Significance, It Is Not a Difference

2165. Dr. Melman testified that pomegranate juice "doesn't work" because the *Forest/Padma-Nathan RCT Study* did not reach statistical significance. (Melman, Tr. 1171-78).

Response to Finding No. 2165:
The proposed finding is incomplete because Dr. Melman testified that the Forest/Padma-Nathan RCT Study did not reach statistical significance on either the GAQ or IIEF, and that the GAQ was not a validated measure. (CCFF ¶¶ 1060, 1076-77).

2166. Dr. Melman insisted that if a difference doesn't reach statistical significance, it's not a difference. (Melman, Tr. 1176-78).

Response to Finding No. 2166:
Complaint Counsel has no specific response.

3. Dr. Melman's Opinions Are Uninformed

(a) Dr. Melman Had Never Heard of the Ubiquitous GAQ

2167. Even though the GAQ is widely used—including in virtually every published study of Viagra, Cialis, and Levitra (Goldstein, Tr. 2602, 2603; Burnett, Tr. 2304)—Dr. Melman testified that he had never heard of it before his involvement in this case. (Melman, Tr. 1180).

Response to Finding No. 2167:
Complaint Counsel does not disagree that this was in part Dr. Melman's testimony, but the proposed finding is incomplete. Dr. Melman testified that studies submitted to the FDA investigating the effect of a drug on erections use the IIEF or one of its variants as the primary outcome measure for statistical significance, not the non-validated GAQ. (Melman, Tr. 1188).

2168. Indeed, Dr. Melman claims that he tried to research the GAQ but was unable to find anything about it—he "tried but failed." (Melman, Tr. 1181-82).

Response to Finding No. 2168:
The proposed finding mischaracterizes the evidence because Dr. Melman stated that he learned that the GAQ was not a validated test after researching the GAQ. (Melman, Tr. 1181).

2169. Dr. Melman conceded that he doesn't "know whether it's widely used or not." (Melman, Tr. 1187-88).

Response to Finding No. 2169:
Complaint Counsel does not disagree that this was in part Dr. Melman's testimony, but the proposed finding is incomplete. Dr. Melman testified that studies submitted to the FDA investigating the effect of a drug on erections use the IIEF or one of its variants as the primary outcome measure for statistical significance, not the non-validated GAQ. (Melman, Tr. 1188).

2170. Dr. Melman was even unaware that Pfizer had used the GAQ questionnaire in their studies on Viagra. (Melman, Tr. 1187-88).

Response to Finding No. 2170:
Complaint Counsel does not disagree that this was in part Dr. Melman's testimony, but the proposed finding is incomplete. Dr. Melman testified that studies submitted to the FDA investigating the effect of a drug on erections use the IIEF or one of its variants as the primary outcome measure for statistical significance, not the non-validated GAQ. (Melman, Tr. 1188).

2171. Dr. Goldstein testified that for Dr. Melman to not know the GAQ is widely used "is a little embarrassing." (Goldstein, Tr. 2602).

Response to Finding No. 2171:
Complaint Counsel does not disagree that this was in part Dr. Goldstein's testimony, but the proposed finding is incomplete. Dr. Melman testified that studies submitted to the FDA investigating the effect of a drug on erections use the IIEF or one of its variants as the primary outcome measure for statistical significance, not the non-validated GAQ. (Melman, Tr. 1188).

2172. Regardless, Dr. Melman called the GAQ questionnaire a "lousy test". (Melman, Tr. 1174, 1182).

Response to Finding No. 2172:
Complaint Counsel has no specific response, except to note that Dr. Melman stated that the GAQ was lousy because it was a nonvalidated test. (Melman, Tr. 1182).

2173. Although Dr. Melman had no experience with the GAQ questionnaire prior to this case, he insisted that pomegranate juice "doesn't work" because the *Forest/Padma-Nathan RCT Study* used the GAQ questionnaire (in addition to the study not reaching statistical significance). (Melman, Tr. 1171-74).

Response to Finding No. 2173:
The proposed finding mischaracterizes the evidence. In addition to the lack of statistically significant results for the GAQ, experts would not rely on a non-validated measure like the GAQ to show efficacy of a product in treating, preventing, or reducing the risk of erectile dysfunction in humans. (CCFF ¶¶ 1056, 1060, 1061). The

Forest/Padma-Nathan RCT Study also did not have statistically significant results for the IIEF, a validated measure. (CCFF ¶¶ 1069, 1076). Both Respondents' and Complaint Counsel's experts testified that pomegranate juice has not been shown to treat, prevent, or reduce the risk of erectile dysfunction in humans. (CCFF ¶¶ 1086-90; *see also* CCFF ¶ 1073).

(b) Dr. Melman's Doesn't Know The Meaning Of "RCT"

2174. Dr. Melman doesn't know the meaning of the term "RCT" which is commonly used by researchers to indicate randomized double-blind, placebo-based trial. (Melman, Tr. 1134-35).

Response to Finding No. 2174:
The proposed finding is incomplete. Dr. Melman did not recognize the "term 'RCT study.'" (Melman, Tr. 1134). However, Dr. Melman was accepted by the court as an expert in clinical testing involving erectile dysfunction and testified extensively about what constitutes a well-designed randomized clinical trial in humans. (CCFF ¶¶ 720, 773-775, 777, 779, 781-83, 1055).

(c) Dr. Melman Believed the FTC Had to Give Approval In Advance to Market a Product

2175. Dr. Melman testified that he thought the FTC "has to give approval in advance to market a product." (Melman, Tr. 1138).

Response to Finding No. 2175:
The proposed finding is irrelevant.

(d) Dr. Melman's Opinions Are Contrary to Recent Supreme Court Precedent

2176. The Supreme Court held in *Matrix Initiatives, Inc. v. Siracusano*, 131 S.Ct. 1309, 1319 (2011), that "medical professionals and researchers do not limit the data they consider to the results of randomized clinical trials or to statistically significant evidence." Dr. Melman disagrees with this statement of the law. (Melman, Tr. 1178-80).

Response to Finding No. 2176:

The proposed finding is irrelevant and mischaracterizes both the law and Dr. Melman's testimony, which was in the context that he would disagree with that statement when ascertaining substantiation for a claim that a product treats, prevents, or reduces the risk of erectile dysfunction. (Melman, Tr. 1171-79).

(e) Dr. Melman Has Never Studied a Food Product

2177. Dr. Melman concedes that he has never conducted any clinical work on a food product. (Melman, Tr. 1165).

Response to Finding No. 2177:
Complaint Counsel has no specific response.

2178. Dr. Melman testified that he has never done any testing on pomegranate juice. (Melman, Tr. 1164).

Response to Finding No. 2178:
Complaint Counsel has no specific response.

2179. Dr. Melman testified he has not written about the oral treatment of ED. (Melman, Tr. 1164).

Response to Finding No. 2179:
Complaint Counsel has no specific response.

2180. Most of Dr. Melman's current research is on gene transfer therapy and overactive bladder condition. (Melman, Tr. 1164-65).

Response to Finding No. 2180:
Complaint Counsel has no specific response.

(f) Dr. Melman Requires That a Patient Have an Orgasm Before His ED Is Deemed Treated

2181. 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." (Melman, Tr. 1146-47).

Response to Finding No. 2181:
Complaint Counsel does not disagree that this was in part Dr. Melman's testimony, but the proposed finding is incomplete. Dr. Melman stated that a clinically significant

treatment of erectile dysfunction means that a man can complete intercourse with sexual satisfaction, and according to the NIH definition, sexual satisfaction for men can include orgasm. (Melman, Tr. 1142-43; CCFF ¶¶ 782, 1055, 1060, 1078).

2182. Dr. Goldstein testified that he "couldn't disagree more" with Dr. Melman's statement. (Goldstein, Tr. 2604).

Response to Finding No. 2182:
Complaint Counsel does not disagree that this was in part Dr. Goldstein's testimony, but disagrees with the conclusion that Dr. Melman testified that an orgasm is required for the treatment of erectile dysfunction. (Melman, Tr. 1142-43).

2183. Dr. Goldstein testified that Dr. Melman's statement was contrary to the IIEF. (Goldstein, Tr. 2604).

Response to Finding No. 2183:
Complaint Counsel does not disagree that this was in part Dr. Goldstein's testimony, but disagrees with the conclusion that Dr. Melman testified that an orgasm is required for the treatment of erectile dysfunction. (Melman, Tr. 1142-43).

2184. This opinion imposing an orgasm prerequisite to the treatment of ED is unsupported by the erectile function domain of the IIEF for which Dr. Melman advocates, as that domain gathers no information regarding a patient's orgasm. (Goldstein, Tr. 2604).

Response to Finding No. 2184:
The proposed finding mischaracterizes the evidence. Dr. Melman stated that a clinically significant treatment of erectile dysfunction means that a man can complete intercourse with sexual satisfaction, and according to the NIH definition, sexual satisfaction for men can include orgasm. (Melman, Tr. 1142-43; *see also* CCFF ¶¶ 782, 1055, 1060, 1078).

(g) Dr. Melman Blindly Critiqued the Forest/Padma-Nathan RCT Study's Placebo

2185. Dr. Melman criticizes the *Forest/Padma-Nathan RCT Study* for not having an identical placebo match, but admits that he "ha[s] no idea" whether any test subject knew he was drinking placebo. (Melman, Tr. 1190).

Response to Finding No. 2185:

The proposed finding of fact is incomplete because the Forest Study authors stated that while minimized, "a potential limitation of the study is that POM has a distinct appearance and taste." (CX1193_0004; *see also* CX0626_0001; CX0689_0001).

2186. In fact, any potential limitation arising from pomegranate juice's unique appearance and taste "was minimized for the study by taste and color matching the placebo beverage as well as providing a 2-week washout so that it would be difficult for subjects to discern any subtle difference in taste or appearance between the study beverages." (CX0908).

Response to Finding No. 2186:
Complaint Counsel does not disagree with the quote from the Forest/Padma-Nathan RCT Study article, but the proposed finding is incomplete because the Forest Study authors stated that "a potential limitation of the study is that POM has a distinct appearance and taste." (CX1193_0004; *see also* CX0626_0001; CX0689_0001). Dr. Melman also testified that while minimized the Forest/Padma-Nathan RCT Study did not state that the taste and appearance of the beverages were identical. (PX0360 (Melman, Dep. at 77)).

(h) Dr. Melman's Characterization of the Davidson Study as Being a Negative ED Study Is Misplaced as the Baseline IIEF Data Collection Was Admittedly Flawed from the Outset

2187. Dr. Melman characterized the Davidson Study as having negative ED findings. (Melman, Tr. 1130).

Response to Finding No. 2187:
Complaint Counsel does not disagree, except to note that the non-statistically significant findings were based on results from the validated IIEF measure. (CCFF ¶ 1080).

2188. The Davidson study, however, 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. (CX0716; PX0019; Melman, Tr. 1092).

Response to Finding No. 2188:
Complaint Counsel has no specific response, except to note that the analysis using the IIEF was planned for in the Davidson Study protocol. (CCFF ¶ 1079).

2189. In fact, the ED findings in the Davidson Study were flawed as one of the two study sites was unable to collect any data for the baseline IIEF measurement. (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.")

Response to Finding No. 2189:
Complaint Counsel has no specific response, except to note that the Davidson Study's IIEF data was analyzed and found to not be statistically significantly. (CCFF ¶ 1080). Neither Dr. Burnett nor Dr. Goldstein reviewed the IIEF data from the Davidson Study. (CCFF ¶ 1081). Also, Respondents' sponsored Davidson Study was designed as an RCT with at least two study sites just as Dr. Melman indicated was the proper design to substantiate a claim that a product treats, prevents, or reduces the risk of erectile dysfunction. (CCFF ¶ 1055; CX0654_0001).

4. Dr. Melman's Opinions Are Hypocritical

(a) Dr. Melman Critiques Respondents' Studies Even Though He Has Conducted Studies Similarly

2190. Dr. Melman criticizes the *Forest/Padma-Nathan RCT Study* for studying a population with a mean age of 46 years old, even though Dr. Melman himself conducted a study in which the mean age of study participants was 40. (Melman, Tr. 1190-92).

Response to Finding No. 2190:
The proposed finding mischaracterizes the evidence. The study conducted by Dr. Melman with a median age of 40 years old did not investigate a treatment for erectile dysfunction, but rather studied whether the purported impairment of erectile function in young men was being properly measured. (Melman, Tr. 1192, 1195-96).

(b) Dr. Melman Holds Respondents to a Higher Standard Than That to Which He Holds Himself

2191. While 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. (Melman, Tr. 1149-55).

Response to Finding No. 2191:
The proposed finding mischaracterizes the evidence. Dr. Melman requires one well-designed, human RCT involving several investigatory sites to substantiate a claim that pomegranate juice prevents, reduces the risk, or treats erectile dysfunction. (CCFF ¶ 1055). *See also* Response to Finding 2189. Furthermore, Dr. Melman testified that the gene transfer therapy product was not on the market, has not been sold, and would require FDA approval before being made available to consumers. (Melman, Tr. 1151).

H. Summary of Erectile Health Claims That Respondents Can Support

2192. The competent and reliable scientific evidence demonstrates that pomegranate juice provides a benefit to erectile health and erectile function. (Goldstein, Tr. 2605; PX0189-0014; PX0149-0006; Burnett, Tr. 2255-56; PX0349 (Burnett, Dep. at 103, 116-118, 137); Heber, Tr. 2012).

Response to Finding No. 2192:
The proposed finding mischaracterizes the evidence. Dr. Heber and Dr. Burnett testified that pomegranate juice "likely" had a benefit for erectile function. (Heber, Tr. 2012; Burnett, Tr. 2255). Moreover, Respondents' and Complaint Counsel's experts both testified that pomegranate juice has not been proven to treat, prevent, or reduce the risk of erectile dysfunction in humans. (CCFF ¶¶ 1086-90). Dr. Heber admitted that he is not an expert in erectile function treatment. (CCFF ¶ 728). Moreover, Mr. Resnick himself testified that the Forest/Padma-Nathan RCT Study was a preliminary study, used a population that was too small, and did not reach the appropriate statistical significance level necessary to show that the effect was caused by the treatment itself. (CX1363 (Resnick, TCCC Dep. at 77-79)).

2193. Pomegranate juice would be recommended as a management tool to promote erectile health in men who are aware that their erectile function is declining but who do not yet meet the clinical definition of ED under the IIEF and therefore do not qualify for pharmacologic treatment. (PX0189-0014-0015; PX0352 (Goldstein, Dep. at 42-45); Goldstein, Tr. 2609; CX2007 (Heber, Dep. at 85)).

Response to Finding No. 2193:
Complaint Counsel does not disagree that this was in part Dr. Goldstein's testimony, but the proposed finding is incomplete because Dr. Goldstein stated that such recommendation would be made in the context of the doctor-patient relationship. (CCFF ¶¶ 1094-95). Dr. Heber admitted that he is not an expert in erectile function treatment. (CCFF ¶ 728) and CX2007 is non-record evidence.

2194. Improving ones erectile function may also help improving ones erectile dysfunction. (Burnett, Tr. 2303).

Response to Finding No. 2194:
Complaint Counsel has no specific response, except to note that Dr. Burnett clearly indicated that pomegranate juice has not been shown to treat, prevent, or reduce the risk of erectile dysfunction in humans. (CCFF ¶ 1088).

2195. The suggestion to utilize the Mediterranean diet, which the pomegranate fruit is part of, to improve endothelial function and erectile health, is logical and rational in men who have been diagnosed with clinical ED but who have an insufficient response to PDE5 inhibitors (like Viagra) and who are unwilling to consider invasive or mechanical therapies (such as injecting needles into the penis, inserting urethral suppositories, using vacuum pumps, or having surgically implanted prostheses), (PX0189-0005, 0014-0015; PX0352 (Goldstein, Dep. at 37-42); Goldstein, Tr. 2605, 2641; PX0190-0006-0007).

Response to Finding No. 2195:
The proposed finding is in part irrelevant and incomplete. According to Dr. Goldstein, the recommendation to drink pomegranate juice would be made in the context of the doctor-patient relationship. (CCFF ¶¶ 1094-95). Moreover, this case involves pomegranate juice and not whole pomegranate fruit. (CCFF ¶¶ 124-26).

2196. Reasonable and competent science shows that pomegranate juice reduces the risk of, or ameliorates erectile dysfunction in men caused by endothelial dysfunction or blood flow impairment or oxidative stress. (Goldstein, Tr. 2605).

Response to Finding No. 2196:
Complaint Counsel does not disagree that this was in part Dr. Goldstein's testimony, but the proposed finding is incomplete because Dr. Goldstein testified that pomegranate juice

is not a treatment for erectile dysfunction in humans. In addition, any recommendation to a consumer to use pomegranate juice to promote erectile health would be made in the context of the doctor-patient relationship. (CCFF ¶¶ 1089-90, 1094-95).

XVII. POM'S ADVERTISEMENTS

A. Overview of Respondents' Contentions Regarding the Advertisements

2197. Complaint Counsel has now, late in trial and afterwards, narrowed the universe of advertisements to approximately 70 ads and more than a dozen website captures, from hundreds and hundreds of ads. (*See infra* XVII(F)).

Response to Finding No. 2197:
The proposed finding is incorrect. Complaint Counsel is challenging 43 individual advertisements or promotional materials as examples of Respondents' claims that violate the FTC Act. (*See* CCFF Section V and Appendix A). Moreover, the cross-referenced section appears to deal with the purported change in POM's ads over time, so this finding is unsupported by the cited evidence.

2198. Of these, approximately eight are the much older ads that have not run in several years, on which Complaint Counsel concentrated on at trial. These eight ads, while accurate and truthful, were "outliers" at POM, using more aggressive language and graphics regarding the health benefits of POM's pomegranate juice. (*See infra* XVII(E)).

Response to Finding No. 2199:
Complaint Counsel has no specific response to the proposed finding, but refers the Court to its Responses to Findings in the cross-referenced section.

2199. The rest of the ads fall into three categories, all of which are qualified claims and are substantiated by competent and reliable scientific evidence. (*See infra* XVII(G)).

Response to Finding No. 2199:
Complaint Counsel has no specific response to the proposed finding, but refers the Court to its Responses to Findings in the cross-referenced section.

2200. Unlike other cases, such as *In re Telebrands Corp.*, 140 F.T.C. 278 (2005), Complaint Counsel failed to present significant extrinsic evidence or expert opinion on the meaning of the ads to support their claims. Contrary to Complaint Counsels' contentions, such extrinsic evidence is necessary because the implied claims they assign to the challenged

ads are not "conspicuous, self-evident, or reasonably clear" so that they can be "determined with confidence" from the face of the ads that the claims can be ascertained without extrinsic evidence. (Appendix of Advertisements; Mazis, Tr. 2752).

Response to Finding No. 2200:
The proposed finding mischaracterizes the evidence, as Complaint Counsel presented extrinsic evidence on the advertisements' meaning. (S*ee, e.g.*, CCFF Sections V.C., V.G). It is also unsupported by the cited evidence, as Dr. Mazis did *not* testify as to the need for extrinsic evidence as to ad meaning in Tr. 2752; he testified that none of the surveys introduced show how many times any POM Juice or POMx ad was run. *See also* Responses to Findings in the cross-referenced Appendix.

2201. 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).

Response to Finding No. 2201:
Complaint Counsel agrees.

2202. Typical consumers of POM products are affluent and health conscious. (CX1375 (L. Resnick, Tropicana Dep. at 131); CX1357 (Kuyoomjian, Dep. at 102).

Response to Finding No. 2202:
Complaint Counsel agrees.

2203. POM consumers understand that the Challenged Products 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 the Challenged Products can treat their diseases or that they should disregard conventional medical treatment if they were to consume the Challenged Products. (Butters Tr. 2817-18; Appendix of Advertisements).

Response to Finding No. 2203:
The proposed finding that "POM consumers understand that the Challenged Products are 100 percent derived from a fruit (which is a fact heavily emphasized in POM's advertising)" is unsupported by the cited testimony. Complaint Counsel has no specific response to the remainder of the finding. *See also* Responses to Findings in the cross-referenced Appendix.

2204. Instead, POM consumers view Respondents' advertising through the lens that the Challenged Products are wholly derived from pomegranates and perceive the Challenged Products 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; Appendix of Advertisements).

Response to Finding No. 2204:
The proposed finding is unsupported by the cited testimony. *See also* Complaint Counsel's Responses to Findings in the cross-referenced Appendix.

2205. As set forth in the further detail below, the implied claims on which Complaint Counsel base their claims are very aggressive and unreasonable interpretations on what messages the ads convey.

Response to Finding No. 2205:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel disagrees with the conclusion drawn about the net impressions of the ads.

B. The Dispute Regarding the Advertisements

1. Complaint Counsel Claim That POM's advertisements Make "Clinically Proven" Disease Claims

2206. The FTC claims that, in its advertising, POM contended that the Challenged Products were "clinically proven" to prevent or treat heart disease, prostate cancer, and erectile dysfunction, and that POM products were a "silver bullet against disease." (FTC Press Release: FTC Complaint Charges Deceptive Advertising by POM Wonderful (9/27/2010), available at http://www.ftc.gov/opa/2010/09/pom.shtm (quoting David Vladek, Director of the FTC's Bureau of Consumer Protection)).

Response to Finding No. 2206:
The proposed finding cites to evidence that is not in the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel also notes that this statement was made to the press, and it is the Complaint that sets out the FTC's allegations in this matter.

2207. The FTC claims that Respondents' "clinically proven" disease claims are false and misleading because Respondents' clinical studies, research and/or trials did not prove the challenged benefits claimed. (CX1426 at 0017-0020).

Response to Finding No. 2207:
Complaint Counsel agrees.

2208. The FTC further claims that Respondents' "clinically proven" disease claims are material to the purchasing decisions of POM's consumers. (Compl. Pretrial Br. at 30).

Response to Finding No. 2208:
The proposed finding cites to evidence that is not in the record. Complaint Counsel has no specific response.

2. Respondents' Deny That They Make "Clinically Proven" Disease Claims

2209. As described in the paragraphs below, Complaint Counsels' contentions that POM's ads make "clinically proven" disease claims are wrong for many reasons. (*See infra* ¶ 2210).

Response to Finding No. 2209:
Complaint Counsel disagrees with the conclusions in the proposed finding. *See also* Response to Finding 2210.

2210. First, POM's advertising do not convey the disease messages that Complaint Counsel assert are expressly made in the advertisements.

(a) 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. (Appendix of Advertisements); and

(b) 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. (Appendix of Advertisements).

Response to Finding No. 2210:
The proposed finding is unsupported by the cited evidence. *See* Complaint Counsel's Responses to Findings in the cross-referenced Appendix.

2211. Second, POM's advertising does not convey the disease messages that Complaint Counsel assert are impliedly made in the advertisements.

(c) Respondents assert that the Commission may rely on its own reasoned analysis to determine what implied claims are conveyed, absent reference to extrinsic evidence, only if those claims are "conspicuous, self-evident, or reasonably clear on the face of the ad." (*Kraft, Inc. v. F.T.C.*, 970 F.2d 311, 320 (7th Cir. 1972) *cert. denied*, 507 U.S. 909 (1993));

Response to Finding No. 2211(c):

The proposed finding is a legal conclusion and is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs.

(d) In this case, however, it is impossible for Complaint Counsel to "conclude with confidence" that POM's advertisements convey the "clinically proven" claims to prevent or treat disease, as alleged, on the face of the challenged ads. (see *In re Thompson Medical Co.*, 104 F.T.C. 648, 789 (1984), *aff'd*, 791 F.2d 189 (D.C. Cir. 1986), *cert. denied*, 479 U.S. 1086 (1987));

Response to Finding No. 2211(d):
The proposed finding is a legal conclusion and is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs.

(e) POM's advertising, viewed as a whole, does not clearly and conspicuously convey to a reasonable consumer that the Challenged Products prevent, treat or reduce the risk of heart disease, prostate cancer and erectile dysfunction under Complaint Counsels' "net impression" analysis or any analysis for implied claims. (Appendix of Advertisements);

Response to Finding No. 2211(e):
The proposed finding is unsupported by the cited evidence. *See* Responses to Findings in the cross-referenced Appendix.

(f) POM's advertising, viewed as a whole, does not clearly and conspicuously convey to a reasonable consumer that the Challenged Products are "clinically proven" to prevent, treat or reduce the risk of heart disease, prostate cancer and erectile dysfunction under Complaint Counsels' "net impression" analysis or any analysis for implied claims. (Appendix of Advertisements);

Response to Finding No. 2211(f):
The proposed finding is unsupported by the cited evidence. *See* Responses to Findings in the cross-referenced Appendix.

(g) To the extent a "proven" claim can be implied from any of POM's advertising (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." (Heber, Tr. 2011; Butters, Tr. 2893-94; PX0361 (Sacks, Dep. at 81)));

Response to Finding No. 2211(g):

Complaint Counsel disagrees with the finding regarding the implication and net impression of POM's advertisements, but Complaint Counsel agrees that "proven" does not mean that "everyone in the study" benefitted.

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

Response to Finding No. 2211(h):
The proposed finding is unsupported by the cited testimony. Dr. Butters did not define "treat" as a substitute for conventional medical treatment. He defined "treat" as medical treatment and then asserted that he didn't see any ad stating or implying that POM Products "treated any disease." Complaint Counsel also disagrees with the proposed finding regarding the net impression of this advertisement. *See* Responses to Findings in the cross-referenced Appendix.

(i) To the extent a "reduce the risk" claim can be implied from any of POM's advertising, 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. (Butters Tr. 2817-18).

Response to Finding No. 2211(i):
Complaint Counsel disagrees with the proposed finding regarding the implication and net impression of POM's advertisements. *See* Responses to Findings in the cross-referenced Appendix. The proposed finding is also unsupported by the cited testimony.

2212. Third, because the challenged implied claims may not be determined with confidence from the face of the challenged advertisements, extrinsic evidence must be examined, including consumer surveys and expert testimony. (*See* Appendix of Advertisements; *In re Stouffer Food Corp.*, 118 F.T.C. 746, 777 (1994) (citing Kraft, 970 F.2d at 318)).

Response to Finding No. 2212:
Complaint Counsel disagrees with the proposed finding regarding the implication and net impression of POM's advertisements and that extrinsic evidence is required. *See*

Responses to Findings in the cross-referenced Appendix. To the extent the proposed finding is a legal conclusion, it is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs.

2213. Here, Complaint Counsel failed to present any reliable extrinsic evidence or expert opinion:

(a) on the meaning of POM's ads, or on consumers' expectations or perceptions on the ads;

(b) that POM's ads conveyed that the Challenged Products are "clinically proven" to prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction;

(c) that POM's ads conveyed that the Challenged Products prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction; or

(d) of Respondents' intent to convey such messages to prove that POM's advertising made the alleged implied disease claims or "clinically proven" disease claims. (CX1287; CX1289; CX1291; CX1293; CX1295; Mazis, Tr. 2752).

Response to Finding No. 2213:

The proposed finding is unsupported by the cited evidence because CX1287-93 refer to Complaint Counsel's science experts. CX1295 is Complaint Counsel's rebuttal marketing expert Dr. Stewart's report; in which he opines on several areas of extrinsic evidence such as Respondent's creative briefs and consumer surveys that provide evidence of the meaning of POM's advertisements, Respondents' intent to convey certain messages, and consumers' likely perceptions of the ads. Dr. Mazis's cited testimony does not provide support for the proposed finding and refers only to the fact that he agreed that there is no survey evidence as to how many times consumers were exposed to an ad. Furthermore, Complaint Counsel has provided reliable extrinsic evidence as to the challenged claims. (*See, e.g.*, CCFF Sections V.C, V.G).

2214. Fourth, Complaint Counsel failed to present any reliable extrinsic evidence or expert opinion rebutting the fact that many of the ads were meant to be hyperbolic, puffery and humorous. (*See, e.g.*, *Sterling Drug, Inc. v. F.T.C.*, 741 F.2d 1146, 1150 (9th Cir. 1984)).

Indeed, most of the statements in the majority of the ads were not meant to be taken literally and cannot be objectively verified, and thus constitute puffery. (*In re Thompson Medical*, 104 F.T.C. 648, 788-89 n.6).

Response to Finding No. 2214:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Furthermore, Complaint Counsel has provided reliable extrinsic evidence as to the challenged claims and the purpose and use of humor in Respondents' advertising. (*See, e.g.*, CCFF Sections V.C, V.G).

2215. Furthermore, as set forth in detail below, to the extent the challenged advertisements do not rely on puffery or hyperbole, POM's advertisements contain carefully qualified statements that convey accurate messages about the health benefits of the Challenged Products, the results of the scientific studies and related information. (Appendix of Advertisements).

Response to Finding No. 2215:
Complaint Counsel disagrees with the proposed finding regarding the net impressions of Respondents' advertisements. *See* Responses to Findings in the cross-referenced Appendix.

2216. Indeed, the overall net impressions of POM's advertising were as follows:

(a) Some of the ads conveyed general health messages, such as the Challenged Products are healthy for your body or promote a healthy heart or a healthy prostate. (Appendix of Advertisements);

(b) Other ads conveyed more specific qualified messages – *e.g.*, the Challenged Products "reduce the risk" of heart disease, prostate cancer or erectile dysfunction, like a healthy diet of fruits and vegetables and exercise "reduce the risk" of disease. (Appendix of Advertisements); and

(c) Others fall somewhere in between. (Appendix of Advertisements).

Response to Finding No. 2216:
Complaint Counsel disagrees with the proposed finding regarding net impressions of POM's advertisements. *See* Responses to Findings in the cross-referenced Appendix.

3. POM's advertisements Are Substantiated by Rigorous, Competent and Reliable Scientific Evidence

2217. Each of the health-related messages conveyed by POM's advertising, as described above, are truthful and not misleading because Respondents had rigorous, competent and reliable scientific evidence to support the messages conveyed in those advertisements. (*See infra* (XVII(G)).

Response to Finding No. 2217:
Complaint Counsel disagrees with the conclusions drawn. *See* Responses to Findings in the cross-referenced section.

2218. Even assuming *arguendo* that POM's advertising do expressly or impliedly convey the "clinically proven" disease messages that Complaint Counsel assign to them, all POM's advertising claims about the Challenged Products are truthful and not misleading because Respondents also had rigorous, competent and reliable scientific evidence to support those representations. (*See infra* (XVII(G)).

Response to Finding No. 2218:
Complaint Counsel disagrees with the conclusions drawn. *See* Responses to Findings in the cross-referenced section.

4. Respondents' Survey Evidence Demonstrates That Their Advertising Claims Are Not Material to Consumers

2219. Additionally, assuming *arguendo* that the presumption of materiality applies in favor of the Commission, such presumption was successfully rebutted by Respondents' expert witness, David Reibstein, a marketing professor at The Wharton School of the University of Pennsylvania. His survey demonstrated that, even if the ads conveyed the messages that Complaint Counsel assign to them, any alleged disease claims made by Respondents were not material to the purchasing decisions of POM consumers. (*See infra* (XVIII(A)).

Response to Finding No. 2219:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Moreover, Complaint Counsel disagrees with the conclusions in the proposed finding. (CCFF ¶¶ 654, 657-61; CX1297 (Mazis, Report at 0008-10)) (showing that Reibstein survey is inadequate to measure materiality of the challenged claims for the POM products). Furthermore, Complaint Counsel has provided ample evidence of the materiality of the challenged claims. (CCFF ¶¶ 621-50, 667-85).

Even Dr. Reibstein conceded that the challenged claims would likely be material to consumers. (CCFF ¶ 638).

2220. Thus, the presumption of materiality has disappeared here. (*See infra* XVIII; *In the Matter of Novartis Corp.*, 127 F.T.C. 580, 686 (1999), citing *St. Mary's Honor Ctr. v. Hicks*, 509 U.S. 502, 506 (1993)).

Response to Finding No. 2220:
The proposed finding is a legal conclusion and is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs.

2221. The Administrative Law Judge ("ALJ") now weighs the evidence on materiality presented by each side, as with any other factual issue, to decide if Complaint Counsel have met their burden of providing a preponderance of evidence on the issue. *In the Matter of Novartis Corp.*, 127 F.T.C. 580, 686 (1999), citing *St. Mary's Honor Ctr. v. Hicks*, 509 U.S. 502, 506 (1993).

Response to Finding No. 2221:
The proposed finding is a legal conclusion and is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs.

2222. Complaint Counsel have presented no reliable evidence to rebut Professor Reibstein's survey findings.

Response to Finding No. 2222:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Moreover, Complaint Counsel disagrees with the conclusions in the proposed finding. (CCFF ¶¶ 651-61 (showing that Reibstein survey is inadequate to measure materiality of challenged POM Juice claims)). Furthermore, Complaint Counsel has provided ample evidence of the materiality of the challenged claims. (CCFF ¶¶ 621-50, 667-85). Even Dr. Reibstein conceded that the challenged claims would likely be material to consumers. (CCFF ¶ 638).

2223. Specifically, Complaint Counsels' own rebuttal expert to Professor Reibstein, Professor Mazis, in contrast to previous work he has done for Complaint Counsel in other litigation, did not (a) conduct any facial analysis of POM's ads or offer any expert opinion on them; (b) conduct any surveys on the ads or (c) provide any expert opinion on the exposure of the ads to consumers (and testified that he was aware of no such evidence), despite

testifying that such exposures were critical to having an effect on consumers. (*See infra* (XVIII(B)). ; Mazis, Tr. 2752).

Response to Finding No. 2223:
The proposed finding is unsupported by the cited evidence and mischaracterizes Dr. Mazis's prior work for Complaint Counsel in other litigation. Furthermore, the statement that Dr. Mazis testified that multiple ad "exposures were critical to having an effect on consumers," mischaracterizes his testimony. Moreover, the number of exposures a consumer had to the challenged ads is irrelevant. *See* Response to Finding 38.

C. Complaint Counsels' Initial Allegations and Complaint

2224. Complaint Counsel claim that in certain of POM's advertising and promotional materials for POM Juice and POMx Pills and POMx Liquid (hereinafter "POMx") (collectively, the "Challenged Products"), described in the paragraphs below, Respondents have represented, expressly or by implication, that clinical studies, research, and/or trials prove to consumers that the Challenged Products will prevent, treat or reduce the risk of heart disease, prostate cancer and erectile dysfunction. (CX1426 at 0017-0020).

Response to Finding No. 2224:
Complaint Counsel has no specific response; the Complaint speaks for itself.

2225. Specifically, in their Complaint, Complaint Counsel take an aggressive position regarding what POM's ads convey and allege generally that Respondents make the following claims in their advertising:

(a) 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 (1) decreasing arterial plaque, (2) lowering blood pressure, and/or (3) improving blood flow to the heart;

(b) Drinking eight ounces of POM Juice, or taking one POMx Pill or one teaspoon of POMx Liquid, daily, treats heart disease, including by (1) decreasing arterial plaque, (2) lowering blood pressure, and/or (3) improving blood flow to the heart;

(c) Drinking eight ounces of POM Juice, or taking one POMx Pill or one teaspoon of POMx Liquid, daily, prevents or reduces the risk of prostate cancer, including by prolonging PSADT;

(d) Drinking eight ounces of POM Juice, or taking one POMx Pill or one teaspoon of POMx Liquid, daily, treats prostate cancer, including by prolonging PSADT;

(e) Drinking eight ounces of POM Juice daily prevents or reduces the risk of erectile dysfunction; and

(f) Drinking eight ounces of POM Juice daily treats erectile dysfunction.

(CX1426 at 0017-0020).

Response to Finding No. 2225:
Complaint Counsel disagrees with the proposed finding's characterization of Complaint Counsel's position as "aggressive," but otherwise has no specific response as the Complaint speaks for itself.

2226. Complaint Counsel complain that POM's advertising, website and promotional materials are false and misleading because Respondents did not have a reasonable basis to substantiate the representations set forth in the paragraph above at the time the representations were made – *i.e.*, that Respondents' clinical studies, research, and/or trials did not prove the challenged benefits claimed. (CX1426 at 0017-0020).

Response to Finding No. 2226:
Complaint Counsel has no specific response as the Complaint speaks for itself.

2227. Complaint Counsel claim that in order to have a reasonable basis that substantiates the allegedly express or implied product claims at issue and for the allegedly express or implied claims to be truthful and non-misleading, Respondents needed "competent and reliable scientific evidence" substantiating those claims at the time they were made. (PX0267-0031, 0054).

Response to Finding No. 2227:
Complaint Counsel agrees.

D. The Changing Universe of the Challenged Advertisements

2228. Since POM's inception in 2001, POM published at least hundreds and hundreds of health-oriented advertisements in various media, including print, "out-of-home" ("OOH") (*e.g.*, billboards, gym posters and bus shelters), Internet and television. (CX135 (Tupper, Dep. at 63:9-22) (types of media); PX0267 at 0002-00035 (identifying hundreds of ads by Bates number); CX0364 (VMS search results listing hundreds of ads)).

Response to Finding No. 2228:
Complaint Counsel does not disagree with the proposed finding, but objects to Mr. Tupper's deposition testimony cited in the proposed finding as non-designated testimony.

2229. Even Complaint Counsel admit that POM disseminated "thousands" of ads in various media. (PX0267 at 0030, 0033).

Response to Finding No. 2229:
Complaint Counsel does not disagree that it used the phrase "thousands" in reference to POM's advertisements but notes that this estimate was based on the assumption that duplicate advertisements were disseminated multiple times, and did not necessarily mean that there were thousands of individual advertisements.

2230. Complaint Counsel initially based their allegations on the hundreds and hundreds of print, OOH and Internet advertisements going as far back as 2003 that Respondents produced in discovery. (PX0263-0002-0013; PX0267-0002-0030).

Response to Finding No. 2230:
Complaint Counsel does not disagree that the allegations are based on advertisements in various media going back as far as 2003.

2231. Indeed, during discovery and throughout most of trial, Complaint Counsel refused to pare down the advertisements at issue from the hundreds and hundreds of ads that POM produced in discovery. (PX0263 at 0003, 0015; PX0267 at 0029-0030; 0033-0034).

Response to Finding No. 2231:
The proposed finding is incorrect, as Complaint Counsel pared down the list of advertisements for the joint exhibit list, JX0002, prior to trial, many of which were very similar variations of the same ad. Ultimately, there were fewer than 40 different headlines represented on the exhibit list.

2232. However, during and throughout trial, Complaint Counsel narrowed the universe of advertisements they are challenging. (*See infra* (XVII(D)).

Response to Finding No. 2232:
The proposed finding is inconsistent with Respondents' Finding 2231. Complaint Counsel has no specific response to the proposed finding, but refers to its Responses to Findings in the cross-referenced section.

1. During Trial, Complaint Counsel, Through Their Experts and Lawyers, Narrowed the Universe of Advertisements "at Issue" by Excluding Billboards, POM Juice Advertisements Disseminated After December 2008 and POM Juice Website Entries After August 2009

2233. During trial, Complaint Counsels admitted, through their lawyers and experts, that Complaint Counsel were not challenging (a) POM's billboard advertisements, (Reibstein, Tr. 2540); (b) any POM juice advertisements disseminated after December 2008; or (c) POM juice website entries after August 2009. (*See infra* (XVII(D)).

Response to Finding No. 2233:
The proposed finding mischaracterizes the statements of Complaint Counsel's expert Dr. Mazis as to his understanding of the times during which challenged POM Juice advertisements were disseminated. *See* Response to Finding 2238. The joint exhibit list, JX0002, does not list any billboard ads, nor does Complaint Counsel's chart of challenged advertisements, Appendix A to CCFF.

2234. First, during the cross-examination of Professor Reibstein, Complaint Counsel admitted that Complaint Counsel were not challenging Respondents' billboards as violating Sections 5 and 12 of the FTC Act. (Reibstein, Tr. 2540.)

Response to Finding No. 2234:
Complaint Counsel has no specific response.

2235. Billboards contain only pictures and headlines. There is no accompanying text or body copy. (CX1359 (L. Resnick, Dep. at 199)).

Response to Finding No. 2235:
The proposed finding is unsupported by the cited evidence, as Mrs. Resnick's cited testimony does not describe or define billboards.

2236. In the advertising industry, billboards are generally referred to as OOH advertisements, which include other outdoor advertising such as gym posters, subway posters and bus shelters. (CX1353 (Tupper, Dep. at 63)). As with billboards, all OOH advertisements contain only pictures and headlines without any accompanying text or body copy.

Response to Finding No. 2236:
Complaint Counsel objects to the deposition testimony cited in the proposed finding as non-designated testimony. The second sentence of the proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs.

2237. Based on their own admissions, Complaint Counsel ostensibly do not contend that any of Respondents' billboards or OOH ads that contain only pictures and headlines without any accompanying text or body copy violate Sections 5 and 12 of the FTC Act. (*See infra* (XVII(D)).

Response to Finding No. 2237:
Complaint Counsel disagrees with the proposed finding. Respondents may also have disseminated other ads making the claims at issue; the fact that those ads have not been challenged by the Commission does not mean that they did not violate Sections 5 and 12 of the FTC Act. *See also* Responses to Findings in the cross-referenced section.

2238. Second, Complaint Counsel further narrowed the universe of ads at issue through evidence presented by their own survey expert, Professor Mazis. Professor Mazis testified that Complaint Counsel informed him that the FTC was only challenging POM Juice print advertisements that ran at least twenty-two months before the execution of the Reibstein Survey and POM Juice website entries that were disseminated in the fourteen months before the execution of the Reibstein Study. (PX0296 at 0010; Mazis, Tr. 2753-54).

Response to Finding No. 2238:
The proposed finding mischaracterizes the cited evidence and is incorrect. Complaint Counsel has not narrowed the universe of challenged ads based on the timing of Dr. Reibstein's survey. During redirect, Dr. Mazis testified that his statements about the dissemination of challenged ads were based upon the *date of his report* (March 2011) not the date Dr. Reibstein's survey was conducted (October 2010). (Mazis, Tr. 2759-60). In his March 29, 2011 expert report, Dr. Mazis stated, "I am informed that the last challenged POM Juice print advertisement in this case was disseminated approximately 22 months ago, the last challenged POM Juice website was available approximately 14 months ago, and that no POM Juice television commercials are being challenged by the FTC." CX1297 (Mazis, Report at_0010-11, 0015). In other words, at the time of his report, Complaint Counsel told Dr. Mazis that the challenged POM Juice print ads were disseminated prior to *approximately* June 2009 and the challenged POM Juice websites

appeared prior to *approximately* February 2010). This is consistent with the Commission's complaint which attached as exhibits the February 2009 "I'm off to save PROSTATES!" print ad and the January 27, 2010 www.pomwonderful.com, "POM Truth – Backed by Science" webpage, CX1426_0004-005, 0008, with Dr. Mazis's statements at his April 21, 2011 deposition (PX0359 (Mazis, Dep. at 1, 133-35), and with the advertisements Complaint Counsel entered into the record on the Joint Exhibit list (JX0002). Further, at the time that Dr. Mazis wrote his March 2011 report, Complaint Counsel did not know when the Reibstein Survey was conducted because the survey's timing was not stated in Dr. Reibstein's report and Dr. Reibstein was not deposed until April 18, 2011, thus Complaint Counsel could not possibly have linked its statement to Dr. Mazis about the approximate dissemination dates for challenged ads to the actual date of Dr. Reibstein's survey. (PX0223 (Reibstein, Report); PX0356 (Reibstein, Dep. at 1, 8-9, 37).

2239. Professor Mazis used this concession to show that the reason for this was because the participants in the Reibstein Survey have forgotten the ads. (Mazis, Tr. 2712-13). Indeed, in his expert report Professor Mazis said that "[e]ven if consumers could recall POM juice advertising, they would be expected to recall more advertising, which is not being challenged by the FTC." (PX0296 at 0010).

Response to Finding No. 2239:

Complaint Counsel has no specific response other than noting that the quoted language misstates and incorrectly cites Dr. Mazis's report. He said, "Even if consumers could recall POM juice advertising, they would be expected to recall more *recent* advertising, which is not being challenged by the FTC." (PX0296 (Mazis, Report at 0011) (emphasis added)).

2240. Professor Reibstein testified that he put his survey in the field around the end of October 2010. (Reibstein, Tr. 2541).

Response to Finding No. 2240:

Complaint Counsel agrees that Dr. Reibstein testified as stated.

2241. Twenty-two months before the execution of the Reibstein Survey is December 2008; and fourteen months before execution of Reibstein Survey is August 2009. (*See infra* (XVIII(B)).

Response to Finding No. 2241:
The proposed finding is factually accurate but irrelevant. It has no bearing on the timing of the dissemination of the challenged POM Juice print advertisements. *See* Response to Finding 2238.

2242. After having sought an advantage against Professor Reibstein's survey by arguing that his survey would not reflect the only ads at issue, which were disseminated years before his survey, Complaint Counsel have effectively narrowed the universe of POM Juice ads at issue to those disseminated prior to December 2008. (*See infra* (XVIII(B)).

Response to Finding No. 2242:
The proposed finding mischaracterizes the record and is incorrect. *See* Response to Finding 2238 (Complaint Counsel is challenging POM Juice print ads disseminated prior to approximately June 2009 (22 months prior to Mazis March 2011 report) and POM Juice websites as they appeared prior to approximately February 2010 (14 months prior to Mazis March 2011 report)).

2243. Similarly, Complaint Counsel have effectively narrowed the universe of POM Juice website ads to those disseminated prior to August 2009. (*See infra* (XVIII(B)).

Response to Finding No. 2243:
The proposed finding mischaracterizes the record and is incorrect. *See* Response to Finding 2238 (Complaint Counsel is challenging POM Juice print ads disseminated prior to approximately June 2009 and POM Juice websites as they appeared prior to approximately February 2010).

2. After the Conclusion of Live Witness Testimony and Days Before the ALJ Closed the Evidentiary Record, Complaint Counsel Again Narrowed the Universe of Advertisements at Issue By Proposing a Stipulation Re: Challenged Advertisements

2244. After the conclusion of live witnesses and at the urging of the ALJ, on or about November 9, 2011 - just nine days before the evidentiary record closed, (11/18/11 Order Closing Hearing Record) - Complaint Counsel proposed a stipulation purporting to narrow the universe of hundreds and hundreds of ads to approximately 43 exhibits, some of which included multiple ads or website entries (hereinafter, "11/9/11 Proposed Ad Stipulation"). (11/9/11 email from Mary Johnson to Counsel for Respondents re POM Wonderful et al., Dkt 9344 -- proposed stips re: challenged ads/misreps (hereinafter "11/9/11 Johnson email"), attached hereto as Exhibit 1; Complaint Counsels' Proposed Stipulations, dated 11/8/11 (hereinafter, "Proposed Stipulations"), attached hereto as Exhibit 2).

Response to Finding No. 2244:
The proposed finding is unsupported because the evidence cited is not in the record, in violation of the Court's Order on Post-Trial Briefs. Proposed stipulations that Respondents declined to agree to are not evidence and are irrelevant.

2245. These are the ads Respondents believe are now at issue, which Complaint Counsel identified in the 11/9/11 Proposed Ad Stipulation as: CX0013; CX0016; CX0029; CX0031; CX0033; CX0034; CX0036; CX0044; CX0065; CX0103; CX0109; CX0120; CX0122; CX0128; CX0169; CX0180; CX0188; CX0192; CX0251; CX0260; CX0274; CX0279; CX0280; CX0314; CX0328; CX0331; CX0336; CX0337; CX0342; CX0348; CX0350; CX0351; CX0353; CX0355; CX0372; CX0379; CX0380; CX0463; CX0466; CX0468; CX0472; CX0473; CX1426 Exhs. A-N. (11/9/11 Johnson email; Proposed Stipulations).

Response to Finding No. 2245:
The proposed finding is unsupported because the evidence cited is not in the record, in violation of the Court's Order on Post-Trial Briefs. Proposed stipulations that Respondents declined to agree to are not evidence and are irrelevant. Complaint Counsel refers the Court to CCFF Section V and Appendix A regarding the specific advertisements being challenged.

2246. Complaint Counsel did not, however, specify what was false and misleading or unsubstantiated about any of the identified advertisements, websites or promotional materials. (11/9/11 Johnson email).

Response to Finding No. 2246:
The proposed finding is unsupported because the evidence cited is not in the record, in violation of the Court's Order on Post-Trial Briefs. Proposed stipulations that Respondents declined to agree to are not evidence and are irrelevant.

2247. Additionally, many of the ads identified in the 11/9/11 Proposed Ad Stipulation included those ads which Complaint Counsels' expert, Professor Mazis, admitted were not being challenged. (*See infra* XVIII(B)).

Response to Finding No. 2247:
The proposed finding mischaracterizes the record and is incorrect. *See* Responses to Findings 2238, 2245.

3. Because Complaint Counsel Failed to Present Evidence That Respondents Disseminated Some of the Ads, the Universe of Ads Identified In The 11/9/11 Proposed Ad Stipulation Should Be Further Narrowed to Those That Were Actually Disseminated

2248. Even prior to addressing whether POM's advertisements are false, within the meaning of Section 12 of the FTC Act, the ALJ must determine as a preliminary matter whether the materials constitute: (1) the dissemination of advertisements; (2) for the purpose of inducing, or which are likely to induce, purchases in or affecting commerce; (3) of "food" or "drugs."

Response to Finding No. 2248:
The proposed finding is a legal conclusion and is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs.

2249. Respondents represent that the chart below summarizes the dissemination information for each exhibit, to the extent such dissemination information is available in the evidentiary record.

Response to Finding No. 2249:
Complaint Counsel disagrees that the chart summarizes the entirety of dissemination information available for each ad, and responds to the specific assertions in its response to Finding 2252.

2250. Where Complaint Counsel failed to present any specific evidence of dissemination, those exhibits are listed under the heading "No Dissemination Evidence Presented."

Response to Finding No. 2250:

Complaint Counsel has no specific response to the proposed finding, but responds to the specific assertions in the chart in its response to Finding 2252.

2251. Complaint Counsel cannot now challenge those ads because they have not proven that Respondents disseminated them, thus narrowing the universe of ads "at issue."

Response to Finding No. 2250:
Complaint Counsel disagrees with the conclusions drawn, and responds to the specific assertions in the chart in its response to Finding 2252.

4. Based On Complaint Counsels' Own Representations and Failings, a Much Smaller Universe of the Advertisements Listed In the 11/9/11 Proposed Ad Stipulation Remain "At Issue"

2252. In summary, based on (a) Complaint Counsels' own admissions during the cross-examination of Professor Reibstein regarding billboards, (b) the trial testimony of Professor Mazis regarding POM Juice print and website ads and (c) Complaint Counsels' failure to establish that certain ads were disseminated, the chart below summarizes the ads that remain "at issue":

Trial Exh. No.	Headline/Description	Dissemination Date	Reference to Evidentiary Record
POM Juice and POMx Pill Ads Disseminated From October 2003 Through December 2008 ("At Issue")			
CX0016	Drink and be healthy	10/12/2003	VMS[1]
CX0029	Studies Show That 10 Out of 10 People Don't Want To Die	11/01/04	VMS
CX0031	Floss your arteries. Daily.	12/01/2004	VMS
CX0033	Life support	12/30/04	VMS
CX0034	Amaze your cardiologist	02/01/2005	VMS
CX0036	Cheat death.	03/10/2005	VMS
CX0103	Decompress	03/01/2007	VMS
CX0109	Heart therapy	04/01/2007	VMS
CX0120	One small pill for mankind	05/28/2007	VMS
CX0122	Science, not fiction	06/01/2007	VMS
CX1426, Exh. M	Your Partner in Promoting Lifelong Health, Volume 1, Issue 1: For Your	Summer 2007	Written on Exhibit

[1] The VMS run date stamped on the face of the ad reflects the dissemination date. (CX0474)

Trial Exh. No.	Headline/Description	Dissemination Date	Reference to Evidentiary Record
	Heart (hereinafter, "Dreher Heart Newsletter")		
CX1426, Exh. N	Your Partner in Promoting Lifelong Health, Volume 1, Issue 2: Prostate Health (hereinafter, "Dreher Prostate Newsletter")	Fall 2007	Written on Exhibit
CX0169	The power of POM in one little pill	01/06/2008	VMS
CX0180	The antioxidant superpill	02/03/2008	VMS
CX0188	Cheat death.	04/01/2008	Grid Below Ad: Date Out
CX0192	What gets your heart pumping?	05/01/2008	VMS
CX0314_0003* *(CX0314_0003-0006)	Drink to prostate health	09/09/08	Grid Below Ad: Date Out
CX0314_0004* *(CX0314_0003-0006)	POM Wonderful and Prostate Health	09/09/08	Grid Below Ad: Release Date
CX0314_0005* *(CX0314_0003-0006)	The proof is in the POM	09/09/2008	Grid Below Ad: Date Out
CX0314_0006* *(CX0314_0003-0006)	The Antioxidant Superpower	09/09/2008	Grid Below Ad: Date Out
CX0314_0008* *(CX0314_0007-0010)	POM Wonderful and Prostate Health	10/23/08	Written on Exhibit
CX0314_0009* *(CX0314_0007-0010)	The proof is in the POM	10/23/08	Written on Exhibit
~~CX0251~~	~~Imitation may be sincere. But is it pure?~~	~~11/01/2008~~	~~VMS~~
CX0260	Drink to prostate health	12/01/2008	VMS
CX1426, Exh. I	Antioxidant Superpill	Not available, but there is evidence that it ran.	(L. Resnick, Tr. 177:18-178:18; Leow, Dep. At 178-179)
POMx Pill Ads Disseminated Between January 2009 Through Present ("At Issue")			
CX0279	Science, Not Fiction	03/01/2009	VMS
CX0280	Live Long Enough To Watch your 401(k) Recover.	03/12/2009	VMS

Trial Exh. No.	Headline/Description	Dissemination Date	Reference to Evidentiary Record
CX0331	Healthy, ~~Wealthy~~ & Wise	09/27/2009	VMS
CX0328	Your New Health Care Plan	11/08/2009	VMS
CX0337	The First Bottle You Should Open in 2010	01/03/2010	VMS
CX342	Take Out a Life Insurance Supplement	02/22/2010	VMS
CX0348	24 Scientific Studies Now In One Easy-To-Swallow Pill	04/01/2010	VMS
CX0350	24 Scientific Studies Now In One Easy-To-Swallow Pill	04/26/2010	VMS
CX0351	The Only Antioxidant Supplement Rated X	06/01/2010	VMS
CX0353	Take Out a Life Insurance Supplement	06/14/2010	VMS
CX0355	The Only Antioxidant Supplement Rated X	07/01/2010	VMS
Website Materials ("At Issue")			
CX1426, Exh. E-1	Website captures from www.pomegranatetruth.com	04/28/2009	Time stamp from website capture
CX1426, Exh. E-2	Website captures from Health Benefits section of www.pomwonderful.com, including "Real Studies" webpage	04/29/2009	Time stamp from website capture
CX1426, Exh. E-3	7 POM Video Ads	4/30/2009	Time stamp from website capture
CX1426, Exh. E-4	Website captures re POM Products from www.pomwonderful.com	04/30/2009	Time stamp from website capture
CX1426, Exh. E-8	Website captures from www.pompills.com	04/29/2009	Time stamp from website capture
CX1426, Exh. E-9	Website captures from www.pompills.com	01/27/2010	Time stamp from website capture
CX0463_0001	Heart Therapy Flash Video	None	N/A
CX0466_0001	Hurry Prostates Everywhere are in Danger Flash video	None	N/A
CX0473	Rushton CD	N/A	N/A
~~CX472_0001~~	~~Roll International Website Video~~	~~None~~	~~N/A~~

Trial Exh. No.	Headline/Description	Dissemination Date	Reference to Evidentiary Record
Press Releases ("At Issue")			
CX0013_0001-0005	Press Release – Consumer Demand for POM Wonderful's Refrigerated All-Natural Pomegranate Juice Grows as the Health Benefits of Pomegranate Juice Become Recognized	01/09/03	CX0013_0001-0005
CX044_0001-0003	Pomegranate Juice May Affect the Progression of Coronary Heart Disease	09/16/2005	CX044_0001-0003
CX0065_0001-0004	Press Release - POMx, a Highly Concentrated Form of Healthy Pomegranate Antioxidants, Becomes Available to Consumers for the First Time	07/10/06	CX0065_0001-0004
CX0128_0001-0004	Press Release - POM Wonderful 100% Pomegranate Juice May Improve Mild to Moderate Cases of Erectile Dysfunction	06/27/07	CX0128_0001-0004
POM Juice Ads Disseminated Between January 2009 Through Present (Not "At Issue" Per Professor Mazis)			
CX0274	I'm off to save prostates!	02/01/2009	
CX0379_0001* *(CX0379_0001-0004)	Lucky I have super HEALTH POWERS	08/20/2009	Grid Below Ad: Date Out CX0379_0001
CX0379_0002* *(CX0379_0001-0004)	Holy Health! $32 million in medical research.	08/20/2009	Grid Below Ad: Release Date CX0379_0002
CX379_0003* *(CX0379_0001-0004)	KA-POM!	08/20/2009	Grid Below Ad: Release Date CX379_0003
CX0379_0004* *(CX0379_0001-0004)	Risk your health in this economy? NEVER!	08/20/2009	Grid Below Ad: Date Out CX0379_0004
CX0372_0001* *(CX0372_0001-0004)	Lucky I have super HEALTH POWERS	09/10/2009	Grid Below Ad: Release Date CX0372_0001
CX372_0002* *(CX0372_0001-0004)	Holy Health! $32 million in medical research.	09/10/2009	Grid Below Ad: Release Date CX372_0002

Trial Exh. No.	Headline/Description	Dissemination Date	Reference to Evidentiary Record
CX0372_0003* *(CX0372_0001-0004)	KA-POM!	09/10/2009	Grid Below Ad: Release Date CX0372_0003
CX0372_0004* *(CX0372_0001-0004)	100% PURE Pomegranate Juice to the Rescue	09/10/2009	Grid Below Ad: Release Date CX0372_0004
CX0380_0001* *(CX0380_0001-0004)	Lucky I have super HEALTH POWERS	09/10/2009	Grid Below Ad: Release Date CX0380_0001
CX00380_0002* *(CX0380_0001-0004)	Holy Health! $32 million in medical research	09/10/2009	Grid Below Ad: Release Date CX00380_0002
CX380_0003* *(CX0380_0001-0004)	KA-POM!	09/10/2009	Grid Below Ad: Release Date CX380_0003
CX0380_0004* *(CX0380_0001-0004)	Have no health fear… POM IS HERE!	09/10/2009	Grid Below Ad: Release Date CX0380_0004
POM Juice Website Ads Disseminated Between September 2009 Through Present (Not "At Issue" Per Professor Mazis)			
CX0336_0001-0019	POM Health Benefits: Fact or Fiction (multiple press releases in Exhibit)	12/2009	CX0336_0001-0019
CX1426, Exh. E-5	Website Excerpt from www.pomwonderful.com	01/27/2010	CX1426, Exh. E-5[1]
No Specific Dissemination Evidence Presented (Not "At Issue")			
CX0314_0010* *(CX0314_0007-0010)	Ingredients: pomegranates, $25 million in medical research	None in record	N/A
CX 1426, Exh. A	Super HEALTH Powers! (Hangtag)	None in record	N/A
CX1426,	Drink to prostate health	None in record	N/A

[1] Date information based on the name of the file and the 2010 copyright on the website.

Trial Exh. No.	Headline/Description	Dissemination Date	Reference to Evidentiary Record
Exh. B			
CX1426, Exh. C	I'm off to save PROSTATES!	None in record	N/A
~~CX1426, Exh. D~~	~~Holy Health! $25 million in medical research.~~	~~None in record~~	~~N/A~~
~~CX1426, Exh. G CX0468~~	~~Amaze your urologist~~	~~None in record~~	~~N/A~~
CX1426, Exh. H	I'm off to save PROSTATES!	None in record	N/A
CX1426 Exhibit J	Healthy, ~~Wealthy~~, and Wise	None in record	N/A
CX1426, Exh. K	The Antioxidant Superpill	None in record	N/A
CX1426, Exh. L	The power of POM in one little pill	None in record	N/A
CX0314_0007* *(CX0314_0007-0010)	Drink to prostate health	None in record	N/A
CX0380_0005* *(CX0380_0005-0007)	Lucky I have super HEALTH POWERS	None in record	N/A
CX0380_0006* *(CX0380_0005-0007)	100% PURE pomegranate juice to the rescue!	None in record	N/A
CX0380_0007* *(CX0380_0005-0007)	Lucky I have super HEALTH POWER	None in record	N/A
Interviews/Discussions (Not "At Issue" Because Not Advertising)			
CX1426, Exh. E-7	Tupper Interview on FOX Business	06/17/08	CX1426, Exh. E-7
CX1426, Exh. E-6	L. Resnick Interview on *The Martha Stewart Show*	11/20/2008	CX1426, Exh. E-6[2]
CX472_0003	Lynda Resnick on the Early Show	02/19/09	CX472_0003[3]
CX1426 Exhibit F	Newsweek Interview with Lynda Resnick	03/20/2009	CX1426 Exhibit F
~~CX0472_0002~~	~~Lynda Resnick Presentation at USC~~	~~04/09/09~~	~~CX0472_0002~~

Response to Finding No. 2252:

[2] The YouTube video was uploaded the following date on 11/21/2008.

[3] The video file is titled 3.25.10 and was uploaded on 2/19/2009.

The proposed finding mischaracterizes the record and is incorrect. *See* Responses to Findings 2238 and 2245 (Complaint Counsel is challenging POM Juice print ads disseminated prior to approximately June 2009 and POM Juice websites as they appeared prior to approximately February 2010).

The 43 individual advertisements or promotional materials that Complaint Counsel is challenging as examples of Respondents' claims that violate the FTC Act are set forth in CCFF Section V and Appendix A. As set forth in Appendix A, Complaint Counsel does NOT challenge the following ads from the above chart: CX0251 ("Imitation May Be Sincere" print ad); CX0472_0001 (Roll International Website Video); CX1426, Exh. D ("Holy Health!" print ad); CX1426, Exh. G / CX0468 ("Amaze your urologist" banner ad); CX0472_0002 (Mrs. Resnick presentation at USC). These ads are noted in ~~strikeout~~ font in the chart above. Complaint Counsel contends the rest of the ads in this chart are "at issue," contrary to the assertions in the proposed finding's chart, and make challenged claims as set forth in the Complaint.

Complaint Counsel further asserts that Respondents' chart mischaracterizes certain documents as individual ads, when in fact they should be considered together as multi-page "magazine wrap" or "cover wrap" ads. These documents are indicated with an asterisk (*) next to the CX number in the above chart, and the pages for the consolidated ad are listed below the asterisk.

Specifically, CX0314_0003-06 together constitute one magazine wrap ad, indicated by the same job number at the bottom of each page (PJ9745). (*See also* CX1356 (Leow, Dep. at 131 (identifying a four-page ad (Tropicana-000019, produced to the Court as CX0236, which is identical to CX0314_0003-06) as a Time cover wrap)).

CX0314_0007-10 constitute another magazine wrap ad (indicated by a similar job number footer PJ0225_TIME-Wrap_Dec08"). Likewise, CX0379_0001-04 is one ad (indicated by the same job number PJ2005 across all pages), as is CX0372_0001-04 (PJ2007) and CX0380_0001-04 (PJ2006). Documents that Respondents produced as dissemination schedules show that POM used unique project numbers starting with "PJ" to indicate individual ads. (CX0436; CX0437). CX0380_0005-0007 lacks a job number but was produced as part of the same document by Respondents and on its face appears to be a Time Magazine cover.

Moreover, the proposed finding is incorrect as to the statement that there is no specific dissemination evidence presented for certain advertisements. Respondents admitted in their Answer that the Complaint Exhibits were disseminated. (PX0364-0002-03). Additionally, several of the Complaint Exhibits that Respondents list in their chart are, in fact, identical to other ads identified by CX number in the same chart, and for which they do not contest dissemination. For example, CX1426, Exh. B is equivalent to CX0260. Complaint Counsel's Findings of Fact, Appendix A, show where the Complaint Exhibits and CX numbers are the same. Specifically, there *is* dissemination evidence is in the record for the following ads:

(a) CX0314_0010, *see* Response to Finding 2419;

(b) CX1426, Exh. A (PX0364-0002);

(c) CX1426, Exh. B (VMS dissemination information at CX0260_0002);

(d) CX1426, Exh. C (VMS dissemination information at CX0274_0002);

(e) CX1426, Exh. H (VMS dissemination information at CX0364_0005);

(f) CX1426, Exh. J (VMS dissemination information at CX0331_0005);

(g) CX1426, Exh. K (VMS dissemination information at CX0270_0002)

(h) CX1426, Exh. L (VMS dissemination information at CX0169_0002); and

(i) CX0314_0007, *see* Response to Finding 2419; and

(j) CX0380_0005-0007 (Time covers are identical to, and were produced as part of the same document as CX0380_0001-04, which is dated 9/10/2009).

Complaint Counsel also provided evidence that several ads were disseminated more than once, and disagrees with the chart to the extent that it implies that each ad was disseminated only once on the date stated. This dissemination information is set forth in CCFF Section V.D - V.F, in the discussion of each ad.

Finally, Complaint Counsel disagrees that the Individual Respondents' publicity statements are not "at issue" or not actionable; *see* CCFF Section V.F.2.

2253. Nevertheless, despite the fact that the evidentiary record reflects that Complaint Counsel have represented that a smaller universe of ads is at issue, out of an abundance of caution, Respondents will analyze in the sections below and in the Appendix of Advertisements, attached hereto, each of the advertisements identified in Complaint Counsels' 11/9/11 Proposed Ad Stipulation.

Response to Finding No. 2253:

Complaint Counsel disagrees with Respondents' mischaracterizations of Complaint Counsel's position as to the ads at issue, as set forth in the Responses to Findings 2238 and 2252. Complaint Counsel also objects to Respondents' selective inclusion and analysis of certain advertisements in this document, while burying analysis of other relevant challenged advertisements in an Appendix. Complaint Counsel addresses those advertisements in its own Findings of Fact, Section V.D - V.F, and in its responses to the findings in the cross-referenced Appendix.

E. Out of Hundreds and Hundreds of Ads Respondents Disseminated, Complaint Counsel Focuses On Only Eight "Outlier" Ads Run During the Very Early Years (2003-2006). These Ads, Although Non-Misleading And

Substantiated, Have Not Run In Several Years, and There Is No Evidence That It Is Probable That Respondents Would Run These Type of Ads Again

2254. Out of the hundreds and hundreds of ads disseminated by Respondents since POM's inception and the full universe of ads now identified by Complaint Counsel in their 11/9/11 Proposed Ad Stipulation, Complaint Counsel focuses on eight "outliers" from POM's ads. (*See supra* XVII(A-D)).

Response to Finding No. 2254:
The proposed finding mischaracterizes Complaint Counsel's position or that it is "focusing" on eight particular ads. (CCFF Section V and Appendix A). *See also* Responses to Findings in the cross-referenced section.

2255. Respondents refer to these eight ads as "outliers," although non-misleading and substantiated, because the images in the ads and the language in the body copy regarding the health benefits of POM Juice were more aggressive than was typical of Respondent, especially in the later years. (*See supra* XVII(D)).

Response to Finding No. 2255:
Complaint Counsel agrees with Respondents' characterization of these ads as "aggressive," but disagrees with Respondents' assertion that these ads are "outliers" or "more aggressive than was typical of Respondent, especially in the later years." *See also* Responses to Findings in the cross-referenced section.

2256. Eight "outliers" is an extremely miniscule percentage, given the hundreds, maybe even thousands, of ads disseminated by Respondents. (*See supra* XVII(A-D)).

Response to Finding No. 2256:
Complaint Counsel disagrees with Respondents' assertion that these ads are "outliers."

See also Responses to Findings in the cross-referenced sections.

2257. The eight "outliers" are as follows:

(a) Cheat death. (CX CX0036_0001);

(b) Drink and be healthy. (CX0016_0001);

(c) Decompress. (CX0103_0001; CX0459_0001);

(d) Floss your arteries. Daily. (CX0031-0001);

(e) Amaze your cardiologist. (CX0034_0001;CX0471_0012);

(f) Imitation may be sincere. But is it pure? (CX0251_001);

(g) Ingredients: pomegranates, $25 million in medical research. (CX314_010); and

(h) pomwonderful.com "Real Studies" webpage (CX1426, Exh. E-2).

Response to Finding No. 2257:
Complaint Counsel disagrees with Respondents' assertion that these ads are "outliers."

See also Responses to Findings about these specific ads.

2258. With the exception of the inadvertent blood pressure reference on POM's website, the eight "outlier" ads were disseminated in the early years of POM or at least six years ago (and some of them eight years ago). (*See supra* XVII(E.1-8)).

Response to Finding No. 2258:
The proposed finding is incorrect, as at least four of the advertisements referenced in Finding 2257 were disseminated in 2007, 2008, and 2009, not "at least six years ago" as Respondents assert. Specifically:

(a) the "Decompress" ad (CX0103) was disseminated in June 2007 (CX0103_0002);

(b) the "Imitation may be sincere" ad (CX0251) was disseminated in November 2008 (CX0251_0002);

(c) the Time Magazine wraps (CX0314) were disseminated in Fall 2008 (CX0314_0001) *see also* Response to Finding 2419; and

(d) the POM Wonderful Health Benefits section website (CX1426, Exh. E-2 / CX0473) was disseminated in April 2009 (Pom Wonderful Health Benefits website, date-stamp of website capture April 29, 2009)).

2259. As described below, a few of these ads were primarily issued as the result of staff mistakes and they immediately ceased being run when the mistake was discovered. (*See supra* XVII(E.1-8)).

Response to Finding No. 2259:

Complaint Counsel has no specific response. *See also* Responses to Findings in the cross-referenced section.

2260. Such mistakes are not likely to occur in the future because Respondents' current advertising review policy is a formalized process, which includes a checklist of individuals who review and sign off on the health-related advertisements, culminating ultimately in legal review. (L. Resnick, Tr. 248; Tupper Tr. 2977-78).

Response to Finding No. 2260:
The proposed finding is unsupported by the cited testimony of Ms. Resnick and Mr. Tupper, which establishes that the science and legal review process was in place at least as early as 2007 and at least by 2008, yet at least three of the eight ads referenced in Finding 2257 were disseminated during or after that time. *See* Response to Finding 2258.

2261. Complaint Counsel have presented no evidence to the contrary or nor have they presented any evidence that it is probable that Respondents will run these type of "outlier" ads, although non-misleading and substantiated, again.

Response to Finding No. 2261:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Moreover, Complaint Counsel presented evidence, including in the Responses to Findings 2258 and 2260, that such ads were run more recently than Respondents assert. Complaint Counsel also presented evidence in CCFF Section VI.E, that Respondents have continued to run advertising claims that they had been told were deceptive or misleading.

2262. Complaint Counsel also have not presented any evidence that any of the eight "outlier" ads, although non-misleading and substantiated, were the result of Respondents' intentionally false or misleading conduct.

Response to Finding No. 2262:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Moreover, Complaint Counsel presented evidence, including in the Responses to Findings 2258 and 2260, that such ads were run more recently than Respondents assert. Complaint Counsel also presented evidence in CCFF

Section VI.E, that Respondents have continued to run advertising claims that they had been told were deceptive or misleading.

2263. Because the "outlier" ads were discontinued so long ago and there is no evidence that Respondents would run these types of ads again, the eight "outliers," although non-misleading and substantiated, pose no real threat that Respondents will violate the FTC Act in the future and cannot form the basis for injunctive relief. (*See supra* XVII(E.1-8)).

Response to Finding No. 2263:
The proposed finding is unsupported by the evidence cited. *See* Responses to Findings 2258 and 2260-62.

1. Cheat Death

2264. According to Complaint Counsel, POM ran an advertisement with the headline "Cheat death" with this body copy:

> **Cheat death**.
>
> Dying is so dead. Drink to life with POM Wonderful Pomegranate 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.
>
> **POM Wonderful Pomegranate Juice. The Antioxidant Superpower**.

(CX0036_0001) (emphasis in original).

Response to Finding No. 2264:
Complaint Counsel agrees.

2265. Complaint Counsel contend that this "Cheat death" headline and exact body copy ran on March 10, 2005. (CX0036_0001).

Response to Finding No. 2265:
Complaint Counsel agrees that the ad was disseminated on March 10, 2005, but has provided evidence that it was disseminated additional times as well, including as late as January 2006. (CX0036_0002; CX0474; CX0371).

2266. Complaint Counsel have presented no other definitive dissemination information regarding this particular ad.

Response to Finding No. 2266:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Moreover, the proposed finding is incorrect. *See* Response to Finding 2265 for the evidence on dissemination.

2267. 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).

Response to Finding No. 2267:
Complaint Counsel agrees that Mr. Tupper testified as such, but notes that Ms. Resnick continued to state, as late as November 2008, that pomegranate juice "helps Alzheimer's." (CCFF ¶ 570; CX0473 (Compl. Ex. E-6)).

2268. 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).

Response to Finding No. 2268:
Complaint Counsel agrees that Mr. Tupper testified as stated.

2269. 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).

Response to Finding No. 2269:
Complaint Counsel agrees that Mr. Tupper testified as such, but notes that even in connection with the ad containing only the "Cheat Death" headline and imagery, POM still directly told consumers that "[t]he 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.'" (CCFF ¶ 354).

2270. 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.

Response to Finding No. 2270:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel has no specific response.

2271. Moreover, Complaint Counsel have presented no evidence that it is probable that Respondents would run this type of ad again.

Response to Finding No. 2271:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel has presented evidence in CCFF Section VI.E that Respondents have continued to run advertising claims that they had been told were deceptive or misleading.

2272. Because this ad ceased running more than five or six 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.

Response to Finding No. 2272:
The proposed finding is a legal conclusion and is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel has presented evidence in CCFF Section VI.E that Respondents have continued to run advertising claims that they had been told were deceptive or misleading.

2273. 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. (CX0036_0001).

Response to Finding No. 2273:

Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 349-56). Complaint Counsel does not contend that this ad makes "clinically proven" claims. (CCFF ¶ 356).

2274. Complaint Counsels' assertion that the ad conveys the message 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 is not conspicuous, self-evident, or reasonably clear from the face of the ad. (CX0036_0001). Consequently, extrinsic evidence must be examined.

Response to Finding No. 2274:
Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 349-56). Complaint Counsel does not contend that this ad makes treatment or "clinically proven" claims. (CCFF ¶ 356). The last sentence of the proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs.

2275. Respondents' linguistics expert, Professor Butters, opined that no reasonable consumer could interpret this ad to communicate that drinking eight ounces of POM juice prevents or reduces the risk of heart disease. (PX0350 (Butters, Dep. at 101-103).

Response to Finding No. 2275:
Complaint Counsel does not disagree that Dr. Butters testified as stated, but disagrees with his conclusion. (CCFF ¶¶ 349-56).

2276. Several of Respondents' witnesses also testified that some of the "Cheat death" ad, including the headline and some words, was meant to be hyperbolic, puffery and humorous. (*See infra* ¶¶ 2278-2280.)

Response to Finding No. 2276:
Complaint Counsel has no specific response to the proposed finding, but refers to its Responses to the cross-referenced Findings.

2277. 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)).

Response to Finding No. 2277:

Complaint Counsel agrees that Mr. Perdigao testified as stated.

2278. 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)).

Response to Finding No. 2278:
Complaint Counsel agrees that Mr. Perdigao testified as stated, but disagrees with the conclusion drawn and notes that POM did not tell consumers its intention in using the language in this ad was puffery, but rather told consumers the intention of the ad was to convey that "disease of the heart and circularity [sic] system . . . are some of the main causes of death . . . . There are preventative actions that can be taken to decrease this risk . . . such as drinking POM, increase[] one's chances to live longer and healthier, to 'cheat death.'" . *See* Response to Finding 2269.

2279. 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).

Response to Finding No. 2279:
Complaint Counsel disagrees that Mr. Tupper testified that "much of the 'Cheat death' advertisement" was not meant to be interpreted literally and was puffery. He only testified regarding the advertisement's headline. Complaint Counsel also disagrees with the proposed finding's conclusion and notes that POM did not tell consumers its intention in using the language in this ad was puffery, but rather told consumers the intention of the ad was to convey that "disease of the heart and circularity [sic] system . . . are some of the main causes of death . . . . There are preventative actions that can be taken to decrease this risk . . . such as drinking POM, increase[] one's chances to live longer and healthier, to 'cheat death.'" *See* Response to Finding 2269.

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).

Response to Finding No. 2280:
Complaint Counsel agrees that Mrs. Resnick testified as stated as to the *headline*, but disagrees that the cited evidence describes the *net impression* of the ad. *See* Response to Finding 2269.

2281. The overall net impression of this "Cheat death" 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. (CX0036_0001). Even, the language of the ad, itself, uses the qualifier "can help." (CX0036_0001).

Response to Finding No. 2281:
Complaint Counsel does not contend that this ad makes "clinically proven" claims. (CCFF ¶ 356 and Appendix A). Complaint Counsel disagrees with this remainder of the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 349-56; *see also* CCFF ¶¶ 610-13 (qualifiers such as "can" are unlikely to affect the message that consumers take from the advertisement)).

2282. 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 certain diseases, such as heart disease or prostate cancer, like a drug with a single target of action, but "may reduce the risk," like a healthy diet of fruits and vegetables and exercise "may reduce the risk" of disease. (CX0036_0001).

Response to Finding No. 2282:
Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 349-56).

2283. 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); and

Response to Finding No. 2283:
Complaint Counsel does not contend that this ad makes "treat" claims and therefore the proposed finding is irrelevant. (CCFF ¶ 356 and Appendix A). To the extent the

proposed finding refers to other POM ads, it is unsupported by the cited testimony. Dr. Butters did not define "treat" as a substitute for conventional medical treatment. He defined "treat" as medical treatment and then asserted that he didn't see any ad stating or implying that POM Products "treated any disease." *See also* Responses to Findings in the cross-referenced Appendix.

2284. To the extent a "proven" claim can be implied from this ad (which it cannot), the overall impression of "Cheat Death" 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 "proven" in science means the "average person in the study benefitted." "Proven" does not mean that "everyone in the study necessarily benefitted." (Heber, Tr. 2011; Butters, Tr. 2893-94; PX0361 (Sacks, Dep. at 81)).

Response to Finding No. 2284:
Complaint Counsel does not contend that this ad makes "clinically proven" claims. (CCFF ¶ 356). However, Complaint Counsel agrees in general that "proven" does not mean that "everyone in the study" benefitted.

2285. Moreover, Complaint Counsel has presented no extrinsic evidence or expert opinion on the meaning of this "Cheat death" ad or of consumer perceptions or interpretations of the ad. ((PX0357 (Stewart Dep. at 49, 52); Mazis, Tr. 2752).

Response to Finding No. 2285:
The proposed finding mischaracterizes the testimony of Drs. Stewart and Mazis. Neither testified that Complaint Counsel did *not* have extrinsic evidence as to the meaning of any challenged ad. In the cited testimony, Dr. Stewart said that he was not asked to do a net impression analysis of the challenged ads and that he did not know whether the Commission had evidence of how consumers perceive the ads at the level of a net impression, and Dr. Mazis simply said that none of the surveys introduced show how many times any POM Juice or POMx ad was run. Moreover, Complaint Counsel presented evidence as to the meaning of this and other POM advertisements. (CCFF ¶¶ 349-56 and Sections V.C – V.G).

2286. Complaint Counsel also have presented no evidence that this "Cheat death" ad conveyed that POM Juice is "clinically proven" to prevent, treat or reduce the risk of any disease.

Response to Finding No. 2286:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial briefs. However, Complaint Counsel does not contend that this ad makes "clinically proven" claims. (CCFF ¶ 356).

2287. 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. (*See infra* (XVIII(A)(1)).

Response to Finding No. 2287:
Complaint Counsel disagrees with the conclusions in the proposed finding. (CCFF ¶¶ 654, 657-61; CX1297 (Mazis, Report at 0008-10) (showing that Reibstein survey is inadequate to measure materiality of the challenged claims for the POM products)).

2288. Indeed, the NAD has found that the tagline "Cheat Death" to be in the realm of puffery and hyperbole. (CX0037; CX0055).

Response to Finding No. 2288:
The proposed finding is incorrect and mischaracterizes the evidence. In the 2005 NAD decision (CX0037), the NAD did not address the "Cheat Death" tagline or advertisement at all. (*See* CX0037_0001, 0010; *see also* CX0055_0020 (noting that the earlier NAD decision did *not* review any claims of puffery)). The 2006 NAD decision *rejected* POM's assertion that the claims it reviewed, which are identical to those in the "Cheat Death" ad challenged in this case, were mere puffery: "[NAD] determined that the advertisements at issue here, indeed, a good portion of the advertiser's campaign, have stepped beyond the bounds of what could have once been considered puffery. . . . [T]he advertiser's once merely hyperbolic headlines and striking visuals have since morphed into objective representations (termed in fact rather than opinion) regarding the performance capabilities of its product, sufficiently specific and material enough to create

expectations in consumers, and requiring substantiation." (CX0055_0022-23, n.75). Moreover, the 2006 NAD decision stated that in "evaluating the message communicated by any particular advertisement, NAD examines each claim at issue *in the context of the entire advertisement in which it appears*," and thus the NAD did not review, or make a finding on, the Cheat Death tagline by itself. (CX0055_0021 (emphasis added)).

2289. 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.

Response to Finding No. 2289:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Moreover, Complaint Counsel disagrees with the conclusions in the proposed finding. (CCFF ¶¶ 654, 657-61; CX1297 (Mazis, Report at 0008-10) (showing that Reibstein survey is inadequate to measure materiality of the challenged claims for the POM products)). Furthermore, Complaint Counsel has provided ample evidence of the materiality of the challenged claims. (CCFF ¶¶ 621-50, 667-85). Even Dr. Reibstein conceded that the challenged claims would likely be material to consumers. (CCFF ¶ 638).

2290. Complaint Counsel failed to present any evidence regarding the number of exposures consumers had to this ad or any particular POM advertisement.

Response to Finding No. 2290:
The proposed finding is not supported by any reference to the record, in violation of this Court's Order on Post-Trial Briefs. Moreover, the proposed finding is irrelevant. *See* Response to Finding 38.

2. Drink And Be Healthy

2291. According to Complaint Counsel, POM ran an advertisement with the headline "Drink and be healthy" with this body copy:

Drink and be healthy.

100% all-natural pomegranate juice.
The delicious, refreshing antioxidant superpower.

- **More naturally occurring antioxidant power than any other drink**, including red wine, blueberry juice, cranberry juice, orange juice and green tea.

- **Antioxidants guard your body against harmful free radicals** that can cause heart disease, premature aging, Alzheimer's disease even cancer.

[comparative chart omitted]

- **Medical studies have shown that drinking 8oz. of POM Wonderful** pomegranate juice daily minimizes factors that lead to atherosclerosis (plaque buildup in the arteries), a major cause of heart disease.

In the refrigerated produce section of your grocer.
www.pomwonderful.com

(CX0016) (emphasis in original).

Response to Finding No. 2291:
Complaint Counsel agrees.

2292. Complaint Counsel contend that this "Drink and be healthy" headline and exact body copy ran on October 12, 2003. (CX0016_0001).

Response to Finding No. 2292**:**
Complaint Counsel agrees that this ad was disseminated as early as October 12, 2003.

(CX0016_0002; CX0474; CX0371).

2293. Complaint Counsel have presented no other definitive dissemination information regarding this particular ad.

Response to Finding No. 2293:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Moreover, the proposed finding is incorrect. *See* Response to Finding 2292 for the evidence on dissemination.

2294. 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).

Response to Finding No. 2294:
Complaint Counsel agrees that Mr. Tupper testified as stated.

2295. 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).

Response to Finding No. 2295:
Complaint Counsel agrees that Mr. Tupper testified as stated.

2296. Mrs. Resnick also testified that this ad was one of the first ads Respondents ever ran. (L. Resnick, Tr. 157).

Response to Finding No. 2296:
Complaint Counsel agrees that Ms. Resnick testified as stated.

2297. 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.

Response to Finding No. 2297:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel has no specific response.

2298. Moreover, Complaint Counsel have presented no evidence that it is probable that Respondents would run this type of ad again.

Response to Finding No. 2298:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel has presented evidence in CCFF Section VI.E that Respondents have continued to run advertising claims that they had been told were deceptive or misleading.

2299. Because this ad stopped running more than nine 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.

Response to Finding No. 2299:
The proposed finding is a legal conclusion and is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel has

presented evidence in CCFF Section VI.E that Respondents have continued to run advertising claims that they had been told were deceptive or misleading.

2300. Nowhere in this ad do Respondents expressly (*i.e.*, unequivocally and directly) state that (a) POM Juice "prevents" or "treats" 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).

Response to Finding No. 2300:
Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 325-28).

2301. Complaint Counsels' assertion that the ad conveys the message 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 is conveyed in this "Drink and be healthy" ad is not conspicuous, self-evident, or reasonably clear from the face of the ad. (CX0016). Consequently, extrinsic evidence must be examined. (Mazis, Tr. 2752).

Response to Finding No. 2301:
Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 325-28). The last sentence of the proposed finding is unsupported by the cited testimony of Dr. Mazis. *See* Response to Finding 2200.

2302. Respondents' linguistics expert, Professor Butters, opined that it was unlikely that a reasonable consumer would conclude that drinking eight ounces of POM Juice would treat atherosclerosis. (Butters, Tr. 2930).

Response to Finding No. 2302:
Complaint Counsel does not disagree that Dr. Butters testified as stated about this ad, but disagrees with his conclusion. (CCFF ¶¶ 325-28). To the extent that the proposed finding implies that Dr. Butters testified generally that a reasonable consumer was unlikely to conclude that drinking eight ounces of POM Juice would treat atherosclerosis, it is unsupported by the cited evidence.

2303. The overall net impression of this "Drink and be health" ad is not that (a) drinking eight ounces of POM Juice prevents or treats 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. (CX0016). Even, the language of the ad, itself, uses the qualifier "can help." (CX0016).

Response to Finding No. 2303:
Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 325-28).

2304. 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. (CX0016).

Response to Finding No. 2304:
Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 325-28).

2305. 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); and

Response to Finding No. 2305:
Complaint Counsel does not contend that this ad makes "treat" claims and therefore the proposed finding is irrelevant. (CCFF ¶ 328 and Appendix A). To the extent the proposed finding refers to other POM ads, it is unsupported by the cited testimony. Dr. Butters did not define "treat" as a substitute for conventional medical treatment. He defined "treat" as medical treatment and then asserted that he didn't see any ad stating or implying that POM Products "treated any disease." *See also* Responses to Findings in the cross-referenced Appendix.

2306. To the extent a "proven" claim can be implied from this ad (which it cannot), the overall impression of "Drink and be healthy" 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 "proven" in science means the "average person in the study benefitted." "Proven" does not mean that "everyone in the study necessarily benefitted." (Heber, Tr. 2011; Butters, Tr. 2893-2894; PX0361 (Sacks, Dep. at 81));

Response to Finding No. 2306:

Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 325-28). However, Complaint Counsel agrees that "proven" does not mean that "everyone in the study" benefitted.

2307. 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).

Response to Finding No. 2307:
The proposed finding is unsupported by the testimony of Dr. Mazis. In the cited testimony, Dr. Mazis simply said that none of the surveys introduced show how many times any POM Juice or POMx ad was run. Moreover, Complaint Counsel presented evidence as to the meaning of this and other POM advertisements. (CCFF ¶¶ 325-28 and Sections V.C – V.G).

2308. Complaint Counsel also have presented no evidence that this "Drink and be healthy" ad conveyed that POM Juice is "clinically proven" to prevent, treat or reduce the risk of heart disease.

Response to Finding No. 2308:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Moreover, Complaint Counsel presented evidence on the meaning of this and other POM advertisements. (CCFF ¶¶ 325-28 and Sections V.C – V.G).

2309. The claim that POM Juice has more naturally occurring antioxidant power than red wine, blueberry juice, cranberry juice, orange juice and green tea is true, (Goldstein, Tr. 2595; PX0051), and Respondents had competent and reliable scientific evidence to support this representation at the time it was made. (*See infra* XVII(G)(3)).

Response to Finding No. 2309:
The proposed finding relates to a superiority claim, which is not challenged in the Complaint. *See also* Responses to Findings in the cross-referenced section.

2310. The statement that "Antioxidants guard your body against free radicals that can cause heart disease, premature aging, Alzheimer's disease even cancer" is also true, (*see infra*

XVII(G)(3)), and Respondents had competent and reliable scientific evidence to support this representation at the time it was made. (*See infra* XVII(G)(3)).

Response to Finding 2310:
Complaint Counsel disagrees with the proposed finding. (CCFF ¶¶ 1103-07 (randomized controlled clinical trials have found no consistent benefit for specific nutrient antioxidants)). *See also* Responses to Findings in the cross-referenced section.

2311. The statement "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" also was true, and Respondents had competent and reliable scientific evidence to support this representation at the time it was made, including the Aviram Study (2004). (*See infra* XVII(G)(3)).

Response to Finding 2311:
Complaint Counsel disagrees with the proposed finding. (CCFF ¶¶ 805-21 (discussion of Aviram Study (2004)). *See also* Responses to Findings in the cross-referenced section.

2312. 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)).

Response to Finding 2312:
Complaint Counsel disagrees with the proposed finding. (CCFF ¶¶ 654, 657-61; CX1297 (Mazis, Report at 0008-10) (showing that Reibstein survey is inadequate to measure materiality of the challenged claims for the POM products)).

2313. 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.

Response to Finding No. 2313:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Moreover, Complaint Counsel disagrees with the conclusions in the proposed finding. (CCFF ¶¶ 654, 657-61; CX1297 (Mazis, Report at 0008-10) (showing that Reibstein survey is inadequate to measure materiality of challenged claims for the POM products)). Furthermore, Complaint Counsel has

provided ample evidence of the materiality of the challenged claims. (CCFF ¶¶ 621-50, 667-85). Even Dr. Reibstein conceded that the challenged claims would likely be material to consumers. (CCFF ¶ 638).

2314. Complaint Counsel failed to present any evidence regarding the number of exposures consumers had to this ad or any particular POM advertisement.

Response to Finding No. 2314:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Moreover, the proposed finding is irrelevant. *See* Response to Finding 38.

3. Decompress

2315. According to Complaint Counsel, POM ran an advertisement with the headline "Decompress" with this body copy:

> **Decompress**.
>
> Amaze your cardiologist. Drink POM 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. POM 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.
>
> **POM Wonderful Pomegranate Juice. The Antioxidant Superpower.**

(CX0103_0001; CX0459_0001) (emphasis in original).

Response to Finding No. 2315:
Complaint Counsel agrees.

2316. Complaint Counsel contend that this "Decompress" headline and exact body copy ran on March 1, 2007. (CX0103_0001).

Response to Finding No. 2316:

Complaint Counsel agrees that this ad was disseminated as early as March 1, 2007, but has provided evidence that it was disseminated additional times as well, including as late as June 2007. (CX0103_0002; CX0474; CX0371).

2317. Complaint Counsel have presented no other definitive dissemination information regarding this particular ad.

Response to Finding No. 2317:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Moreover, the proposed finding is incorrect. *See* Response to Finding 2316.

2318. Mr. Tupper testified that Respondents has not disseminated this advertisement since at least 2008. (Tupper, Tr. 3004).

Response to Finding No. 2318:
Complaint Counsel agrees that Mr. Tupper testified as stated.

2319. Complaint Counsel have presented no evidence to contradict Mr. Tupper's testimony that this "Decompress" ad has not run in over four years.

Response to Finding No. 2319:
The proposed finding is not supported by any citation to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel has no specific response.

2320. Moreover, Complaint Counsel have presented no evidence that it is probable that Respondents would run this type of ad again.

Response to Finding No. 2320:
The proposed finding is not supported by any citation to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel has presented evidence in CCFF Section VI.E that Respondents have continued to run advertising claims that they had been told were deceptive or misleading.

2321. 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.

Response to Finding No. 2321:

The proposed finding is a legal conclusion and is not supported by any citation to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel has presented evidence in CCFF Section VI.E that Respondents have continued to run advertising claims that they had been told were deceptive or misleading.

2322. 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).

Response to Finding 2322:
Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 357, 359-62).

2323. The "Decompress" advertisement featured the image of a POM Juice bottle with a blood pressure cuff wrapped around it. (CX0103_0001; CX0459_0001).

Response to Finding 2323:
Complaint Counsel agrees.

2324. Complaint Counsels' assertion that the ad conveys the message 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 is not conspicuous, self-evident, or reasonably clear from the face of the ad. (CX0103_0001; CX0459_0001). Consequently, extrinsic evidence must be examined. (See supra ¶ 2348).

Response to Finding 2324:
Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 357, 359-62). The last sentence of the proposed finding is unsupported by the cross-referenced testimony of Dr. Mazis. *See* Response to Finding 2200.

2325. 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).

Response to Finding 2325:
Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 357, 359-62).

2326. 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. (CX0103_0001; CX0459_0001).

Response to Finding 2326:
Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 357, 359-62).

2327. 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).

Response to Finding 2327:
The proposed finding is unsupported by the cited testimony. Dr. Butters did not define "treat" as a substitute for conventional medical treatment. He defined "treat" as medical treatment and then asserted that he didn't see any ad stating or implying that POM Products "treated any disease." Complaint Counsel also disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 357, 359-62). *See also* Responses to Findings in the cross-referenced Appendix.

2328. 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 because "proven" in science means the "average person in the study benefitted." "Proven" does not mean that "everyone in the study necessarily benefitted." (Heber, Tr. 2011; Butters, Tr. 2893-2894; PX0361 (Sacks, Dep. at 81)).

Response to Finding 2328:

Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 357, 359-62). However, Complaint Counsel agrees that "proven" does not mean that "everyone in the study" benefitted.

2329. The body copy of the ad itself does not use the words "blood pressure" or say anything about "blood pressure." (CX0103_0001; CX0459_0001).

Response to Finding 2329:
Complaint Counsel agrees that the body copy does not include the words "blood pressure," but disagrees with Respondents' assertions regarding the net impression of this advertisement. (CCFF ¶¶ 357, 359-62).

2330. Several of Respondents' witnesses also testified that the intended message of the "Decompress" ad was not related to blood pressure. (*See infra* ¶¶ 2331-2336).

Response to Finding 2330:
Complaint Counsel has no specific response. *See* Responses to the cross-referenced Findings.

2331. 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).

Response to Finding 2331:
Complaint Counsel does not disagree that Mr. Tupper testified as such in this trial, but notes that Mr. Tupper's testimony is inconsistent with his prior testimony in the November 2010 trial in *POM Wonderful, LLC vs. Tropicana Products, Inc.*, in which, when asked whether part of what POM was communicating to consumers in the Decompress advertisement was that POM Juice was beneficial to blood pressure, he testified that POM was "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." (CX1406 (Tupper, Trop. Tr. at 179)).

2332. 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).

Response to Finding 2332:
Complaint Counsel agrees that Mr. Tupper testified as stated.

2333. 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).

Response to Finding 2333:
Complaint Counsel agrees that Mr. Tupper testified as stated, and notes that he further testified that the blood pressure cuff was "a symbol of something that, for example, you would associate with a cardiologist's office, similar to other ads we've run where there's a bottle with little EKG stickers on it." (Tupper, Tr. 3005; *see also* CCFF ¶ 360).

2334. 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).

Response to Finding 2334:
The proposed finding is incomplete, as Ms. Leow testified that the purpose of the blood pressure cuff was to show or suggest that POM Juice may be healthy for "your heart and your arteries[.]" (Leow, Tr. 489).

2335. 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)).

Response to Finding 2335:
Complaint Counsel agrees that Mr. Resnick testified as stated.

2336. 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).

Response to Finding 2336:

Complaint Counsel does not disagree as to the nature of Dr. Butters's testimony, but disagrees with his conclusion. Complaint Counsel further states that the proposed finding is irrelevant, as the Complaint allegations related to daily use of POM Products, as opposed to one-time use. (CX1426_00017).

2337. 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 supra* ¶¶ 2331-2336; CX0103_0001; CX0459_0001).

Response to Finding 2337:
Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 357, 359-62).

2338. 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.

Response to Finding 2338:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs.

2339. Complaint Counsel also have presented no reliable evidence that this "Decompress" ad conveyed that POM Juice is "clinically proven" to prevent, treat or reduce the risk of heart disease.

Response to Finding No. 2339:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. The Bovitz Survey evidences that elements of the "Decompress" ad communicate that drinking POM Juice "helps/lowers blood pressure" and that the benefits of POM Juice are "research based" and "proven." (CCFF ¶¶ 585-96).

2340. Instead, 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).

Response to Finding No. 2340:
The proposed finding is incomplete. Fourteen percent of the general target audience and seventeen percent of POM Juice users gave such a response to an initial question about the ad's main idea. (CCFF ¶ 588). Survey respondents were asked a subsequent open-ended question and 21% said a benefit was "helps/lowers blood pressure." (CCFF ¶ 590).

2341. As testified to by Professor Reibstein, the Bovitz Survey is methodologically flawed, *see infra* (XVIII(C)(1)(b)), and substantively only relates to the "Decompress" ad without body copy. (*See* PX0223-0412).

Response to Finding No. 2341:
Complaint Counsel does not disagree that Dr. Reibstein testified that the Bovitz Survey is methodologically flawed, but disagrees with his conclusions. *See* Responses to Findings 2752-71. The proposed finding's assertion that Dr. Reibstein testified that the Bovitz Survey substantively *only* relates to the "Decompress" ad *without* body copy is not supported by the cited evidence, and Complaint Counsel disagrees with that conclusion. (CCFF ¶¶ 584-85, 596).

2342. 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.

Response to Finding No. 2342:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Moreover, the Bovitz Survey evidences that elements of the "Decompress" ad communicate that drinking POM Juice "helps/lowers blood pressure" and that the benefits of POM Juice are "research based" and "proven." (CCFF ¶¶ 584-96)

2343. 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 supra* (XVIII(C)(1)(b)), Complaint Counsel has not presented any evidence that it is probable that Respondents would run this type of ad again.

Response to Finding No. 2343:
The proposed finding is not supported by any citation to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel has presented evidence in CCFF Section VI.E that Respondents have continued to run advertising claims that they had been told were deceptive or misleading.

2344. 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* i*nfra* (XVII(G)(3)), and was substantiated by competent and reliable scientific evidence at the time it was made. (*See infra* (XVII(G)(3))).

Response to Finding No. 2344:
The proposed finding is not supported by the cited evidence. (CCFF ¶¶ 1103-07 (randomized controlled clinical trials have found no consistent benefit for specific nutrient antioxidants)). *See also* Responses to Findings in the cross-referenced section.

2345. The advertisement's statement that POM Juice "is supported by $20 million of initial scientific research from leading universities" is also true. (*See infra* (XVII(G)(2))(emphasis added)).

Response to Finding No. 2345:
The proposed finding is not supported by the cited evidence. (CCFF ¶¶ 319-24 (showing that "supported by" medical research figures included incomplete and negative studies, as well as other non-study expenses)). *See also* Responses to Findings in the cross-referenced section.

2346. 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. (*See infra* (XVII(G)(2))(emphasis added).

Response to Finding No. 2346:

The proposed finding is not supported by the cited evidence. (*See* CCFF Sections VII.D, VII.E (analyzing human studies conducted by the listed investigators)). *See also* Responses to Findings in the cross-referenced section.

2347. The words "can help," "initial" and "encouraging" also qualified the health-related message contained in the ad. (CX0103_0001; CX0459_0001).

Response to Finding No. 2347:
Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 357, 359-62; s*ee also* CCFF ¶¶ 610-15 (qualifiers such as "can" and "initial" are unlikely to affect the message that consumers take from the advertisement)).

2348. Complaint Counsel have to present any evidence regarding the number of exposures consumers had to this ad or any particular POM advertisement. (Mazis, Tr. 2752).

Response to Finding No. 2348:
The proposed finding states a legal conclusion, is unsupported by the cited evidence and is irrelevant. *See* Response to Finding 38.

4. Floss your arteries. Daily

2349. According to Complaint Counsel, Respondents ran an advertisement with the headline "Floss your arteries. Daily" with this body copy:

> **Floss your arteries. Daily.**
>
> Clogged arteries lead to heart trouble. It's that simple. That's where we come in. Delicious POM Wonderful Pomegranate Juice has more naturally occurring antioxidants than any other drink. Theses antioxidants fight free radicals - - molecules that are the cause of sticky, artery clogging plaque. Just eight ounces a day can reduce plaque up to 30%! So every day: wash your face, brush your teeth, and drink your POM Wonderful.
>
> **POM Wonderful Pomegranate Juice. The Antioxidant Superpower.**

(CX0031_001) (emphasis in original).

Response to Finding No. 2349:
Complaint Counsel agrees.

2350. In contrast to future ads which specifically described Respondents' scientific studies on the Challenged Products, the "Floss your arteries" ad included a quantified performance claim. (CX0031_001; CX0055_0011-0012).

Response to Finding No. 2350:
The proposed finding is unsupported by the cited evidence, which does not refer to or specify any "future ads which specifically described Respondents' scientific studies." Complaint Counsel does not disagree that CX0055_0011-12 (the 2006 NAD decision) appears to describe a "quantified performance claim," but notes that this description appears in a section of the document summarizing the advertiser's [*i.e.*, POM's] position and does not reflect any finding by the NAD.

2351. Complaint Counsel contend that this "Floss your arteries" headline and exact body copy ran on December 1, 2004. (CX0031_0001).

Response to Finding No. 2351:
Complaint Counsel agrees that the ad was disseminated in at least two media outlets as early as December 1, 2004. (CX0031_0002; CX0474; CX0371).

2352. Complaint Counsel have presented no other definitive dissemination information regarding this particular ad.

Response to Finding No. 2352:
The proposed finding is incorrect. *See* Response to Finding 2351.

2353. Mr. Tupper testified that POM first ran this advertisement in 2004 and stopped running it that same year. 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).

Response to Finding No. 2353:
Complaint Counsel does not disagree that Mr. Tupper testified as stated.

2354. Complaint Counsel have presented no evidence to contradict Mr. Tupper's or Mrs. Resnick's testimony that this "Floss your arteries" ad has not run in more than seven years.

Response to Finding No. 2354:
The proposed finding is not supported by any citation to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel has no specific response.

2355. Moreover, Complaint Counsel have presented no evidence that it is probable or likely that Respondents would run this type of ad again.

Response to Finding No. 2355:
The proposed finding is not supported by any citation to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel has presented evidence in CCFF Section VI.E that Respondents have continued to run advertising claims that they had been told were deceptive or misleading.

2356. 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.

Response to Finding No. 2356:
The proposed finding is a legal conclusion and is not supported by any citation to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel has presented evidence in CCFF Section VI.E that Respondents have continued to run advertising claims that they had been told were deceptive or misleading.

2357. Moreover, 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))).

Response to Finding No. 2357:
The proposed finding is unsupported by the cited evidence and by the record as a whole. (CCFF ¶¶ 805-21, 951 (analysis of Aviram Study (2004)). *See also* Responses to Findings in the cross-referenced section.

2358. 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).

Response to Finding 2358:
Complaint Counsel does not disagree that Dr. Butters testified as such, but his opinion is unsupported to the record as a whole. Qualifiers such as "can" and "up to" are unlikely to affect the messages of the ad communicated to consumers. (CCFF ¶¶ 610-13). Dr.

Butters was not aware of any consumer survey research showing that the words "up to" have any effect on consumer understanding. (PX0350 (Butters, Dep. at 99)).

2359. Moreover, the advertisement's statement that "antioxidants fight free radicals that cause plaque is true and substantiated by competent and reliable scientific evidence. (*see supra* XVII(G)).

Response to Finding No. 2359:
The proposed finding is unsupported by the cited evidence and by the record as a whole. (CCFF ¶¶ 1103-07 (randomized controlled clinical trials have found no consistent benefit for specific nutrient antioxidants)). *See also* Responses to Findings in the cross-referenced section.

2360. 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. (CX0031).

Response to Finding No. 2360:
Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 336-38, 340).

2361. Complaint Counsels' 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. (CX0031). Consequently, extrinsic evidence must be examined. (Mazis, Tr. 2752).

Response to Finding No. 2361:
Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 336-38, 340). The last sentence of the proposed finding is unsupported by the cited testimony of Dr. Mazis. *See* Response to Finding 2200.

2362. The overall net impression of this "Floss your arteries" 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. (CX0031).

Response to Finding No. 2362:

Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 336-38, 340).

2363. Indeed, 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).

Response to Finding No. 2363:
Complaint Counsel does not disagree that the NAD stated the claim "can reduce plaque up to 30%" was not a "clinically proven" claim.

2364. The "Floss your arteries daily" advertisement featured the image of a POM 100% Pomegranate Juice bottle on a shelf next to, among other things, a toothbrush and a tube of tooth paste. (CX0031_0001). As such, the headline "Floss your arteries" is hyperbolic and humorous. (Butters, Tr. 2914-15).

Response to Finding No. 2364:
Complaint Counsel agrees with the proposed finding's description of the images in the ad, but the characterization of the headline "Floss your arteries" as "hyperbolic and humorous" is unsupported by the cited testimony, which refers to a headline from a different ad. Moreover, the proposed finding as to the headline is irrelevant, as Dr. Butters 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. (CCFF ¶ 605).

2365. Viewing the "Floss your arteries" 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 and good for you. (CX0031). Mr. Butters testified that no reasonable person would take this ad literally. (Butters, Tr. 2914).

Response to Finding No. 2365:
Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 336-38, 340). Moreover, the last sentence of the proposed finding is unsupported by the cited evidence, in which Dr. Butters is testifying about a different ad.

2366. In contrast, Complaint Counsel have presented no extrinsic evidence or expert opinion on the meaning of this "Floss your arteries" ad or of consumer perceptions or interpretations of the ad. ((PX0357 (Stewart Dep. at 49, 52); (Mazis, Tr. 2752)).

Response to Finding No. 2366:
The proposed finding mischaracterizes the testimony of Drs. Stewart and Mazis. Neither testified that Complaint Counsel did *not* have extrinsic evidence as to the meaning of any challenged ad. In the cited testimony, Dr. Stewart said that he was not asked to do a net impression analysis of the challenged ads and that he did not know whether the Commission had evidence of how consumers perceive the ads at the level of a net impression, and Dr. Mazis simply said that none of the surveys introduced show how many times any POM Juice or POMx ad was run. Moreover, Complaint Counsel presented evidence as to the meaning of this and other POM advertisements. (CCFF ¶¶ 336-38, 340 and Sections V.C – V.G).

2367. 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 "may reduce the risk," like a healthy diet of fruits and vegetables and exercise "may reduce the risk" of heart disease. (CX0031).

Response to Finding No. 2367:
Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 336-38, 340).

2368. 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).

Response to Finding No. 2368:
The proposed finding is unsupported by the cited testimony. Dr. Butters did not define "treat" as a substitute for conventional medical treatment. He defined "treat" as medical treatment and then asserted that he didn't see any ad stating or implying that POM Products "treated any disease." Complaint Counsel also disagrees with the proposed

finding regarding the net impression of this advertisement. (CCFF ¶¶ 336-8, 340). *See also* Responses to Findings in the cross-referenced Appendix.

2369. To the extent a "proven" claim can be implied from this ad (which it cannot), the overall impression of "Floss your arteries" is not that POM Juice is "proven" to be 100% effective in preventing, treating or reducing the risk of heart disease because "proven" in science means the "average person in the study benefitted." "Proven" does not mean that "everyone in the study necessarily benefitted." (Heber, Tr. 2011; Butters, Tr. 2893-2894; PX0361 (Sacks, Dep. at 81)).

Response to Finding No. 2369:
Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 336-38, 340). However, Complaint Counsel agrees that "proven" does not mean that "everyone in the study" benefitted.

2370. Complaint Counsel have presented no evidence that this "Floss your arteries" ad conveyed that POM Juice is "clinically proven" to prevent, treat or reduce the risk of any disease.

Response to Finding No. 2370:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Moreover, Complaint Counsel presented evidence on the meaning of this and other POM advertisements. (CCFF ¶¶ 336-38, 340 and Sections V.C – V.G).

2371. Even assuming *arguendo* that this "Floss your arteries" 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. (*See infra* (XVIII(A)(1)).

Response to Finding No. 2371:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Moreover, Complaint Counsel disagrees with the conclusions in the proposed finding. (CCFF ¶¶ 654, 657-61; CX1297 (Mazis, Report at 0008-10) (showing that Reibstein survey is inadequate to measure materiality of challenged claims for the POM products)).

2372. 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.

Response to Finding No. 2372:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Moreover, Complaint Counsel disagrees with the conclusions in the proposed finding. (CCFF ¶¶ 654, 657-61; CX1297 (Mazis, Report at 0008-10) (showing that Reibstein survey is inadequate to measure materiality of the challenged claims for the POM products)). Furthermore, Complaint Counsel has provided ample evidence of the materiality of the challenged claims. (CCFF ¶¶ 621-50, 667-85). Even Dr. Reibstein conceded that the challenged claims would likely be material to consumers. (CCFF ¶ 638).

2373. Complaint Counsel failed to present any evidence regarding the number of exposures consumers had to this ad or any particular POM advertisement.

Response to Finding No. 2373:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Moreover, the proposed finding is irrelevant. *See* Response to Finding 38.

5. Amaze your cardiologist

2374. According to Complaint Counsel, Respondents ran an advertisement with the headline "Amaze your cardiologist" with this body copy:

> **Amaze your cardiologist**.
>
> Ace your EKG: just drink 8 ounces of delicious POM Wonderful Pomegranate 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.
>
> **POM Wonderful Pomegranate Juice. The Antioxidant Superpower**.

(CX0034_0001;CX0471_0012) (emphasis in original).

Response to Finding No. 2374:
Complaint Counsel agrees.

2375. Complaint Counsel contend that this "Amaze your cardiologist" headline and exact body copy ran on February 1, 2005. (CX0034_0001).

Response to Finding No. 2375:
Complaint Counsel agrees that the ad was disseminated as early as February 1, 2005.

(CX0034_0002; CX0474; CX0371).

2376. Complaint Counsel have presented no other definitive dissemination information regarding this particular ad.

Response to Finding No. 2376:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Moreover, the proposed finding is incorrect. *See* Response to Finding 2376 for the evidence on dissemination.

2377. As with the "Floss your arteries" ad described above, which has similar body copy, Mr. Tupper testified that this advertisement stopped running in 2005 and has not been disseminated in more than six years. (Tupper, Tr. 2996-97; CX1353 (Tupper. Dep. at 131)).

Response to Finding No. 2377:
Complaint Counsel agrees that Mr. Tupper testified as stated in the trial in this matter, but the proposed finding is unsupported by the citation to Mr. Tupper's deposition transcript; moreover, Complaint Counsel objects to the deposition testimony as non-designated testimony.

2378. Complaint Counsel have presented no evidence to contradict Mr. Tupper's testimony that this "Amaze your cardiologist" advertisement has not run in more than six years.

Response to Finding No. 2378:
The proposed finding is not supported by any citation to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel has no specific response.

2379. Moreover, Complaint Counsel has presented no evidence that it is probable that Respondents would run this type of ad again.

Response to Finding No. 2379:
The proposed finding is not supported by any citation to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel has presented evidence in CCFF Section VI.E that Respondents have continued to run advertising claims that they had been told were deceptive or misleading.

2380. Because this ad has not run for eight years and there is no evidence that Respondents are likely to run this ad in the future, the ad provides no basis for injunctive relief.

Response to Finding No. 2380:
The proposed finding is a legal conclusion and is not supported by any citation to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel has presented evidence in CCFF Section VI.E that Respondents have continued to run advertising claims that they had been told were deceptive or misleading.

2381. At the time the "Amaze your cardiologist" 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)).

Response to Finding No. 2381:
The proposed finding is unsupported by the cited Tupper evidence. (*See* CCFF ¶¶ 805-21, 951 (analysis of Aviram Study (2004)). *See also* Responses to Findings in the cross-referenced section.

2382. 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).

Response to Finding No. 2382:
The proposed finding is based upon Dr. Butters's unsupported assertion and is contrary to the record as a whole. Qualifiers such as "can" and "up to" are unlikely to affect the messages of the ad communicated to consumers. (CCFF ¶¶ 610-13). Dr. Butters was not

aware of any consumer survey research showing that the words "up to" have any effect on consumer understanding. (PX0350 (Butters, Dep. at 99)).

2383. Moreover, the advertisement's statement that "Antioxidants fight free radicals" is true and substantiated by competent and reliable scientific evidence. (*See supra* XVII(G)).

Response to Finding No. 2383:
The proposed finding, including the cross-referenced section, does not cite to any record evidence, in violation of the Court's Order on Post-Trial Briefs. Moreover, this finding is unsupported by the record as a whole. (*See* CCFF ¶¶ 1103-07 (randomized clinical trials have found no consistent benefit for specific nutrient antioxidants)).

2384. 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).

Response to Finding No. 2384:
Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 344-46, 348).

2385. Complaint Counsels' 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).

Response to Finding No. 2385:
Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 344-46, 348). The last sentence of the proposed finding is unsupported by the cited testimony of Dr. Mazis. *See* Response to Finding 2200.

2386. 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).

Response to Finding No. 2386:
Complaint Counsel does not disagree that the NAD stated the claim "can reduce plaque up to 30%" was not a "clinically proven" claim.

2387. The "Amaze your cardiologist" advertisement featured the image of a POM Wonderful 100% Pomegranate Juice bottle attached with EKG sensors. (CX0034_0001;CX0471_0012).

Response to Finding No. 2387:
Complaint Counsel agrees with the description of the images in the ad.

2388. 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;CX0471_0012).

Response to Finding No. 2388:
Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 344-46, 348).

2389. 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 "may reduce the risk," like a healthy diet of fruits and vegetables and exercise "may reduce the risk" of heart disease. (CX0034_0001;CX0471_0012).

Response to Finding No. 2389:
Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 344-46, 348).

2390. 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).

Response to Finding No. 2390:
The proposed finding is unsupported by the cited testimony. Dr. Butters did not define "treat" as a substitute for conventional medical treatment. He defined "treat" as medical treatment and then asserted that he didn't see any ad stating or implying that POM Products "treated any disease." Complaint Counsel also disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 344-46, 348). *See also* Responses to Findings in the cross-referenced Appendix.

2391. 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 because "proven" in science means the "average person in the study benefitted." "Proven" does not mean that "everyone in the study necessarily benefitted." (Heber, Tr. 2011; Butters, Tr. 2893-2894; PX0361 (Sacks, Dep. at 81)).

Response to Finding No. 2391:
Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 344-46, 348). However, Complaint Counsel agrees that "proven" does not mean that "everyone in the study" benefitted.

2392. The image in the advertisement, the headline "Amaze your cardiologist," and the phrases "ACE your EKG" and "your cardiologist will be amazed" were intended as puffery. Dr. Butters testified that the headline "Amaze your cardiologist" is hyperbolic. (Butters, Tr. 2914-15). Even Dr. Stewart, Complaint Counsels' own expert, testified that the headline "Amaze your cardiologist" is not to be taken literally. (Stewart, Tr. 3230).

Response to Finding No. 2392:
The first sentence in the proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Even assuming *arguendo* that those elements were intended as puffery, that does not make the ad as a whole puffery. Although Dr. Stewart testified that the "Amaze your cardiologist" headline might not to be taken literally, he testified that it and similar headlines can still communicate serious health messages, such as that POM Juice offers significant cardiovascular health benefits. (CCFF ¶ 608). He further testified that such headlines contribute to the overall net impressions from the advertisements. (CCFF ¶ 608).

2393. 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).

Response to Finding No. 2393:
Complaint Counsel agrees that Mr. Tupper testified as stated, and notes that he further equated the blood pressure cuff in the "Decompress" ad with the EKG leads in the

"Amaze your cardiologist" ad as "a symbol of something that, for example, you would associate with a cardiologist's office[.]" (Tupper, Tr. 3005).

2394. Viewing the "Amaze your cardiologist" 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 and good for you. (CX0034_0001;CX0471_0012; Tupper, Tr. 3005).

Response to Finding No. 2394:
Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 344-46, 348). Moreover, the proposed finding is not supported by Mr. Tupper's cited testimony, in which he was testifying about a different ad.

2395. In contrast, 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 the ad. (PX0357 (Stewart Dep. at 49, 52); (Mazis, Tr. 2752)).

Response to Finding No. 2395:
The proposed finding mischaracterizes the testimony of Drs. Stewart and Mazis. Neither testified that Complaint Counsel did *not* have extrinsic evidence as to the meaning of any challenged ad. In the cited testimony, Dr. Stewart said that he was not asked to do a net impression analysis of the challenged ads and that he did not know whether the Commission had evidence of how consumers perceive the ads at the level of a net impression, and Dr. Mazis simply said that none of the surveys introduced show how many times any POM Juice or POMx ad was run. Moreover, Complaint Counsel presented evidence as to the meaning of this and other POM advertisements. (CCFF ¶¶ 344-346, 348 and Sections V.C – V.G).

2396. 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.

Response to Finding No. 2396:

The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Moreover, Complaint Counsel presented evidence on the meaning of this and other POM advertisements. (CCFF ¶¶ 344-46, 348 and Sections V.C – V.G).

2397. 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. (*See infra* (XVIII(A)(1)).

Response to Finding No. 2397:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Moreover, Complaint Counsel disagrees with the conclusions in the proposed finding. (*See* CCFF ¶¶ 654, 657-61; CX1297 (Mazis, Report at 0008-10) (showing that Reibstein survey is inadequate to measure materiality of the challenged claims for the POM products)).

2398. Complaint Counsel failed to present any evidence regarding the number of exposures consumers had to this ad or any particular POM advertisement.

Response to Finding No. 2398:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Moreover, the proposed finding is irrelevant. *See* Response to Finding 38.

2399. 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.

Response to Finding No. 2399:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Moreover, Complaint Counsel disagrees with the conclusions in the proposed finding. (*See* CCFF ¶¶ 651-61; CX1297 (Mazis, Report at 0008-10) (showing that Reibstein survey is inadequate to measure materiality of

challenged claims for the POM products)). Furthermore, Complaint Counsel has provided ample evidence of the materiality of the challenged claims. (CCFF ¶¶ 621-50, 667-85). Even Dr. Reibstein conceded that the challenged claims would likely be material to consumers. (CCFF ¶ 638).

6. Imitation May Be Sincere. But Is It Pure?

2400. According to Complaint Counsel, Respondents ran an advertisement with the headline "Imitation may be sincere. But is it pure?" with this body copy:

> **Imitation may be sincere. But is it pure?**
>
> There are a lot of pomegranate juices on the market, but only one is guaranteed to be 100% pure pomegranate juice: the original POM Wonderful. It's the only pomegranate juice that's actually quality-controlled from tree to bottle. The only one that doesn't add sugar, colorants or cheap filler juices. And, perhaps most importantly, the only one that's backed by $25 million in published medical research. So be aware of what's in your pomegranate juice. Beware of impostors. **Trust in POM**.

(CX0251_001) (emphasis in original).

Response to Finding No. 2400:
Complaint Counsel agrees.

2401. Complaint Counsel contends that this "Imitation may be sincere ad" and exact body copy ran on November 1, 2008. (CX0251_0001).

Response to Finding No. 2401:
Complaint Counsel agrees that the ad was disseminated as early as November 1, 2008 (CX0251_0002; CX0474; CX0371).

2402. Complaint Counsel has presented no other dissemination information regarding this particular ad.

Response to Finding No. 2402:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Moreover, the proposed finding is incorrect. *See* Response to Finding 2401 for the evidence on dissemination.

2403. Mr. Tupper testified that the ad ran only once in 2008, over three years ago. Mr. Tupper testified that the reference to a number of "published studies" was simply an inadvertent mistake because some of the studies had not been "published". The ad should have said "backed by $25 million in medical research" and when the mistake was discovered, the word "published" was quickly eliminated. (Tupper, Tr. 1041, 3003).

Response to Finding No. 2403:
Complaint Counsel agrees that Mr. Tupper testified as stated.

2404. Complaint Counsel have presented no evidence to contradict Mr. Tupper's testimony that this ad has not run again.

Response to Finding No. 2404:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs.

2405. Moreover, Complaint Counsel have presented no evidence that it is probable that Respondents would run this type of ad again.

Response to Finding No. 2405:
The proposed finding is not supported by any citation to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel has presented evidence in CCFF Section VI.E that Respondents have continued to run advertising claims that they had been told were deceptive or misleading, and the same claim was used in a magazine cover wrap advertisement. *See* Responses to Findings 2419-34. Moreover, this ad was disseminated in November 2008, *after* Respondents' purported "formalized process" for advertising review was implemented to prevent such mistakes, per their own assertion. *See* Finding 2260.

2406. Because this ad last ran more than three years ago, it was the result of an inadvertent, one-time mistake and there is no evidence that Respondents are likely to run this ad in the future, the ad provides no basis for injunctive relief.

Response to Finding No. 2406:
The proposed finding is a legal conclusion and is not supported by any citation to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel has presented evidence in CCFF Section VI.E that Respondents have continued to run

advertising claims that they had been told were deceptive or misleading, and the same claim was used in a magazine cover wrap advertisement. *See* Responses to Findings 2419-34. Moreover, this ad was disseminated in November 2008, *after* Respondents' purported "formalized process" for advertising review, *see* Finding 2260, was implemented to prevent such mistakes, per their own assertion.

2407. 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. (CX0251).

Response to Finding No. 2407:
Complaint Counsel is not challenging the claims from this ad as an example of Respondents' conduct violating the FTC Act; therefore the proposed finding is irrelevant. (*See* CCFF Section V and Appendix A).

2408. Complaint Counsels' assertion that the ad conveys the message 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 is not conspicuous, self-evident, or reasonably clear from the face of the ad. (CX0251). Consequently, extrinsic evidence must be examined. (Mazis, Tr. 2752).

Response to Finding No. 2408:
Complaint Counsel is not challenging the claims from this ad as an example of Respondents' conduct violating the FTC Act; therefore the proposed finding is irrelevant. (*See* CCFF Section V and Appendix A).

2409. 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, prostate cancer or erectile dysfunction; 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, prostate cancer or erectile dysfunction. (CX0251).

Response to Finding No. 2409:

Complaint Counsel is not challenging the claims from this ad as an example of

Respondents' conduct violating the FTC Act; therefore the proposed finding is irrelevant.

(*See* CCFF Section V and Appendix A).

2410. 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, prostate cancer or erectile dysfunction, 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. (CX0251).

Response to Finding No. 2410:
Complaint Counsel is not challenging the claims from this ad as an example of

Respondents' conduct violating the FTC Act; therefore the proposed finding is irrelevant.

(*See* CCFF Section V and Appendix A).

2411. 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).

Response to Finding No. 2411:
Complaint Counsel is not challenging the claims from this ad as an example of

Respondents' conduct violating the FTC Act; therefore the proposed finding is irrelevant.

(*See* CCFF Section V and Appendix A).

2412. To the extent a "proven" claim can be implied from this ad (which it cannot), the overall impression of 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 "proven" in science means the "average person in the study benefitted." "Proven" does not mean that "everyone in the study necessarily benefitted." (Heber, Tr. 2011; Butters, Tr. 2893-2894; PX0361 (Sacks, Dep. at 81)).

Response to Finding No. 2412:
Complaint Counsel is not challenging the claims from this ad as an example of

Respondents' conduct violating the FTC Act; therefore the proposed finding is irrelevant.

(*See* CCFF Section V and Appendix A).

2413. Complaint Counsel, however, have presented no extrinsic evidence or expert opinion on the meaning of this "Imitation may be sincere" ad or of consumer perceptions or interpretations of the ad. (PX0357 (Stewart Dep. at 49, 52) (Mazis, Tr. 2752)).

Response to Finding No. 2413:
Complaint Counsel is not challenging the claims from this ad as an example of

Respondents' conduct violating the FTC Act; therefore the proposed finding is irrelevant.

(*See* CCFF Section V and Appendix A).

2414. Complaint Counsel also have presented no evidence that this "Imitation may be sincere" ad conveyed that POM Juice is "clinically proven" to prevent, treat or reduce the risk of any disease.

Response to Finding No. 2414:
Complaint Counsel is not challenging the claims from this ad as an example of

Respondents' conduct violating the FTC Act; therefore the proposed finding is irrelevant.

(*See* CCFF Section V and Appendix A).

2415. Even assuming *arguendo* that this "Imitation may be sincere" 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. (*See infra* (XVIII(A)(1))).

Response to Finding No. 2415:
Complaint Counsel is not challenging the claims from this ad as an example of

Respondents' conduct violating the FTC Act; therefore the proposed finding is irrelevant.

(*See* CCFF Section V and Appendix A).

2416. Moreover, because Professor Reibstein's uncontroverted survey showed that none of the respondents bought POM because of the number of "published" studies versus "unpublished" studies, it is not likely that any significant number of consumers bought POM because of the numerous studies that had been "published". (PX0223-0006-0007, 00020).

Response to Finding No. 2416:
Complaint Counsel is not challenging the claims from this ad as an example of

Respondents' conduct violating the FTC Act; therefore the proposed finding is irrelevant.

(*See* CCFF Section V and Appendix A).

2417. Complaint Counsel have presented no reliable evidence to rebut Professor's Reibstein's survey findings.

Response to Finding No. 2417:

Complaint Counsel is not challenging the claims from this ad as an example of Respondents' conduct violating the FTC Act; therefore the proposed finding is irrelevant. (*See* CCFF Section V and Appendix A).

2418. Complaint Counsel failed to present any evidence regarding the number of exposures consumers had to this ad or any particular POM advertisement.

Response to Finding No. 2418:
Complaint Counsel is not challenging the claims from this ad as an example of Respondents' conduct violating the FTC Act; therefore the proposed finding is irrelevant. (*See* CCFF Section V and Appendix A).

7. Ingredients: Pomegranates, $25 Million In Medical Research.

2419. Complaint Counsel has presented no definitive evidence that Respondents ran an advertisement with the headline "Ingredients: pomegranates, $25 million in medical research." (CX314_010).

Response to Finding No. 2419:
Complaint Counsel disagrees and states that the proposed finding mischaracterizes the evidence by pulling one page out of context when, in fact, it is part of a magazine cover wrap. CX0314_0010 is part of a multi-page attachment to a June 2, 2009 email produced by Respondents. (CX0314_0001). In CX0314_0001, Diane Kuyoomjian of POM Marketing asks for the "Time Mag cover wrap from last year [*i.e.*, 2008]." A follow-up email forwarding the request from Claire Nelson of POM Marketing requests the "Trust in POM TIME magazine cover wraps (from last fall) [*i.e.*, Fall 2008]." Finally, the latest email in the thread states "For the TIME wrap, we ran two versions (attached)," and attaches two magazine wraps, which evidences that the two cover wraps ran in Fall 2008. (Although it is difficult to read due to the quality of the copy produced and the background, CX0314_0010 contains a footer, similar to the prior pages, in the bottom left corner, "PJ0225_TIME-Wrap_Dec08" indicating it is part of the same document).

Respondents produced CX0314 from their own files, and the document was admitted without objection in this matter. Moreover, Respondents admitted that they disseminated magazine wraps. (Leow, Tr. 426, 496-97; Perdigao, Tr. 648; Tupper, Tr. 926).

2420. Complaint Counsel accordingly cannot challenge this ad because they have not proven that Respondents disseminated it, thus narrowing the universe of ads "at issue."

Response to Finding No. 2420:
Complaint Counsel disagrees. *See* Response to Finding 2419.

2421. According to CX0314_0010, the body copy of the ad read, in pertinent part:

> **Ingredients: pomegranates, $25 million in medical research.**
>
> What goes into our POM Wonderful bottle goes into you – 100% authentic Wonderful variety pomegranate juice, your daily dose of free-radical fighting antioxidants, $25 million in published medical research and proven health benefits. Nothing else. That means no cheap filler juices. No sweeteners. And no added colorants. So read the label. And drink to your health. **Trust in POM**.

(CX314_010) (emphasis in original).

Response to Finding No. 2421:
The proposed finding is incomplete, as this was not a single ad, but part of a multi-page magazine wrap. *See* Response to Finding 2419. However, Complaint Counsel agrees that the proposed finding accurately states the body copy of one page of the magazine wrap. (CX0314_0010).

2422. Assuming the advertisement did run, Mr. Tupper testified with respect to a very similar ad - the "Imitation may be sincere" ad. Specifically, Mr. Tupper testified that the phrase "$25 million in published medical research" was simply an inadvertent mistake that word "published" was used in the phrase "backed by $25 million in published medical research." (Tupper, Tr. 1041, 3003).

Response to Finding No. 2422:
Complaint Counsel agrees that Mr. Tupper testified as stated with respect to a different ad, but the proposed finding's characterization that the ad he testified about was "very similar" to the magazine wrap at issue is unsupported by the cited evidence.

2423. 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. (CX000314_0010).

Response to Finding No. 2423:
The proposed finding is incomplete, as this was not a single ad, but part of a multi-page magazine wrap. *See* Response to Finding 2419. Complaint Counsel disagrees with the proposed finding regarding the net impression of the magazine wrap advertisements. (CCFF ¶¶ 377-81, 384).

2424. Complaint Counsels' assertion that the ad conveys the message 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 is not conspicuous, self-evident, or reasonably clear from the face of the ad. (CX000314_0010). Consequently, extrinsic evidence must be examined. (Mazis, Tr. 2752).

Response to Finding No. 2424:
The proposed finding is incomplete, as this was not a single ad, but part of a multi-page magazine wrap. *See* Response to Finding 2419. Complaint Counsel disagrees with the proposed finding regarding the net impression of the magazine wrap advertisements. (CCFF ¶¶ 377-81, 384). The last sentence of the proposed finding is unsupported by the cited testimony of Dr. Mazis. *See* Response to Finding 2200.

2425. 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, prostate cancer or erectile dysfunction; 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, prostate cancer or erectile dysfunction. (CX000314_0010).

Response to Finding No. 2425:
The proposed finding is incomplete, as this was not a single ad, but part of a multi-page magazine wrap. *See* Response to Finding 2419. Complaint Counsel disagrees with the proposed finding regarding the net impression of the magazine wrap advertisements. (CCFF ¶¶ 377-81, 384).

2426. 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, prostate cancer or erectile dysfunction, 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. (CX000314_0010).

Response to Finding No. 2426:
The proposed finding is incomplete, as this was not a single ad, but part of a multi-page magazine wrap. *See* Response to Finding 2419. Complaint Counsel disagrees with the proposed finding regarding the net impression of the magazine wrap advertisements. (CCFF ¶¶ 377-81, 384).

2427. 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).

Response to Finding No. 2427:
The proposed finding is incomplete, as this was not a single ad, but part of a multi-page magazine wrap. *See* Response to Finding 2419. Moreover, the proposed finding is unsupported by the cited testimony. Dr. Butters did not define "treat" as a substitute for conventional medical treatment. He defined "treat" as medical treatment and then asserted that he didn't see any ad stating or implying that POM Products "treated any disease." Complaint Counsel also disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 377-81, 384). *See also* Responses to Findings in the cross-referenced Appendix.

2428. To the extent a "proven" claim can be implied from this ad (which it cannot), the overall impression of 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 "proven" in science means the "average person in the study benefitted." "Proven" does not mean that "everyone in the study necessarily benefitted." (Heber, Tr. 2011; Butters, Tr. 2893-2894; PX0361 (Sacks, Dep. at 81)).

Response to Finding No. 2428:
The proposed finding is incomplete, as this was not a single ad, but part of a multi-page magazine wrap. *See* Response to Finding 2419. Complaint Counsel disagrees with the

proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 377-81, 384). However, Complaint Counsel agrees that "proven" does not mean that "everyone in the study" benefitted.

2429. Complaint Counsel, however, have presented no extrinsic evidence or expert opinion on the meaning of this "Ingredients: pomegranates, $25 million in medical research" ad or of consumer perceptions or interpretations of the ad. (PX0357 (Stewart Dep. at 49, 52); (Mazis, Tr. 2752)).

Response to Finding No. 2429:
The proposed finding is incomplete, as this was not a single ad, but part of a multi-page magazine wrap. *See* Response to Finding 2419. The proposed finding mischaracterizes the testimony of Drs. Stewart and Mazis. Neither testified that Complaint Counsel did *not* have extrinsic evidence as to the meaning of any challenged ad. In the cited testimony, Dr. Stewart said that he was not asked to do a net impression analysis of the challenged ads and that he did not know whether the Commission had evidence of how consumers perceive the ads at the level of a net impression, and Dr. Mazis simply said that none of the surveys introduced show how many times any POM Juice or POMx ad was run. Moreover, Complaint Counsel presented evidence as to the meaning of this and other POM advertisements. (*See* CCFF ¶¶ 377-81, 384 and Sections V.C – V.G).

2430. Complaint Counsel also have presented no evidence that this "Ingredients: pomegranates, $25 million in medical research" ad conveyed that POM Juice is "clinically proven" to prevent, treat or reduce the risk of any disease.

Response to Finding No. 2430:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Moreover, Complaint Counsel presented evidence on the meaning of this and other POM advertisements. (*See* CCFF ¶¶ 377-81, 384 and Sections V.C – V.G).

2431. Even assuming *arguendo* that this "Ingredients: pomegranates, $25 million in medical research" 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. (*See infra* (XVIII(A)(1)).

Response to Finding No. 2431:
Complaint Counsel disagrees with the conclusions in the proposed finding. (CCFF ¶¶ 651-61; CX1297 (Mazis, Report at 0008-10) (showing that Reibstein survey is inadequate to measure materiality of challenged POM Juice claims)).

2432. Moreover, because Dr. Reibstein's uncontroverted survey showed that none of the respondents bought POM because of the number of "published" studies versus "unpublished" studies, it is not likely that any significant number of consumers bought POM because of the numerous studies that had been "published." (PX0223-0006-0007, 00020).

Response to Finding No. 2432:
The proposed finding is not supported by the record as a whole. The Reibstein survey was seriously flawed and inadequate as a measure of the purchase motivations of POM Juice purchasers, asking only asked broad open-ended questions with no probing. (PX0359 (Mazis, Dep. at 54-56); CX1297 (Mazis, Report at 0009-10); Mazis, Tr. 2731).

2433. Complaint Counsel have presented no reliable evidence to rebut Professor's Reibstein's survey findings.

Response to Finding No. 2433:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Moreover, Complaint Counsel disagrees with the conclusion in the proposed finding. (CCFF ¶¶ 651-61; CX1297 (Mazis, Report at 0008-10) (showing that Reibstein survey is inadequate to measure materiality of challenged POM Juice claims)). Furthermore, Complaint Counsel has provided ample evidence of the materiality of the challenged claims. (CCFF ¶¶ 621-50, 667-85). Even Dr. Reibstein conceded that the challenged claims would likely be material to consumers. (CCFF ¶ 638).

2434. Complaint Counsel failed to present any evidence regarding the number of exposures consumers had to this ad or any particular POM advertisement.

Response to Finding No. 2434:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Moreover, the proposed finding is irrelevant. *See* Response to Finding 38.

8. pomwonderful.com "Real Studies" Web Page

2435. Paragraph 9.F of the Complaint and Exh. E-2, attached thereto, (CX1426, Exh. E-2) identify a screen capture from POM's pomwonderful.com "Real Studies" web page, which allegedly contained the following text as of April 29, 2009:

> ACE and Systolic Blood Pressure.
>
> With hypertension, or high blood pressure, the heart works harder. Arteries are under pressure and the chances of a stroke or heart attack are greater. [footnote omitted] ACE (or angiotensin converting enzyme) is an enzyme that the body produces which may lead to high blood pressure resulting in atherosclerosis. [footnote omitted] In a preliminary research study, ten elderly patients with hypertension drank 8 oz. of POM Wonderful 100% Pomegranate Juice a day for just two weeks. After those two weeks, in those patients drinking POM Wonderful ACE activity was significantly decreased by 36%, and, they also saw their systolic blood pressure drop by 5%. [footnote omitted]

(CX1426, Exh. E-2).

Response to Finding No. 2435:
The proposed finding is incomplete and mischaracterizes the evidence, as it does not reflect the entire Exhibit E-2 to the Complaint (CX0473, "POM Wonderful Health Benefits").

2436. Complaint Counsel have presented no other definitive dissemination information regarding this particular ad.

Response to Finding No. 2436:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs.

2437. Historically, Respondents ran advertisements that mentioned blood pressure among a list of other health conditions for which pomegranate juice may have some benefit. (Tupper, Tr. 2992). POM, however, never ran advertisements that explicitly focused on blood pressure. (Tupper, Tr. 2992).

Response to Finding No. 2437:
Complaint Counsel has no specific response to the first sentence of the proposed finding.

The second sentence of the proposed finding is unsupported by the record as a whole.

(CCFF ¶¶ 357-62).

2438. Any very early ads that referred to blood pressure benefits were supported by competent and reliable scientific evidence, including the Aviram Study (2001) that found a 5% decrease in systolic blood pressure and the Aviram Study (2004) that found a 12% decrease in systolic blood pressure. (*See infra* XIV(F)).

Response to Finding No. 2438:
Complaint Counsel notes that the cross-referenced section consists of 38 pages and 361 findings, therefore it is unclear which, if any, are the basis for the proposed finding. Nevertheless, the proposed finding that these two studies provided competent and reliable evidence to support claims that the POM Products treat, prevent, or reduce the risk of heart disease, including by lowering blood pressure is unsupported by the cited evidence or the record as a whole. (CCFF ¶¶ 796-819, 955-56).

2439. When subsequent studies did not a show a similar result, although they did not use the specialized equipment needed for an accurate blood pressure study, (Heber, Tr. 2040), and Mr. Resnick did not receive a satisfactory explanation, Mr. Resnick requested that Respondents stop mentioning blood pressure in any advertisements. Mr. Resnick's view was that the science was too ambiguous to justify any claim. Mr. Tupper testified that this occurred in 2007, if not even sooner. (Tupper, Tr. 2993).

Response to Finding No. 2439:
The proposed finding is unsupported by and mischaracterizes the cited evidence. In the cited transcript, Dr. Heber testified only that "a specific claim on blood pressure requires a very specific study," and did not state whether the unspecified "subsequent studies" in the proposed finding used such equipment. He further agreed that he does not hold himself out to be an expert in cardiovascular disease. (Heber, Tr. 2040-41). In the cited

transcript, Mr. Tupper testified that POM in fact felt their blood pressure science was "promising" but that the company decided to "focus on the areas of science that were further along in the process[.]" (Tupper, Tr. 2993-94). The cited testimony contains no reference to Mr. Resnick's views or actions to stop blood pressure claims in POM advertisements.

2440. All references to blood pressure should have been removed when the website was updated between 2006 and 2007 to conform to Respondents' change in policy about how Respondents discuss scientific findings with the public. (Tupper, Tr. 2977, 2986-87, 2993).

Response to Finding No. 2440:
Complaint Counsel agrees that Mr. Tupper testified that the website was updated and that the references to blood pressure were not removed, but the proposed finding's statement that the references to blood pressure "should have been removed . . . to conform with Respondents' change in policy" is unsupported by the cited evidence. In fact, Mr. Tupper testified that blood pressure claims were purportedly discontinued because POM "decided to in our advertising focus on the areas of science that were further along in the process, and that's the point in time in which we stopped talking about blood pressure[,]" not due to any policy change. (Tupper, Tr. 2993-94).

2441. After 2007, any lingering reference to blood pressure on any of the POM Wonderful web pages was an inadvertent mistake, (Tupper, Tr. 2993), including the short reference to blood pressure in POM's pomwonderful.com "Real Studies" web page quoted above. (Tupper, Tr. 3006). These lines have since been deleted from POM's webpage. (Tupper, Trial Tr. 3006).

Response to Finding No. 2441:
Complaint Counsel has no specific response.

2442. Nowhere on this web page do Respondents expressly (*i.e.*, unequivocally and directly) state that (a) POM Juice "prevents," "treats," or "reduces the risk" of heart disease by lowering blood pressure; or (b) POM Juice is "clinically proven" to "prevent," "treat," or "reduce the risk" of heart disease. (CX1426, Exh. E-2).

Response to Finding No. 2442:

Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 443-69, 471).

2443. Complaint Counsels' 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. (CX1426, Exh. E-2). consequently, extrinsic evidence must be examined. (Mazis, Tr. 2752).

Response to Finding No. 2443:
Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 443-69, 471). The last sentence of the proposed finding is unsupported by the cited testimony of Dr. Mazis. *See* Response to Finding 2200.

2444. The overall net impression of this web page is not that (a) drinking eight ounces of POM Juice prevents or treats heart disease by lowering blood pressure; or (b) drinking eight ounces of POM Juice is "clinically proven" to prevent, treat or reduce the risk of heart disease. (CX1426, Exh. E-2).

Response to Finding No. 2444:
Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 443-69, 471).

2445. 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 heart disease, 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 heart disease. (CX1426, Exh. E-2).

Response to Finding No. 2445:
Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 443-69, 471).

2446. 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).

Response to Finding No. 2446:
The proposed finding is unsupported by the cited testimony. Dr. Butters did not define "treat" as a substitute for conventional medical treatment. He defined "treat" as medical

treatment and then asserted that he didn't see any ad stating or implying that POM Products "treated any disease." Complaint Counsel also disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 443-69, 471). *See also* Responses to Findings in the cross-referenced Appendix.

2447. To the extent a "proven" claim can be implied from this ad (which it cannot), the overall impression of this web page is not that POM Juice is "proven" to be 100% effective in preventing, treating or reducing the risk of heart disease because "proven" in science means the "average person in the study benefitted." "Proven" does not mean that "everyone in the study necessarily benefitted." (Heber, Tr. 2011; Butters, Tr. 2893-2894; PX0361 (Sacks, Dep. at 81)).

Response to Finding No. 2447:
Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 443-69, 471). However, Complaint Counsel agrees that "proven" does not mean that "everyone in the study" benefitted.

2448. Complaint Counsel, however, have presented no extrinsic evidence or expert opinion on the meaning of these website lines or of consumer perceptions or interpretations of the website lines. (PX0357 (Stewart Dep. at 49, 52); (Mazis, Tr. 2752)).

Response to Finding No. 2448:
The proposed finding mischaracterizes the testimony of Drs. Stewart and Mazis. Neither testified that Complaint Counsel did *not* have extrinsic evidence as to the meaning of any challenged ad. In the cited testimony, Dr. Stewart said that he was not asked to do a net impression analysis of the challenged ads and that he did not know whether the Commission had evidence of how consumers perceive the ads at the level of a net impression, and Dr. Mazis simply said that none of the surveys introduced show how many times any POM Juice or POMx ad was run. Moreover, Complaint Counsel presented evidence as to the meaning of this and other POM advertisements. (*See* CCFF ¶¶ 232-51, 443-69, 471 and Sections V.B.5 and V.C – V.G).

2449. Complaint Counsel also have presented no evidence that this "Real Studies" web page conveyed that POM Juice is "clinically proven" to prevent, treat or reduce the risk of any disease.

Response to Finding No. 2449:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Moreover, Complaint Counsel presented evidence on the meaning of this and other POM advertisements. (*See* CCFF ¶¶ 232-51, 443-69, 471 and Sections V.B.5 and V.C – V.G).

2450. Even assuming *arguendo* that this "Real Studies" web page 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. (*See infra* (XVIII(A)(1)).

Response to Finding No. 2450:
Complaint Counsel disagrees with the conclusions in the proposed finding. (CCFF ¶¶ 651-61; CX1297 (Mazis, Report at 0008-10) (showing that Reibstein survey is inadequate to measure materiality of the challenged claims for the POM products)).

2451. 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.

Response to Finding No. 2451:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Moreover, Complaint Counsel disagrees with the conclusions in the proposed finding. (CCFF ¶¶ 651-61; CX1297 (Mazis, Report at 0008-10) (showing that Reibstein survey is inadequate to measure materiality of the challenged claims for the POM products)). Furthermore, Complaint Counsel has provided ample evidence of the materiality of the challenged claims. (CCFF ¶¶ 621-50, 667-85). Even Dr. Reibstein conceded that the challenged claims would likely be material to consumers. (CCFF ¶ 638).

2452. Complaint Counsel failed to present any evidence regarding the number of exposures consumers had to this website material or any particular POM advertisement.

Response to Finding No. 2452:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Moreover, the proposed finding is irrelevant. *See* Response to Finding 38.

F. POM's advertisements Changed Significantly Throughout the Later Years From 2006 to 2011, Largely As a Result of the NAD Decisions in 2005 and 2006

2453. POM's ads have changed significantly over time since the early years when the "outlier" ads ran. (L. Resnick, Tr. 162, 168).

Response to Finding No. 2453:
Complaint Counsel disagrees with the characterization of the ads listed in Finding 2257 as "outliers" and that they ran only in the "early years," because several of the ads ran as late as 2008 and 2009. *See* Response to Finding 2258. The proposed finding is unsupported by the cited evidence with respect to those contentions, but Complaint Counsel agrees that Mrs. Resnick testified that POM's ads have changed over time.

2454. In 2005 and 2006, the NAD issued two decisions. Notably, the NAD agreed with Respondents that the images and headlines in their ads constituted puffery. The following headlines, for example, were deemed to be in the realm of puffery and hyperbole: "Outlive Your Spouse," "Cheat Death," "Life Preserver," "Life Guard," "Relax You'll Live Longer," "Forever Young," and "The New Shape of Protection". (CX0037; CX0055).

Response to Finding No. 2454:
The proposed finding is incorrect and mischaracterizes the evidence. Specifically, the 2005 NAD decision (CX0037) only reviewed two specific advertising claims and did *not* review, or find that, the images and headlines in Respondents' ads were puffery. The only individual ads it ruled on were "Amaze your cardiologist" and "Floss your arteries daily," and it recommended that the claims under review for both ads be modified or discontinued. (CX0037_0001, 0010). While the 2005 NAD decision stated, in a

footnote, that some ads "*could* be deemed mere puffery," it made clear that it was only reviewing POM's claim of quantified product performance; of the seven headlines listed in the proposed finding, the only one mentioned was "Life Preserver." (CX0037_0006 and n.21 (emphasis added); s*ee also* CX0055_0020 (2005 NAD review only reviewed one quantified claim and "not any claims of puffery")). The 2006 NAD decision (CX0055) stated that the advertisements cited in the prior decision were only *possible* examples of puffery, not that there was any such finding. (CX0055_0021). The NAD also emphasized that it reviewed claims "in the context of the entire advertisement in which it appears" and that even if the headlines were "fanciful" *in isolation*, "when accompanied by language that . . . POM Wonderful prevents or reduces the risk of heart disease, Alzheimer's, stroke, heart disease, premature aging, cancer, etc. and viewing these advertisements as a whole, these claims are beyond the realm of puffery and hyperbole[.]" (CX0055_0047). The NAD also questioned whether, "having so pervasively promoted its campaign before the public for such a lengthy period of time, it is possible to step back once again, to . . . fanciful puffing advertising copy[.]" (CX0055_0023).

2455. And, although, the NAD took issue with some of the language used to describe and qualify the science in the body copy of the advertisements, the NAD did not take issue with whether the science itself was significantly strong, valid or substantive. (Tupper, Tr. 2983-2984). Moreover, for some of the ads such as "Amaze your cardiologist" and "Floss your arteries," the NAD simply recommended that Respondents modify their claims. (CX0037).

Response to Finding No. 2455:

The proposed finding is incorrect and mischaracterizes the evidence. Although the NAD's 2005 decision (CX0037) did not criticize the conduct of the Aviram 2004 study *per se*, it made clear that the ads needed to be modified *because* the study was not sufficient to substantiate POM's claims. The NAD stated that its 2005 decision

"*specifically* found . . . that this pilot study did *not* support the implied (let alone an express) claim that [POM Juice] could *prevent* or help otherwise healthy individuals to *avoid* arterial plaque build-up[.]" (CX0055_0044 (emphasis in original). The NAD further found that POM's *in vitro* and *in vivo* [animal] studies, as well as the 2005 Ornish MP study, were not sufficient to support its claims. (CX0055_0045).

2456. In response to those NAD decisions, starting in 2006, Respondents shifted the focus of their ads away from general statements and quantified performance claims, like those made in the "Floss your arteries" and "Amaze your cardiologist" ads. (Tupper, Tr. 2985-87; *see supra* (XVIII)).

Response to Finding No. 2456:
Although Complaint Counsel agrees that Mr. Tupper testified as stated, his testimony is contradicted by the record on POM's conduct. (*See* CCFF ¶¶ 665-74 (showing that POM continued to make plaque reduction claims, citing the Aviram study, after the NAD rulings)). Moreover, the cross-referenced section, which consists of 22 pages and 167 findings, does not support the proposed finding.

2457. Instead, when Respondents wanted to advertise the science behind the Challenged Products, Respondents would summarize and describe the specific results of studies that were completed using appropriate language to qualify the description of the studies. (Tupper, Tr. 2985-87, 3026).

Response to Finding No. 2457:
Although Complaint Counsel agrees that Mr. Tupper testified as stated, his testimony is contradicted by the record on POM's conduct. (*See* CCFF ¶¶ 665-74 (showing that POM continued to make plaque reduction claims, citing the Aviram study, after the NAD rulings)).

2458. Also, as a result of the NAD's decisions, Respondents would direct people back to their website to read the full study in some of their ads. (Tupper, Tr. 2985).

Response to Finding No. 2458:
Complaint Counsel has no specific response.

G. Respondents' Later Advertisements (2006 To 2011) Generally Fall Into Three Major Categories, All of Which are Truthful and Not Misleading and Which Were Substantiated by Competent and Reliable Scientific Evidence

2459. The vast majority of POM's ads from 2006 through 2010 fall into three general categories: (a) specific study; (b) "backed by" and (c) antioxidant.

Response to Finding No. 2459:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs.

2460. The first category of ads, "specific study" ads, summarized some of Respondents' scientific studies on the Challenged Products in the areas of cardiovascular, prostate and erectile health.

Response to Finding No. 2460:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs.

2461. The second category, "backed by" ads, stated that Respondents spent a particular amount of money on their scientific studies on the Challenged Products to back-up Respondents' healthy claims.

Response to Finding No. 2461:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs.

2462. The third category, "antioxidant" ads, includes general antioxidant ads, comparative antioxidant ads, antioxidant benefits ads and multi-step ads. Generally, these antioxidant ads discussed the potential benefits of antioxidants and stated that the Challenged Products contained antioxidants.

Response to Finding No. 2462:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs.

2463. The ads in each of the three categories are qualified and substantiated by competent and reliable scientific evidence. (*See supra* (XIV, XV, XVI)).

Response to Finding No. 2463:
This finding is unsupported by the cited evidence; *see* Responses to Findings in the cross-referenced sections.

2464. As analyzed in detail below, some ads fall into multiple and overlapping categories.

(a) For example, one ad may summarize a specific study and may make reference to a number of dollars spent on research. (*See, e.g.*, CX0328 (Your New Health Care Plan); CX0331 (Healthy, Wealthy, and Wise.); CX0337 (The First Bottle You Should Open in 2010); CX0280 (Live Long Enough to Watch your 401(k) Recover); CX0355 (The Only Antioxidant Supplement Rated X); CX0279 (Science, not fiction.); CX0180 (The antioxidant superpill); CX1426, Exh. J (Healthy, Wealthy, and Wise.); CX1426, Exh. K (The antioxidant superpill); CX0342 (Take Out a Life Insurance Supplement); CX0353 (Take Out a Life Insurance Supplement); CX0350 (24 Scientific Studies Now in One Easy-To-Swallow Pill); CX0348 (24 Scientific Studies Now in One Easy-To-Swallow Pill); CX0351 (The Only Antioxidant Supplement Rated X); CX0169 (The power of POM, in one little pill); CX1426, Exh. L (The power of POM, in one little pill); CX1426, Exh. M (Dreher Heart Newsletter); CX1426, Exh. I (Antioxidant Superpill); CX0122 (Science, not fiction); CX0372_0002 (HOLY HEALTH! $32 million in medical research); CX0379_0002 (HOLY HEALTH! $32 million in medical research); and CX0380_0002 (HOLY HEALTH! $32 million in medical research);

(b) Another ad may reference a specific study and also discuss the benefits of antioxidants found in pomegranate juice. (*See, e.g*., CX0328 (Your New Health Care Plan);); CX0331 (Healthy, Wealthy, and Wise.); CX0337 (The First Bottle You Should Open in 2010);); CX0280 (Live Long Enough to Watch your 401(k); CX0355 (The Only Antioxidant Supplement Rated X); CX0279 (Science, not fiction.); CX0180 (The antioxidant superpill); CX1426, Exh. K (The antioxidant superpill); CX0120 (One small pill for mankind); CX0122 (Science, not fiction); CX1426, Exh. J (Healthy, Wealthy, and Wise); CX0342 (Take Out a Life Insurance Supplement); CX0353 (Take Out a Life Insurance Supplement); CX0350 (24 Scientific Studies Now in One Easy-To-Swallow Pill); CX0348 (24 Scientific Studies Now in One Easy-To-Swallow Pill); CX0351 (The Only Antioxidant Supplement Rated X); CX0169 (The power of POM, in one little pill); CX1426, Exh. L (The power of POM, in one little pill); CX1426, Exh. M (Dreher Heart Newsletter); CX0029 (Studies Show That 10 Out of 10 People Don't Want to Die); CX1426, Exh. I (Antioxidant Superpill); and CX1426, Exh. N (Dreher Prostate Newsletter); and

(c) Another ad may describe a specific study, describe the benefits of antioxidants and also state the number of dollars Respondents spent on scientific research. (See, e.g., CX0328 (Your New Health Care Plan); CX0331 (Healthy, Wealthy, and Wise.); CX0337 (The First Bottle You Should Open in 2010); CX0280 (Live Long Enough to Watch your 401(k) Recover); CX0355 (The Only Antioxidant Supplement Rated X); CX0279 (Science, not fiction.); CX0180 (The antioxidant superpill); CX1426, Exh. J (Healthy, Wealthy, and Wise); CX1426, Exh. K (The antioxidant superpill); CX0342 (Take Out a Life Insurance Supplement); CX0353 (Take Out a Life Insurance Supplement); CX0350 (24 Scientific Studies Now in One Easy-To-Swallow Pill); CX0348 (24 Scientific Studies Now in One Easy-To-

Swallow Pill); CX0351 (The Only Antioxidant Supplement Rated X); CX0169 (The power of POM, in one little pill); CX1426, Exh. L (The power of POM, in one little pill); CX1426, Exh. M (Dreher Heart Newsletter); CX0122 (Science, not fiction); CX1426, Exh. I (Antioxidant Superpill); and CX1426, Exh. N (Dreher Prostate Newsletter).

Response to Finding No. 2464:

Complaint Counsel does not disagree that POM's cited ads include *some* of the elements described above, among many others, but Complaint Counsel disagrees that these elements can be analyzed in isolation or that the ads can be categorized by these elements. Complaint Counsel asserts that the appropriate analysis is to look at the overall, net impression created by each advertisement through the interaction of different elements in the advertisement, including language and visual elements, rather than focusing on individual elements or phrases in isolation. (*See* CCFF Sections V.D – V.F for the net impression analysis of each challenged ad). Complaint Counsel also notes that some of the ads cited in Finding No. 2464(a) are individual pages of a multi-page magazine wrap, and not individual ads. *See* Response to Finding 2252.

2465. No matter how the ads are categorized, the overarching commonality among all the ads is that they used qualified language to describe the health-related benefits of the Challenged Products. (*See infra* (XVII(G)(1-3)).

Response to Finding No. 2465:

Complaint Counsel disagrees with the proposed finding regarding the net impression of POM's advertising. (*See* CCFF Section V.D – V.F and Appendix A). *See also* Responses to Findings in the cross-referenced section.

2466. For example and as described in detail below and in the attached Appendix of Advertisements, POM's ads generally conveyed the restrained and qualified message that scientific studies show results that are merely "promising," "encouraging" or "hopeful" for prostate, cardiovascular and erectile health or stated that POM "may" help with a particular condition or that POM is "fighting" for better health in a particular area. (*See* Appendix of Advertisements).

Response to Finding No. 2466:

Complaint Counsel disagrees with the proposed finding regarding the net impression of POM's advertising. (*See* CCFF Section V.D – V.F and Appendix A). *See also* Responses to Findings in the cross-referenced Appendix.

2467. Nowhere in the three categories of ads 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. (*See* Appendix of Advertisements).

Response to Finding No. 2467:
Complaint Counsel disagrees with the proposed finding regarding the net impression of POM's advertising. (*See* CCFF Section V.D – V.F and Appendix A). *See also* Responses to Findings in the cross-referenced Appendix.

2468. Nowhere in the three categories of ads 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. (*See* Appendix of Advertisements).

Response to Finding No. 2468:
Complaint Counsel disagrees with the proposed finding regarding the net impression of POM's advertising. (*See* CCFF Section V.D – V.F and Appendix A). *See also* Responses to Findings in the cross-referenced Appendix.

2469. The overall net impression of POM's ads that use qualified language, such as "promising," "encouraging" or "hopeful", is not that the Challenged Products are a "silver bullet against disease" or "clinically proven" to "prevent," "treat" or "reduce the risk" of heart disease, prostate cancer or erectile dysfunction. (*See* Appendix of Advertisements).

Response to Finding No. 2469:
Complaint Counsel disagrees with the proposed finding regarding the net impression of POM's advertising. (*See* CCFF Section V.D – V.F and Appendix A). *See also* Responses to Findings in the cross-referenced Appendix.

2470. POM's advertising, viewed as a whole, do not clearly and conspicuously convey to a reasonable consumer that the Challenged Products prevent, treat or reduce the risk of heart disease, prostate cancer and erectile dysfunction under Complaint Counsels' "net impression" analysis or any analysis for implied claims. (*See* Appendix of Advertisements);

Response to Finding No. 2470:
Complaint Counsel disagrees with the proposed finding regarding the net impression of POM's advertising. (*See* CCFF Section V.D – V.F and Appendix A). *See also* Responses to Findings in the cross-referenced Appendix.

2471. POM's advertising, viewed as a whole, do not clearly and conspicuously convey to a reasonable consumer that the Challenged Products are "clinically proven" to prevent, treat or reduce the risk of heart disease, prostate cancer and erectile dysfunction under Complaint Counsels' "net impression" analysis or any analysis for implied claims. (*See* Appendix of Advertisements);

Response to Finding No. 2471:
Complaint Counsel disagrees with the proposed finding regarding the net impression of POM's advertising. (*See* CCFF Section V.D – V.F and Appendix A). *See also* Responses to Findings in the cross-referenced Appendix.

2472. To the extent a "proven" claim can be implied from any of POM's advertising (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." (Heber, Tr. 2011; Butters, Tr. 2893-2894; PX0361 (Sacks, Dep. at 81)).

Response to Finding No. 2472:
Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (*See* CCFF Section V.D – V.F and Appendix A). However, Complaint Counsel agrees that "proven" does not mean that "everyone in the study" benefitted.

2473. To the extent a "treat" claim can be implied from any of POM's advertising (which it cannot), the overall net impression of any ad is not that the Challenged Products are a substitute for conventional medical treatment. (Butters, Tr. 2821-22; Appendix of Advertisements); and

Response to Finding No. 2473:
The proposed finding is unsupported by the cited testimony. Dr. Butters did not define "treat" as a substitute for conventional medical treatment. He defined "treat" as medical

treatment and then asserted that he didn't see any ad stating or implying that POM Products "treated any disease."

2474. To the extent a "reduce the risk" claim can be implied from any of POM's advertising, 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. (Butters Tr. 2817-18).

Response to Finding No. 2474:
Complaint Counsel disagrees with the proposed finding regarding the implication and net impression of POM's advertisements. (*See* Complaint Counsel's CCFF Section V.D – V.F and Appendix A). The proposed finding is also unsupported by the cited testimony.

2475. Moreover, as set for the below and in the attached Appendix of Advertisements, Complaint Counsel failed to present any reliable extrinsic evidence or expert opinion (a) on the meaning of POM's ads or of consumers' expectations or perceptions or the ads, (b) that POM's ads conveyed that they are "clinically proven" to prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction; (c) that POM's ads conveyed that the Challenged Products prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction; or (d) of Respondents' intent to convey such messages to prove that POM's advertising made the alleged implied "clinically proven" disease claims. (*See* Appendix of Advertisements; Mazis, Tr. 2752).

Response to Finding No. 2475:
The proposed finding mischaracterizes the testimony of Dr. Mazis, who did not testify that Complaint Counsel did not have extrinsic evidence as to the meaning of any challenged ad. In the cited testimony, Dr. Mazis simply said that none of the surveys introduced show how many times any POM Juice or POMx ad was run. Moreover, Complaint Counsel presented evidence as to the meaning of POM advertisements. (*See* CCFF Sections V.C – V.G).

2476. Additionally, 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.

Response to Finding No. 2476:

The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Moreover, Complaint Counsel disagrees with the conclusions in the proposed finding. (CCFF ¶¶ 651-61; CX1297 (Mazis, Report at 0008-10) (showing that Reibstein survey is inadequate to measure materiality of the challenged claims for the POM products)). Furthermore, Complaint Counsel has provided ample evidence of the materiality of the challenged claims. (CCFF ¶¶ 621-50, 667-85). Even Dr. Reibstein conceded that the challenged claims would likely be material to consumers. (CCFF ¶ 638).

2477. Complaint Counsel also failed to present any evidence regarding the number of exposures consumers had to this ad or any particular POM advertisement.

Response to Finding No. 2477:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Moreover, the proposed finding is irrelevant. *See* Response to Finding 38.

1. Respondents Disseminated "Specific Study" Ads That Are Not False and Misleading Because They Accurately and Truthfully Summarized Respondents' Scientific Studies on the Challenged Products and Described the Studies Using Qualified Language

2478. The first category, "specific study" ads, summarized some of the Respondents' scientific studies on the Challenged Products and described the results of the studies using qualified language. (*See, e.g.*, CX0328); CX0331 (Healthy, ~~Wealthy~~, and Wise.); CX0337 (The First Bottle You Should Open in 2010); CX0280 (Live Long Enough to Watch your 401(k) Recover); CX0355 (The Only Antioxidant Supplement Rated X); CX0279 (Science, not fiction.) CX0180 (The antioxidant superpill); CX1426, Exh. J (Healthy, ~~Wealthy~~, and Wise.); CX1426, Exh. K (The antioxidant superpill); CX0342 (Take Out a Life Insurance Supplement); CX0353 (Take Out a Life Insurance Supplement); CX0350 (24 Scientific Studies Now in One Easy-To-Swallow Pill); CX0348 (24 Scientific Studies Now in One Easy-To-Swallow Pill); CX0351 (The Only Antioxidant Supplement Rated X); CX0169 (The power of POM, in one little pill); CX1426, Exh. L (The power of POM, in one little pill); CX1426, Exh. M (Dreher Heart Newsletter); CX0120 (One small pill for mankind); CX0122 (Science, not fiction); CX1426, Exh. B (Drink to prostate health); CX0260 (Drink to prostate health); CX1426 Exh. I (Antioxidant Superpill); CX1426, Exh. N (Dreher Prostate Newsletter);CX0372_0002 (HOLY HEALTH! $32 million in medical research); CX0379_0002 (HOLY HEALTH! $32 million in medical

research); CX0380_0002 (HOLY HEALTH! $32 million in medical research); CX0314_0004 (POM Wonderful and Prostate Health); and CX0314_0008 (POM Wonderful and Prostate Health)

Response to Finding No. 2478:
Complaint Counsel does not disagree that POM's cited ads include some of the elements described above, among many others, but Complaint Counsel disagrees that these elements can be analyzed in isolation or that the ads can be categorized by these elements. Complaint Counsel asserts that the appropriate analysis is to look at the overall, net impression created by each advertisement through the interaction of different elements in the advertisement, including language and visual elements, rather than focusing on individual elements or phrases in isolation. (*See* CCFF Sections V.D – V.F for the net impression analysis of each challenged ad). Complaint Counsel also notes that some of the ads cited are individual pages of a multi-page magazine wrap, and not individual ads. *See* Response to Finding 2252.

2479. While Respondents have sponsored at least one hundred scientific studies on the Challenged Products conducted in forty-four different and renowned medical institutions, sixty-seven of which were published in peer-reviewed journals and seventeen of which were human clinical studies, (*see supra* V), Respondents only specifically described four of these studies in the areas of prostate, cardiovascular and erectile health in their ads.

Response to Finding No. 2479:
The proposed finding is incorrect, as Respondents specifically described at least five studies in the areas of prostate, cardiovascular and erectile health in their ads and marketing materials. (*See* CCFF ¶ 168).

2480. These four studies include:

Prostate Health

(a) Pantuck AJ, Leppert JT, Zomorodian N, Aronson W, Hong J, Bardnard RJ, Seeram N, Liker H, Wang J, Elashoff R, Heber D, Aviram M, Ignarro L, Belldegrun A, *Phase II Study of Pomegranate Juice for Men with Rising Prostate-Specific Antigen following Surgery or Radiation for Prostate Cancer*, Clin.

Cancer Research 12 (13): 4018-4026 (2006) (hereinafter "Pantuck Study (2006)"). (PX0060);

Cardiovascular Health

(b) Aviram M, Rosenblat M, Gaitini M, Nitecki S, Hoffman A, Dornfeld L, Volkova N, Presser D, Attias J, Liker H, and Hayek T, *Pomegranate juice consumption for 3 years by patients with carotid artery stenosis reduces common carotid intimamedia thickness, blood pressure and LDL oxidation*, 23 Clin. Nutr. 423-33 (2004). Erratum in 27 Clin. Nutr. 671 (2008) (hereinafter, "Aviram Study 2004") (CX0611);

(c) Sumner M, Elliott-Eller M, Weidner G, Daubenmier JJ, Chew MH, Marlin R, Raisin CJ, and Ornish D, *Effects of pomegranate juice consumption on myocardial perfusion in patients with coronary heart disease*, 96 Am. J. Cardiology 810 (2005) (hereinafter "Bev I Coronary Perfusion Study") (PX0023);

Erectile Health

(d) CP Forest, H Padma-Nathan and HR 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, 19 Int J Impot Res. 564-67 (2007) (hereinafter "Forest/Padma-Nathan RCT Study") (CX908).

Response to Finding No. 2480:
Complaint Counsel agrees that these four studies were described in Respondents' ads and marketing materials, but the contention that these were the only studies described is incorrect. *See* Responses to Findings 2479 and 2499.

2481. As described below, the "specific study" ads on prostate, cardiovascular and erectile health ads are not false and misleading.

Response to Finding No. 2481:
Complaint Counsel disagrees with the proposed finding. *See* Responses to Findings below.

2482. They accurately and truthfully summarize the scientific studies in question. (*See supra* XVI(D)).

Response to Finding No. 2482:
Complaint Counsel disagrees with the proposed finding. Complaint Counsel further notes that the cross-referenced section refers only to Respondents' erectile dysfunction

claims, and thus does not support the proposed finding. (*See also* CCFF Sections VII.C.4, VII.D.4, and VII.E.3 (analyzing Respondents' heart, prostate and erectile claims in light of the scientific evidence)).

2483. Moreover, as detailed below, each "specific study" ad uses qualified language to describe the studies and other claims in the ads.

Response to Finding No. 2483:
Complaint Counsel disagrees with the proposed finding. *See* Responses to Findings below. Complaint Counsel further disagrees that any single element can be analyzed in isolation or that the ads can be categorized by these elements. Complaint Counsel asserts that the appropriate analysis is to look at the overall, net impression created by each advertisement through the interaction of different elements in the advertisement, including language and visual elements, rather than focusing on individual elements or phrases in isolation. (*See* CCFF Sections V.D – V.F for the net impression analysis of each challenged ad).

(b) Prostate Health - Pantuck Study (2006)

2484. In the Pantuck Study (2006), Dr. Pantuck and his colleagues at UCLA Medical School found that through the consumption of pomegranate juice, the mean PSA doubling time significantly increased with treatment from a mean of 15 months at baseline to 54 months post-treatment. (PX0060). Forty-six men with recurrent prostate cancer following radical prostatectomy treatment, were given 8 ounces of pomegranate juice. The consumption of POM was associated with statistically significant prolongation of PSADT. (CX06110).

Response to Finding No. 2484:
Complaint Counsel has no specific response.

2485. When describing the results of the Pantuck Study (2006) in their advertisements, Respondents' used the following body copy:

(a) 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 at least two years, these men experienced significantly longer PSA doubling times. (CX_0260 and CX1426, Exh. B (Drink to prostate health));

(b) A recently published preliminary medical study followed 46 men previously treated for prostate cancer either with surgery or radiation. After drinking eight ounces of POM Wonderful 100% Pomegranate Juice daily for at least two years, these men experienced significantly longer 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. . . . 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 not underway to further investigate the effects of POM on prostate health. (CX314_0008 and CX314_0004 (Time Wrap – POM Wonderful and Prostate Health));

(c) 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 8 oz. 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 8 oz. 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% decrease in cancer cell death (apoptosis). In another study, in vitro laboratory testing at UCLA showed that POMx significant decreased human prostate cancer cell growth and increased cancer cell death. (CX1426, Exh. N and CX1426_0049-0051 (Dreher Prostate Newsletter));

(d) An initial UCLA medical study on POM Wonderful 100% Pomegranate Juice showed hopeful results for men with prostate cancer. (CX0120 (One Small Pill for Mankind); CX0122 (Science, Not Fiction));

(e) "Findings from a small study suggest that pomegranate juice may one day prove an effective-weapon against prostate cancer." *The New York Times* (July 4, 2006) … According to a UCLA study of 46 men age 65 to 70 with advanced prostate cancer, drinking an 8 oz glass of POM Wonderful 100% Pomegranate Juice every day slowed their PSA doubling time by nearly 350%. 83% of those who participated in the study showed a significant decrease in their cancer regrowth rate. (CX1426, Exh. I and CX1426_0038-0042(Antioxidant Superpill));

(f) After drinking eight ounces of POM Wonderful 100% Pomegranate Juice daily for at least two years, these men experience significantly slower average 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 binning 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 four-fold improvement, *"This is a big increase. I was surprised when I saw such an improvement in PSA numbers," said Dr. Allen Pantuck, lead author of the UCLA study*. … 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 not underway to further investigate the effects of POM on prostate health. (CX0372_0002, CX0379_0002, CX0380_0002 (Holy Health! $32 million in medical research));

(g) 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 J. Pantuck in *Clinical Cancer Research, '06*. (CX0328 (Your New Healthcare Plan); CX0331 (Healthy, ~~Wealthy~~ & Wise); CX0337 (The First Bottle You Should Open in 2010); CX0280) (Live Long Enough to Watch Your 401(k) Recover); CX0355 (The Only Antioxidant Supplement Rated X); CX0279 (Science, not fiction); CX0180 (The Antioxidant Superpill); CX1426, Exh. K (The Antioxidant Superpill); CX0342 (Take Out a Life Insurance Supplement); CX0353 (Take Out a Life Insurance Supplement); CX0350 (24 Scientific Studies Now In One Easy-To-Swallow Pill); CX0348 (24 Scientific Studies Now In One Easy-To-Swallow Pill); CX0351 (The Only Antioxidant Supplement Rated X)); and

(h) 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. (CX0169 and CX1426, Exh. L (The power of POM in one little pill)).

(i) In a clinical study involving 46 men with rising PSA after prostate cancer treatment (surgery or radiation) who consumed 8 ounces of POM Wonderful 100% Pomegranate Juice daily over two years, PSA doubling time increased from 15 to 54 months ($p<0.001$).5 A longer term (6-year) continued evaluation of active sub-group patients showed a further increase in PSA doubling time to 88 months. (CX1426, Exh. E-1_0006[4], Rushton_006[5])

[4] Complaint Counsel attached several POM website captures to their complaint as Exhibit E. For ease of reference, Respondents sequentially numbered the pages discussed herein beginning with CX1426, Exh. E_001.

(j) Recently, the American Association for Cancer Research published research that indicates that a daily pomegranate regimen has a positive effect for men with prostate cancer. Specifically, drinking 8 ounces of POM 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. 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)).

Response to Finding No. 2485:

Complaint Counsel does not disagree that the body copy excerpts in the proposed finding were *part of* the body copy of the ads cited, but disagrees that these descriptions can be analyzed in isolation or that the ads can be categorized by these descriptions. Complaint Counsel asserts that the appropriate analysis is to look at the overall, net impression created by each advertisement through the interaction of different elements in the advertisement, including language and visual elements, rather than focusing on individual elements or phrases in isolation. (*See* CCFF Sections V.D – V.F for the net impression analysis of each challenged ad). The body copy in these excerpts were among the elements that resulted in a net impression in each of these ads that the POM products referenced therein were clinically proven to treat, prevent, or reduce the risk of prostate cancer. Complaint Counsel also notes that some of the ads cited in Finding 2485(b) and (f) are individual pages of a multi-page magazine wrap, and not individual ads. *See* Response to Finding 2252.

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[5] Complaint Counsel marked a CD containing POM website captures as Exhibit 2 to Mr. Rushton's deposition on December 21, 2010. For ease of reference, Respondents sequentially numbered the pages discussed herein beginning with Rushton_001.

2486. As described in the findings of fact related to Respondents' studies on prostate health, the language quoted above accurately summarized the Pantuck Study (2006). (*See supra infra* XV(B)).

Response to Finding No. 2486:
The proposed finding is unsupported by the cited evidence. *See* Responses to Findings in the cross-referenced section.

2487. Moreover, as further described in the findings of fact related to Respondents' studies on prostate health, at the time the representations were made, Respondents had competent and reliable scientific evidence to support the statements made above. (*See supra infra* XV(B)).

Response To Finding No. 2487:
The proposed finding is unsupported by the cited evidence. *See* Responses to Findings in the cross-referenced section.

(c) Cardiovascular Health

(1) Aviram Study (2004)

2488. In the Aviram Study (2004), Dr. Aviram and his co-workers investigated, among other things, the effects of pomegranate juice consumption by patients with CAS or the narrowing of the inner surface of the carotid artery. (CX0611). In the study, ten patients received pomegranate juice for one year and five of them continued for up to three years. In the control group that did not consume pomegranate juice, CIMT increased by 9% during one year, whereas, pomegranate juice consumption resulted in a significant CIMT reduction, by up to 30%, after one year. (CX0611). The results of this study indicated that pomegranate juice consumption by patients with CAS decreased CIMT which were related to the potent antioxidant characteristics of pomegranate juice polyphenols. (CX0611).

Response to Finding No. 2488:
The proposed finding is incomplete. There were a total of nineteen patients in the Aviram CIMT/BP Study (2004) who had severe carotid artery stenosis. (CCFF ¶ 805). Ten patients in the first group consumed 50 ml of concentrated pomegranate juice daily for one year and five of them continued for up to three years. (CCFF ¶ 805). The second group, who did not consume pomegranate juice, consisted of nine patients and received dissimilar treatments from the juice group. (CCFF ¶¶ 806, 808). This study was

unblinded and not placebo-controlled (CCFF ¶¶ 806-07). The article reports that no additional improvements in CIMT were seen in the five patients who continued drinking the juice for two additional years. (CCFF ¶ 809). The article concludes that further clinical trials are needed to prove the beneficial effect of dietary antioxidants in patients in general and in patients with cardiovascular disease. (CCFF ¶ 821). (*See also* CCFF ¶¶ 814-21 (analysis of the study)).

2489. When describing the results of the Aviram Study (2004) in their advertisements, Respondents' used the following body copy:

(a) And 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%. (CX0029 (Studies Show That 10 Out Of 10 People Don't Want To Die));

(b) And preliminary human research suggests that our California-grown pomegranate juice also promotes heart health. (CX0120 (One small pill for mankind); CX0122 (Science, not fiction));

(c) "Pomegranate juice consumption resulted in significant reduction in IMT (thickness of arterial plaque) by up to 30% after one year," said Dr. Michael Aviram in Clinical Nutrition, '04. (CX0328 (Your new healthcare plan); CX0331 (Healthy, Wealthy & Wise); CX0337 (The First Bottle You Should Open in 2010); CX0280 (Live Long Enough to Watch Your 401(k) Recover); CX0355 (The Only Antioxidant Supplement Rated X); CX0279 (Science, Not Fiction); CX0180 (The Antioxidant Superpill); CX1426, Exh. K (The Antioxidant Superpill));

(d) Two additional preliminary studies on our juice showed promising results for heart health. … "Pomegranate juice pilot research suggests anti-atherosclerosis benefits," according to M. Aviram, et al, in Clinical Nutrition, 2004. (CX0169 and CX1426, Exh. L(The power of POM in one little pill));

(e) 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% Juice daily… "POM Wonderful Pomegranate Juice has been proven to promote cardiovascular health, and we believe that POMx may have the same health benefits." Dr. Michael Aviram quote. (CX1426, Exh. I and CX1426_0038-0042 (Antioxidant Superpill)); and

(f) A randomized, placebo-controlled, double-blind clinical trial followed 289 subjects at moderate risk for coronary heart disease. These subjects consumed 8 ounces per day of either POM Wonderful 100% Pomegranate Juice or a placebo beverage. After 18 months, there was no reduction in the progression of intima-media thickness of the carotid artery (CIMT) in the group as a whole. However, further analysis revealed an indication that the rate of CIMT progression slowed in nearly one third of patients, those with elevated cardiovascular disease risk factors. Read the Study. (CX1426, Exh. E-1_0004, Rushton_004).

Response to Finding No. 2489:

Complaint Counsel does not disagree that the body copy excerpts in the proposed finding were *part of* the body copy of the ads cited, but disagrees that these descriptions can be analyzed in isolation or that the ads can be categorized by these descriptions. Complaint Counsel asserts that the appropriate analysis is to look at the overall, net impression created by each advertisement through the interaction of different elements in the advertisement, including language and visual elements, rather than focusing on individual elements or phrases in isolation. (*See* CCFF Sections V.D – V.F for the net impression analysis of each challenged ad). The body copy in these excerpts were among the elements that resulted in a net impression in each of these ads that the POM products referenced therein were clinically proven to treat, prevent, or reduce the risk of heart disease, including by decreasing arterial plaque.

2490. As described in the findings of facts related to Respondents' studies on heart health, the language quoted above accurately and truthfully summarized the Aviram Study (2004), which showed a comparative improvement in CIMT of 39% (CX0611). (*See infra* XIV(D)).

Response to Finding No. 2490:

The proposed finding mischaracterizes the cited evidence. *See* Responses to Findings in the cross-referenced section.

2491. Moreover, as further described in the findings of fact related to Respondents' studies on cardiovascular health, at the time the representations were made, Respondents had competent and reliable scientific evidence to support the statements made above. (*See infra* XIV(D)).

Response to Finding No. 2491:
The proposed finding is unsupported by the cited evidence. *See* Responses to Findings in the cross-referenced section.

2492. Complaint Counsel, however, claim that certain ads disseminated after May 2007 are false and misleading because these ads purportedly did not take into the accounts the results of the Davidson CIMT Study, which became available in May 2007. (Compl., ¶ 11). This is an erroneous view because Dr. Heber and Mr. Tupper both testified that the Dr. Davidson CIMT study was not inconsistent with Dr. Aviram's 2004 clinical study. Indeed, Dr. Davidson's CIMT Study was not a plaque study at all because he did not study anyone with significant plaque or stenosis. The subjects in Dr. Davidson's CIMT Study had a baseline IMT of .84/.78 mm, which were significantly below the 1.5 mm baseline in Dr. Aviram's 2004 study. This differences at baseline show that the participants in Dr. Aviram's study were at significant cardiovascular risk to the point of stenosis, while the participants in Dr. Davidson's were not. In fact, Dr. Davison excluded from his study anyone with significant plaque or stenosis. Accordingly, because Dr. Davidson's findings are in no way inconsistent with Dr. Aviram's, it was not false or misleading for POM to continue describing the results of Dr. Aviram's plaque study. (*See supra* XVI).

Response to Finding No. 2492:
The proposed finding is unsupported by the cited evidence and by the record as a whole. Respondents targeted their advertising to people with heart disease in their family, or who have a fear of having it themselves. (CCFF ¶ 300). Given the severity of disease in the population tested in the Aviram CIMT study, Respondents were aware that the study population was not representative of the target audience or the general public to whom they made the heart disease treatment and prevention claims. (CCFF ¶¶ 817-19). Thus, Respondents sponsored the Davidson study, which was designed to study persons at "moderate risk for coronary heart disease," specifically, those having one or more heart disease risk factors (high LDL, low HDL, hypertension, or current cigarette smoking) and a baseline CIMT of 0.2 to 2.0 mm. (*See* CCFF ¶ 879; CX1062_0001-02). This larger study showed that in persons at moderate risk of coronary heart disease, there was no improvement in CIMT. Thus, for the purpose of the Respondents' advertising, the Davidson Study is, in fact, inconsistent with the Aviram IMT study and establishes that

Respondents had no basis for their treatment and prevention claims related to heart disease targeted to a population with either no or mild to moderate risk of heart disease.

See also Responses to Findings in the cross-referenced section.

2493. Complaint Counsel are incorrect. As described at length, Respondents have proffered substantial evidence that (a) the Davidson CIMT study was not inconsistent with the Aviram Study (2004). (*See infra* XIV(F)).

Response to Finding No. 2493:
The proposed finding is unsupported by the cited evidence and by the record as a whole.

See Response to Finding 2492.

(3) Bev I Coronary Perfusion Study

2494. In the Bev I Study, Dr. Ornish and colleagues investigated whether the daily consumption of pomegranate juice for three months would affect myocardial perfusion (or blood flow) in forty-five patients who had coronary heart disease and myocardial ischemia (narrowing of the arteries) in a randomized, placebo-controlled, double-blind study. (PX0023). After three months, the extent of stress-induced ischemia (restriction of blood flow) decreased in the pomegranate group, but increased in the control group. (PX0023). In conclusion, the authors found that the daily consumption of pomegranate juice may improve stress-induced myocardial ischemia in patients who have coronary heart disease. (PX0023).

Response to Finding No. 2494:
The proposed finding is incomplete. The Bev I Study was a twelve month study that had two arms: (1) a 45-person "cardiac" group who underwent myocardial perfusion testing, and (2) a 17-person "carotid" group who underwent CIMT testing. (CCFF ¶¶ 824-25). The "cardiac" group, the results of which were published as the Ornish MP Study (2005), was based on testing to evaluate whether the daily consumption of pomegranate juice for 12 months would affect myocardial perfusion (blood flow) to the heart in patients with CHD and myocardial ischemia. (CCFF ¶¶ 826-27). The myocardial perfusion data was based on measures at baseline and *three months* (rather than twelve months) for myocardial perfusion – SSS, SRS, and SDS. (CCFF ¶ 827). The Ornish MP Study (2005) reported that a significant improvement at $p = .05$ was shown in SDS but not SSS

or SRS. (CCFF ¶ 827). In addition, the article reported no significant changes in blood pressure, cholesterol, LDL, HDL, or triglycerides. (CCFF ¶ 829). The authors of the study concluded that "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." (CCFF ¶ 828). With regard to the "carotid" group, the results CIMT results showed that POM Juice did not provide a benefit. (CCFF ¶ 829). (*See also* CCFF ¶¶ 843-54 (analysis of the study)).

2495. When describing the results of the Bev I Coronary Perfusion Study, POM's ads used the following body copy:

(a) 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. (CX0328 (Your New Healthcare Plan); CX0331 (Healthy, Wealthy & Wise); CX0337 (The First Bottle You Should Open in 2010); CX0280 (Live Long Enough To Watch Your 401(k) Recover); CX355 (The Only Antioxidant Supplement Rated X); CX279 (Science, not fiction); CX0180 (The Antioxidant Superpill); CX1426, Exhs. J Healthy, Wealthy & Wise) and K (The Antioxidant Superpill));

(b) 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, '05. (CX0342 (Take Out a Life Insurance Supplement); CX0353 (Take Out a Life Insurance Supplement); CX0350 (24 Scientific Studies Now In-One-Easy to Swallow Pill); CX0348));

(c) 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," Dr. Dean Ornish reported in the American Journal of Cardiology, '05. (CX0351 (The Only Antioxidant Supplement Rated X));

(d) 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. (CX0169 and CX1426, Exh. L(The power of POM in one little pill));

(e) And preliminary human research suggests that our California-grown pomegranate juice also promotes heart health. (CX0120 (One small pill for mankind); CX0122 (Science, not fiction);

(f) In two groundbreaking preliminary studies, patients who drank POM Wonderful 100% Pomegranate Juice experienced impressive cardiovascular results… 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, Exh. I and CX1426_0038-0042 (Antioxidant Superpill); and

(g) 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. This research is 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. Promising results from this research will be published in the September 16th issue of the American Journal of Cardiology, one of the leading peer-reviewed cardiology journals (www.ajconline.org). Researchers from the non-profit Preventive Medicine Research Institute, University of California, San Francisco, and California Pacific Medical Center studied patients with coronary heart disease who had reduced blood flow to the heart. These 45 patients were randomly assigned into one of two groups: one group who drank a glass of pomegranate juice each day (240 ml/day, which is approximately 8.5 oz/day) or to a placebo group, who drank a beverage of similar caloric content, amount, flavor and color. After only three months, blood flow to the heart improved approximately 17% in the pomegranate juice group but worsened approximately 18% in the comparison group (i.e., a 35% relative between-group difference). These differences were statistically significant. This benefit was observed without changes in cardiac medications or revascularization in either group. Also, there were no negative effects on lipids, blood glucose, hemoglobin Alc, body weight or blood pressure…. "Although the sample in this study was relatively small, the strength of the design and the significant improvements in blood flow to the heart observed after only three months suggest that pomegranate juice may have important clinical benefits in those with coronary heart disease," said senior author, Dean Ornish, M.D., who is founder of the Preventive Medicine Research Institute and clinical professor of medicine at UCSF. "Also, it may help to prevent it." (CX0044 (Press Release – Pomegranate Juice May Affect the Progression of Coronary Heart Disease)).

Response to Finding No. 2495:

Complaint Counsel does not disagree that the body copy excerpts in the proposed finding were *part of* the body copy of the ads cited, but disagrees that these descriptions can be analyzed in isolation or that the ads can be categorized by these descriptions. Complaint Counsel asserts that the appropriate analysis is to look at the overall, net impression created by each advertisement through the interaction of different elements in the advertisement, including language and visual elements, rather than focusing on individual elements or phrases in isolation. (*See* CCFF Sections V.D – V.F for the net impression analysis of each challenged ad). The body copy in these excerpts were among the elements that resulted in a net impression in each of these ads that the POM products referenced therein were clinically proven to treat, prevent, or reduce the risk of heart disease, including by improving blood flow to the heart.

2496. As described in the findings of fact related to Respondents' studies on heart health, the language quoted above accurately and truthfully summarized the Bev I Coronary Perfusion Study. (*See supra* XIV(D)).

Response to Finding No. 2496:
The proposed finding is unsupported by the cited evidence. *See* Responses to Findings in the cross-referenced section.

2497. Moreover, as further described in the findings of fact related to Respondents' studies on heart health, at the time the representations were made, Respondents had competent and reliable scientific evidence to support the statements made above. (*See supra* XIV(D)).

Response to Finding No. 2497:
The proposed finding is unsupported by the cited evidence. *See* Responses to Findings in the cross-referenced section.

(4) Aviram Study (2006)

2498. In an article entitled, "Pomegranate byproduct administration to apolipoprotein e-deficient mice attenuates atherosclerosis development as a result of decreased macrophage oxidative stress and reduced cellular uptake of oxidized low-density lipoprotein, J Agric Food Chem. 2006 Mar 8;54(5):1928-35, Dr. Aviram and colleagues found that the consumption of POMx by atherosclerotic mice E-deficient mice resulted in

a significant reduction in the mouse macrophage oxidative stress and in the atherogenic oxidized LDL uptake by the cells, and these effects were associated with a significant attenuation atherosclerotic lesion development. The authors concluded that POMx significantly attenuates atherosclerosis development by its antioxidant properties in vitro and in E-deficient mice. (CX0053).

Response to Finding No. 2498:

The proposed finding is incomplete. The study is on pomegranate by-product (PBP), made of pureed pomegranate husks after the juice was removed, which Respondents have not shown is the same as POMx. (*Compare* CX0053_0003 with CCFF ¶ 132). The authors concluded that PBP "possesses greater antiatherosclerotic characteristics compared to PJ, which could be related to its antioxidative properties and its impressive ability to inhibit macrophage uptake of atherogenic oxidized LDL." (CX0053_0008).

2499. The only alleged "ad" that summarized the Aviram Study (2006) was a July 2006 Press Release - POMx, a Highly Concentrated Form of Healthy Pomegranate Antioxidants, Becomes Available to Consumers for the First Time, which used the following body copy:

> According to Michael Aviram, DSc, Professor of Biochemistry and Head Lipid Research Laboratory, Technion Faculty of Medicine and Rambam Medical Center, Haifa, Israel, who was at the forefront of the initial research on pomegranates, the research on POMx looks very promising. In 2006, Aviram led a study on POMx which was recently published (*Journal of Agriculture and Food Chemistry*, 2006 54:1928-1935). Commenting on this research, Professor Aviram remarks, "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)

Response to Finding No. 2499:

Complaint Counsel does not disagree that the body copy excerpt in the proposed finding was *part of* the body copy of the ad cited, but disagrees that this descriptions can be analyzed in isolation or that the ad can be categorized by this description. Complaint Counsel asserts that the appropriate analysis is to look at the overall, net impression

created by each advertisement through the interaction of different elements in the advertisement, including language and visual elements, rather than focusing on individual elements or phrases in isolation. (*See* CCFF Sections V.D – V.F for the net impression analysis of each challenged ad). The body copy in this excerpt was among the elements that resulted in a net impression that the POM products referenced therein were clinically proven to treat, prevent, or reduce the risk of heart disease.

2500. As described in the findings of fact related to Respondents' studies on heart health, the language quoted above accurately and truthfully summarized the Aviram Study (2006). (*See supra* XIV(F)).

Response to Finding No. 2500:
The proposed finding is unsupported by the cited evidence. *See* Responses to Findings in the cross-referenced section.

2501. Moreover, as further described in the findings of fact related to Respondents' studies on heart health, at the time the representations were made, Respondents had competent and reliable scientific evidence to support the statements made above. (*See supra* XIV(D)).

Response to Finding No. 2501:
The proposed finding is unsupported by the cited evidence. *See* Responses to Findings in the cross-referenced section.

(d) Erectile Health – Forest/Padma-Nathan RCT Study

2502. The Forest/Padma-Nathan RCT Study engaged 53 completed subjects with mild-to-moderate erectile dysfunction who underwent two four-week treatment periods separated by a two-week washout. (PX0189 at ¶ 32; CX0908). A total of 42 subjects demonstrated improved Global Assessment Question (GAQ) scores, 25 after drinking pomegranate juice. (PX0189 at ¶ 32; CX0908). Overall, the GAQ scores demonstrated that pomegranate juice drinkers enjoyed a nearly 50% better improvement in erections over placebo drinkers. (CX0908-0003; PX0352 (Goldstein, Dep. at 109, 144); CX1338 (Padma-Nathan, Dep. at 191 – 192)).

Response to Finding No. 2502:
The proposed finding is incomplete because the Forest Erectile Dysfunction Study (2007) lacked statistically significant results for the GAQ, which is not a validated tool for

measuring erectile function, and does not show that pomegranate juice treats, prevents, or reduces the risk of erectile dysfunction. (CCFF ¶¶ 1067, 1069, 1072-74, 1076-77, 1086-90).

2503. When describing the results of the Forest/Padma-Nathan Study, POM's ads used the following body copy:

(a) 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 power 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. (CX0351 (The Only Antioxidant Supplement Rated X));

(b) 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 [sic] of POM Wonderful 100% Pomegranate Juice daily for four weeks were 50% more likely to experience improved erections. (CX1426, Exh. E-2 (POM Wonderful website)); and

(c) According 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) … This randomized, placebo-controlled, double-blind, crossover pilot study examined the efficacy of pomegranate juice versus placebo in improving erections in 61 male subjects. To qualify, participants had to experience mild to moderate ED for at least 3 months; be in a stable, monogamous relationship with a consenting female partner, and be willing to attempt sexual intercourse on at least one occasion per week during each study period. … For the first four weeks of the study, the subjects were assigned to drink either 8 oz of POM Wonderful Pomegranate Juice or 8 oz. or placebo beverage daily with their evening meal or shortly after. After a two-week washout period during which the subjects did not consume any study beverage nor utilize any ED treatment, they were assigned to drink 8 oz. of the opposite study beverage every evening for another four weeks. … Forty seven percent of the subjects reported that their erections improved with POM Wonderful Pomegranate Juice, while only 32% reported improved erections with the placebo ($p=0.058$). … Although the study did not achieve overall statistical significance, the authors conclude that additional studies with more patients and longer treatment periods may in fact reach statistical significance. The strong directional results of this pilot study are encouraging because almost half of the test subjects experienced a benefit simply by adding pomegranate juice to their daily diet, without the use of ED drugs. Researchers believe that the results might be due to the potent antioxidant content of pomegranate juice, which can prevent free radical molecules from disrupting proper circulatory function. … According

to study co-author Harin Padma-Nathan, MD, FACS, FRCS, Clinical Professor of Urology at the Keck School of Medicine, University of Southern California, "These findings are very encouraging as they suggest there is a non-invasive, non-drug way to potentially alleviate this qualify 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 (Press Release – POM Wonderful 100% Pomegranate Juice May Improve Mild to Moderate Cases of Erectile Dysfunction)).

Response to Finding No. 2503:

Complaint Counsel does not disagree that the body copy excerpts in the proposed finding were *part of* the body copy of the ads cited, but disagrees that these descriptions can be analyzed in isolation or that the ads can be categorized by these description. Complaint Counsel asserts that the appropriate analysis is to look at the overall, net impression created by each advertisement through the interaction of different elements in the advertisement, including language and visual elements, rather than focusing on individual elements or phrases in isolation. (*See* CCFF Sections V.D – V.F for the net impression analysis of each challenged ad). The body copy in these excerpts were among the elements that resulted in a net impression in each of these ads that the POM products referenced therein were clinically proven to treat, prevent, or reduce the risk of erectile dysfunction.

2504. As described in the findings of fact related to Respondents' studies on erectile health, the language quoted above accurately and truthfully summarized the Forest/Padma-Nathan Study. (*See supra* XVI).

Response to Finding No. 2504:

The proposed finding mischaracterizes the evidence and is incomplete. The Forest Erectile Dysfunction Study (2007) studied men with mild to moderate erectile dysfunction and not erectile health. (CCFF ¶¶ 426-27, 429, 1064). The cited advertisements did not accurately or completely communicate the findings from the Forest Erectile Dysfunction Study (2007), such as how the GAQ and IIEF results were

not statistically significant, or that the GAQ was not a validated tool for measuring erectile function. (CCFF ¶¶ 1067, 1069, 1072-74, 1076-77, 1086-90).

See also Responses to Findings in the cross-referenced section.

2505. Moreover, as further described in the findings of fact related to Respondents' studies on erectile health, at the time the representations were made, Respondents had competent and reliable scientific evidence to support the statements made above. (*See supra* XVI).

Response to Finding No. 2505:
The proposed finding mischaracterizes the evidence. The Respondents' evidence involved erectile dysfunction, not erectile health, and did not support a claim that drinking eight ounces of pomegranate juice daily treats, prevents, or reduces the risk of erectile dysfunction in humans. (*See* CCFF ¶¶ 1086-90). *See also* Responses to Findings in the cross-referenced section.

(e) Each Category Of "Specific Study" Ads Are Also Qualified

2506. Each of the "specific study" ads discussed above describes the results of the studies using very qualified language.

(a) For example, the science was described as being "emerging science". (CX0328 (Your New Healthcare Plan); CX0331 (Healthy, Wealthy & Wise); CX0280 (Live Long Enough to Watch Your 401(k) Recover); CX0355 (The Only Antioxidant Supplement Rated X); CX1426, Exh. I (Antioxidant Superpill), J (Healthy, Wealthy & Wise), and L (The power of POM in one little pill); CX0342 (Take Out a Life Insurance Supplement); CX0353 (Take Out a Life Insurance Supplement); CX0350 (24 Scientific Studies Now In One Easy-To-Swallow Pill); CX0348 (24 Scientific Studies Now In One Easy-To-Swallow Pill); CX0351 (The Only Antioxidant Supplement Rated X); CX0169 (The power of POM in one little pill));

(b) The research results were described using qualified language such as being either "promising", "hopeful" or encouraging. ((CX0328 (Your New Healthcare Plan); CX0331 (Healthy, Wealthy & Wise); CX0280 (Live Long Enough to Watch Your 401(k) Recover); CX0355 (The Only Antioxidant Supplement Rated X); CX0180 (The Antioxidant Superpill); CX1426, Exhs. J (Healthy, Wealthy & Wise), K (The Antioxidant Superpill), L (The power of POM in one little pill), and M (Dreher Heart Newsletter); CX0342 (Take Out a Life Insurance Policy); CX0353 (Take Out a Life Insurance Policy) ; CX0350 (24 Scientific Studies Now In One Easy-To-Swallow Pill); CX0348 (24 Scientific Studies Now In One Easy-To-Swallow Pill); CX0351 (The Only Antioxidant Supplement Rated X); CX0169

(The power of POM in one little pill); CX0120 (One small pill for mankind); CX0314_0008 (POM Wonderful and Prostate Health); CX0314_0004 (POM Wonderful and Prostate Health); CX0372_0002 (Holy Health! $32 million in medical research); CX0379_0002 (Holy Health! $32 million in medical research); CX0380_0002 (Holy Health! $32 million in medical research) ; CX0128 (Press Release – POM Wonderful 100% Pomegranate Juice May Improve Mild to Moderate Cases of Erectile Dysfunction); CX0065 (Press Release – POMx, a Highly Concentrated Form of Healthy Pomegranate Antioxidants, Becomes Available to Consumers for the First Time); CX0044 (Press Release – Pomegranate Juice May Affect the Progression of Coronary Heart Disease));

(c) Likewise, the benefits from the research only "suggest" or "may indicate" benefits. (CX0169 (The power of POM in one little pill0; CX1426, Exh. L (The power of POM in one little pill) and N (Dreher Prostate Newsletter); CX0314_0008 (POM Wonderful and Prostate Health); CX0314_ 0004 (POM Wonderful and Prostate Health); CX0372_0002 (Holy Health! $32 million in medical research); CX0379_0002 (Holy Health! $32 million in medical research); CX0380_0002 (Holy Health! $32 million in medical research); CX0120 (One small pill for mankind); CX0122 (Science, not fiction));

(d) And the studies were either "initial" or "preliminary". (CX0328 (Your New Healthcare Plan); CX0331 (Healthy, Wealthy & Wise); CX0280 (Live Long Enough To Watch Your 401(k) Recover); CX0355 (The Only Antioxidant Supplement Rated X); CX0279 (Science, not fiction); CX0180 (The Antioxidant Superpill); CX1426, Exh. B (Drink to prostate health), I (Antioxidant Superpill), J (Healthy, Wealthy & Wise), K (The Antioxidant Superpill), L (The power of POM in one little pill), M (Dreher Heart Newsletter) and N (Dreher Prostate Newsletter); CX0342 (Take Out a Life Insurance Supplement); CX0353(Take Out a Life Insurance Supplement); CX0350 (24 Scientific Studies Now In One-Easy-To Swallow Pill); CX0348 (24 Scientific Studies Now In One-Easy-To Swallow Pill); CX0351 (The Only Antioxidant Supplement Rated X); CX0169 (The power of POM in one little pill); CX 0120 (One small pill for mankind); CX0260 (Drink to prostate health); CX0122 (Science, not fiction); CX0128 (Press Release – POM Wonderful 100% Pomegranate Juice May Improve Mild to Moderate Cases of Erectile Dysfunction));

(e) Rather than a definitive statement, the ads stated that "pomegranate juice may help" and that the juice "promotes" health. (CX1426, Exh. M (Dreher Heart Newsletter)); and

(f) Similarly, the ads stated that antioxidants are "helping to prevent". (CX0029 (Studies Show That 10 Out of 10 People Don't Want to Die); CX1426, Exhs. I (Antioxidant Superpill) and M (Dreher Heart Newsletter)).

Response to Finding No. 2506:

Complaint Counsel does not disagree that POM's cited ads include *some* of the elements described above, among many others, but Complaint Counsel disagrees that these elements can be analyzed in isolation or that the ads can be categorized by these elements. Complaint Counsel asserts that the appropriate analysis is to look at the overall, net impression created by each advertisement through the interaction of different elements in the advertisement, including language and visual elements, rather than focusing on individual elements or phrases in isolation. (*See* CCFF Sections V.D – V.F for the net impression analysis of each challenged ad). Complaint Counsel also notes that some of the ads cited in Finding No. 2506(b) and (c) are individual pages of a multi-page magazine wrap, and not individual ads. *See* Response to Finding 2252.

2. POM Disseminated "Backed By" Ads That Are Not False and Misleading Because They Accurately and Truthfully Represented Respondents' Expenditures on Scientific Studies on the Challenged Products and Conveyed Qualified Messages

2507. The second category, "backed by" ads, stated that Respondents spent a particular amount of money on their scientific studies on the Challenged Products to back-up Respondents' healthy claims.

Response to Finding No. 2507:

Complaint Counsel does not disagree that many of POM's ads included the claim described above, among many others, but Complaint Counsel disagrees that this element can be analyzed in isolation or that the ads can be categorized by this element. Complaint Counsel asserts that the appropriate analysis is to look at the overall, net impression created by each advertisement through the interaction of different elements in the advertisement, including language and visual elements, rather than focusing on individual elements or phrases in isolation. (*See* CCFF Sections V.D – V.F for the net impression analysis of each challenged ad).

2508. Examples of the body copy used in the "backed by" ads read, in pertinent part:

(a) POM 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. (CX0109 (Heart therapy));

(b) 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. (CX0188 (Cheat death); CX0192 (What gets your heart pumping?));

(c) Backed by $25 million in medical research. (CX1426, Exh. A (Super HEALTH Powers!); CX0314_0009 (The proof is in the POM); CX0314_0005 (The proof is in the POM); CX1426_0027 (Super HEALTH Powers!));

(d) Backed by an unheard of $25 million in medical research. (CX1426, Exh. D (Holy Health! $25 million in medical research));

(e) Backed by $25 million in vigilant medical research. (CX0274 (I'm off to save prostates));

(f) Only POM products are backed by $32 million in medical research conducted at the world's leading universities, primarily in the areas of cardiovascular, prostate and erectile function. (CX0372_0003 (KA-POM!); CX0379_0003 (KA-POM!); CX0380_0003 ((KA-POM!));

(g) Can POM products $32 million in medical research truly make a difference in the current state of your health? (CX0380_0006 and CX0372_0004 (100% PURE pomegranate juice to the rescue)); and

(h) One of the POM products backed by $32 million in medical research. (CX0379_0004 (Risk your health in this economy? NEVER!); CX1426, Exh. C (I'm off to save PROSTATES!));

(i) POM is the only pomegranate juice backed by $25 million in medical research. (CX1426, Exh. E-003, Rushton_003 (POM Truth website); and

(j) POM Wonderful 100% Pomegranate Juice is the only pomegranate juice backed by $25 million in medical research. (CX1426, Exh. E-1_0001, Rushton_001) POM Truth website)).

Response to Finding No. 2508:

Complaint Counsel does not disagree that the body copy excerpts in the proposed finding were *part of* the body copy of the ads cited, but disagrees that these descriptions can be analyzed in isolation or that the ads can be categorized by these description. Complaint Counsel asserts that the appropriate analysis is to look at the overall, net impression

created by each advertisement through the interaction of different elements in the advertisement, including language and visual elements, rather than focusing on individual elements or phrases in isolation. (*See* CCFF Sections V.D – V.F for the net impression analysis of each challenged ad). Complaint Counsel also notes that some of the ads cited in Findings 2508 (c), (f), (g) and (h) are individual pages of a multi-page magazine wrap, *see* Response to Finding 2252, and not individual ads. The body copy in these excerpts were among the elements that resulted in a net impression in these ads that the POM products referenced therein were clinically proven to treat, prevent, or reduce the risk of heart disease, prostate cancer, or erectile dysfunction.

2509. The following ads also fall into the "backed by" category and contain body copy that is similar or almost identical to the ads described above: CX0251 (Imitation may be sincere. But is it pure?); CX0314_0010 (Ingredients: pomegranates, $25 million in medical research) CX0103 (Decompress); CX0328 (Your New Health Care Plan); CX0331 (Healthy, ~~Wealthy~~, and Wise.); CX0337 (The First Bottle You Should Open in 2010); CX0280 (Live Long Enough to Watch your 401(k) Recover); CX0355 (The Only Antioxidant Supplement Rated X); CX0279 (Science, not fiction.); CX0180 (The antioxidant superpill); CX1426, Exh. J (Healthy, ~~Wealthy~~, and Wise.); CX1426, Exh. K (The antioxidant superpill); CX0342 (Take Out a Life Insurance Supplement); CX0353 (Take Out a Life Insurance Supplement); CX0350 (24 Scientific Studies Now in One Easy-To-Swallow Pill); CX0348 (24 Scientific Studies Now in One Easy-To-Swallow Pill); CX0351 (The Only Antioxidant Supplement Rated X); CX0169 (The power of POM, in one little pill); CX1426, Exh. L (The power of POM, in one little pill); CX1426, Exh. M (Dreher Heart Newsletter); CX0122 (Science, not fiction); CX1426, Exh. I (Antioxidant Superpill); CX1426, Exh. N (Dreher Prostate Newsletter); CX0372_0002 (HOLY HEALTH! $32 million in medical research); CX0372_0003 (KA-POM!); CX0372_0004 (100% PURE pomegranate juice to the rescue!); CX0379_0002 (HOLY HEALTH! $32 million in medical research); CX0379_0003 (KA-POM!) CX0379_0004 (Risk your health in this economy? NEVER!) CX0380_0002 (HOLY HEALTH! $32 million in medical research); CX0380_0003 (KA-POM!); CX0380_0006 (100% PURE pomegranate juice to the rescue!); CX0314_0005 (The proof is POM); CX0314_0009 (The proof is POM); CX0109 (Heart therapy); CX0188 (Cheat death); CX0192(What gets your heart pumping?); CX1426, Exh. A (Super HEALTH POWERS!); CX1426, Exh. D (HOLY HEALTH! $25 million in medical research); CX0274 (I'm off to save PROSTATES!); and CX1426, Exh. C (I'm off to save PROSTATES!))

Response to Finding No. 2509:

Complaint Counsel does not disagree that the ads cited in the proposed finding include body copy identical or very similar to the excerpts in Finding 2508, and that these excerpts were *part of* the body copy of the ads cited. However, Complaint Counsel disagrees that these phrases can be analyzed in isolation or that the ads can be categorized by these phrases. Complaint Counsel asserts that the appropriate analysis is to look at the overall, net impression created by each advertisement through the interaction of different elements in the advertisement, including language and visual elements, rather than focusing on individual elements or phrases in isolation. (*See* CCFF Sections V.D – V.F for the net impression analysis of each challenged ad). The body copy in these excerpts were among the elements that resulted in a net impression in these ads that the POM products referenced therein were clinically proven to treat, prevent, or reduce the risk of heart disease, prostate cancer, or erectile dysfunction. Complaint Counsel also notes that some of the ads cited in the proposed finding are individual pages of a multi-page magazine wrap, and not individual ads. *See* Response to Finding 2252.

2510. Respondents' "backed by" ads described above are not false or misleading because they accurately represented the dollars spent by Respondents on the totality of the science on the Challenged Products, including basic, animal and human studies, at the time the representations were made. (S*ee supra* XVII(G)(2)).

Response to Finding No. 2510:

The proposed finding is incorrect and unsupported by the cited evidence. (*See* CCFF ¶¶ 309-11, 318-24). The cited evidence is nonsensical because it is simply a general reference to this entire subsection.

2511. The studies done 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. (CX1276)

Response to Finding No. 2511:

The proposed finding is unsupported by the cited evidence, which does not show that the studies "are sufficiently interrelated," and by the record as a whole. (*See* CCFF ¶¶ 309-11, 318-24). Moreover, Mr. Tupper admitted in testimony that some of the research, for example, that on cattle health, was not done as an animal model for human research, but "to see if there's a benefit to the cattle themselves." (Tupper, Tr. 934).

2512. Even the fact that POM's ads listed an amount of money spent on Respondents' scientific studies that had a null or even negative result is not false or misleading. (S*ee supra* XI(B),(C)).

Response to Finding No. 2511:
Complaint Counsel disagrees with the proposed finding. (*See* CCFF ¶¶ 309-11, 318-24).

See also Responses to Findings in the cross-referenced sections.

2513. 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).

Response to Finding No. 2513:
Complaint Counsel has no specific response.

2514. In fact, Respondents' substantially understated the dollars spent on research in their advertising because they excluded all overhead items, such as rent and salaries very significant added costs. (Tupper, Tr. 2999-3000).

Response to Finding No. 2514:
Complaint Counsel has no specific response.

2515. Moreover, Complaint Counsel has presented no evidence that any significant number of consumers bought POM Juice because they thought Respondents spent a certain amount of money in a particular area of research.

Response to Finding No. 2515:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel reiterates its response that it is inappropriate to focus on isolated elements or phrases in the ads, rather than the net impression of the ads as a whole.

2516. Indeed, Professor Reibstein's uncontroverted survey showed that no one bought POM Juice because of the amount of money spent on science. (PX0223-0006)

Response to Finding No. 2516:
The proposed finding is unsupported by the record as a whole. The Reibstein survey was seriously flawed and inadequate as a measure of the purchase motivations of POM Juice purchasers, asking only asked broad open-ended questions with no probing. (PX0359 (Mazis, FTC Dep. at 54-56); CX1297 (Mazis, Report at 0009-10); Mazis, Tr. 2731).

2517. Each of the "backed by" ads discussed above conveyed qualified messages.

(a) For example, the ads stated that the juice is "committed" to keeping you healthy or that it would "help guard" or "help fight". (CX0109 (Heart therapy); CX0188 (Cheat death); CX0192 (What gets your heart pumping?); CX0274 (I'm off to save PROSTATES!); CX1426, Exh. A (Super HEALTH Powers!0; CX1426, Exh. C (Drink to prostate health));

(b) The science was described as being "emerging science". (CX0109 (Heart therapy); CX0188 (Cheat death); CX0192 (What gets your heart pumping?));

(c) The research results were described using qualified language such as being either "encouraging". (CX0109 (Heart therapy); CX0188 (Cheat death); CX0192 (What gets your heart pumping?)); and

(d) Likewise, the scientific research was described as being "initial". (CX0109 (Heart therapy); CX0192 (What gets your heart pumping?)).

Response to Finding No. 2517:
Complaint Counsel disagrees with the proposed finding. Moreover, Complaint Counsel disagrees that particular phrases or elements can be analyzed in isolation or that the ads can be categorized by use of these phrases. Complaint Counsel asserts that the appropriate analysis is to look at the overall, net impression created by each advertisement through the interaction of different elements in the advertisement, including language and visual elements, rather than focusing on individual elements or phrases in isolation. (*See* CCFF Sections V.D – V.F for the net impression analysis of each challenged ad).

3. POM Disseminated "Antioxidant" Ads That Are Not False or Misleading Because They Are Supported By Competent and Reliable Scientific Evidence and Conveyed Qualified Messages

2518. The third category, "antioxidant" ads, discussed the potential benefits of antioxidants and stated that the Challenged Products contained antioxidants. (*See* Appendix of Ads).

Response to Finding No. 2518:
Complaint Counsel does not disagree that POM's ads include some of the elements described above, among many others, but Complaint Counsel disagrees that these elements can be analyzed in isolation or that the ads can be categorized by these elements. Complaint Counsel asserts that the appropriate analysis is to look at the overall, net impression created by each advertisement through the interaction of different elements in the advertisement, including language and visual elements, rather than focusing on individual elements or phrases in isolation. (*See* CCFF Sections V.D – V.F for the net impression analysis of each challenged ad and Responses to Findings in the cross-referenced Appendix).

2519. The "antioxidant" ads can be grouped into four sub-categories: (a) general antioxidant; (b) comparative antioxidant, (c) antioxidant benefits and (d) multi-step.

Response to Finding No. 2519:
Complaint Counsel disagrees that these elements can be analyzed in isolation or that the ads can be categorized by these elements. Complaint Counsel asserts that the appropriate analysis is to look at the overall, net impression created by each advertisement through the interaction of different elements in the advertisement, including language and visual elements, rather than focusing on individual elements or phrases in isolation. (*See* CCFF Sections V.D – V.F for the net impression analysis of each challenged ad).

(b) General Antioxidant

2520. The first sub-category, "general antioxidant", described POM Juice as the "Antioxidant Superpower" and/or full of antioxidants and POMx Pills as the "Antioxidant Superpill" and/or a concentrated and potent source of antioxidants. (*See* Appendix of Ads).

Response to Finding No. 2520:

Complaint Counsel does not disagree that POM's ads include some of the elements and phrases described above, among many others, but Complaint Counsel disagrees that these elements can be analyzed in isolation or that the ads can be categorized by these elements. Complaint Counsel asserts that the appropriate analysis is to look at the overall, net impression created by each advertisement through the interaction of different elements in the advertisement, including language and visual elements, rather than focusing on individual elements or phrases in isolation. (*See* CCFF Sections V.D – V.F for the net impression analysis of each challenged ad). *See also* Responses to Findings in the cross-referenced Appendix.

2521. Examples of the body copy used in POM's "general antioxidant" ads include the following:

(a) The Antioxidant Superpower. (CX1426, Exh. A (Super HEALTH Powers); CX1426, Exh. C (I'm off to save PROSTATES!); CX1426, Exh. D (Holy Health $25 million in medical research); CX1426, Exh. H (I'm off to save PROSTATES!); CX1426, Exh. G (Amaze your urologist); CX0468 (Amaze your urologist); CX0314_0005 (The Proof is in the POM); CX0314_0006 (The Antioxidant Superpower); CX0314_0009 (The proof is in the POM); CX0380_0001 (Lucky I have super HEALTH POWERS!); CX0380_0003 (KA-POM!); CX0380_0004 (Have no health fear… POM IS HERE!); CX0380_0005 (Lucky I have HEALTH POWERS!); CX0380_0006 (100% PURE pomegranate juice to the rescue); CX0380_0007 (Lucky I have super HEALTH POWERS!); CX0372_0001 (Lucky I have super HEALTH POWERS!); CX0372_0003 (KA-POM!); CX0372_0004 (100% PURE pomegranate juice to the rescue); CX0379_0001 (Lucky I have super HEALTH POWERS!); CX0379_0003 (KA-POM!); CX0379_0004 (Risk your health in this economy? NEVER!); CX0036 (Cheat death); CX0031 (Floss your arteries. Daily); CX0034 (Amaze your cardiologist); CX0103 (Decompress); CX0109 (Heart therapy); CX0192 (What gets your heart pumping?) ; CX0274 (I'm off to save PROSTATES!));

(b) The Antioxidant Superpill. (CX0328 (Your New Health Care Plan); CX0331 (Healthy, Wealthy, and Wise); CX0337 (The First Bottle You Should Open in 2010); CX0280 (Live Long Enough to Watch your 401(k) Recover); CX0355 (The Only Antioxidant Supplement Rated X); CX1426, Exh. K (The Antioxidant Superpill); CX0342 (Take Out a Life Insurance Supplement); CX0353 (Take Out a Life Insurance Supplement); CX0350 (24 Scientific Studies Now In One Easy-To-Swallow Pill); CX0348 (24 Scientific Studies Now In One Easy-To-Swallow

Pill); CX0351 (The Only Antioxidant Supplement Rated X); CX0169 (The power of POM, in one little pill); CX1426, Exh. L (The power of POM, in one little pill); CX1426, Exh. I (Antioxidant Superpill));

(c) We only grow "Wonderful" variety pomegranates, renowned for their superior antioxidants and delicious taste. (CX0314_0005 (The proof is in the POM); CX0314_0009 (The proof is in the POM); CX0372_0003 (KA-POM!); CX0379_0003 (KA-POM!); CX0380_0003 (KA-POM!);

(d) Pomegranate contains powerful antioxidants. (CX1426, E-3 (POM Wonderful Video Ads));

(e) POMx is an all-natural, ultra potent antioxidant extract. Containing a full spectrum of pomegranate polyphenols, POMx is so concentrated that a single capsule has the antioxidant power of a full glass of POM Wonderful 100% Pomegranate Juice. (CX0328 (Your New Health Care Plan); CX0331 (Healthy, Wealthy, and Wise); CX0337 (The First Bottle You Should Open in 2010); CX0355 (The Only Antioxidant Supplement Rated X); CX1426, Exh. J (Healthy, Wealthy, and Wise); CX0342 (Take Out a Life Insurance Supplement); CX0353 (Take Out a Life Insurance Supplement); CX0350 (24 Scientific Studies Now In One Easy-To-Swallow Pill); CX0348 (24 Scientific Studies Now In One Easy-To-Swallow Pill); CX0351 (The Only Antioxidant Supplement Rated X));

(f) The unique and superior antioxidant power of pomegranates. (CX0328 (Your New Health Care Plan); CX0331 (Healthy, Wealthy, and Wise); CX0337 (The First Bottle You Should Open in 2010); CX0280 (Live Long Enough to Watch your 401(k) Recover); CX0355 (The Only Antioxidant Supplement Rated X); CX1426, Exh. J (Healthy, Wealthy, and Wise); CX0342 (Take Out a Life Insurance Supplement); CX0353 (Take Out a Life Insurance Supplement); CX0350 (24 Scientific Studies Now In One Easy-To-Swallow Pill); CX0348 (24 Scientific Studies Now In One Easy-To-Swallow Pill); CX0351(The Only Antioxidant Supplement Rated X));

(g) Ready to take on free radicals? Put up your POMx and fight them with a mighty 1000mg capsule – that's more concentrated pomegranate polyphenol antioxidants than any other 100% pomegranate supplement. (CX0120 (One small pill for mankind); CX0122 (24 Scientific Studies Now In One Easy-To-Swallow Pill)); and

(h) POMx is a highly concentrated, powerful blend of polyphenol antioxidants made from the very same pomegranates as POM Wonderful 100% Pomegranate Juice … just 100% pomegranate polyphenol antioxidants . . . . (CX0169 (The power of POM, in one little pill); CX1426, Exh. L (The power of POM, in one little pill)).

Response to Finding No. 2521:

Complaint Counsel does not disagree that the body copy excerpts in the proposed finding were *part of* the body copy of the ads cited, but disagrees that these descriptions can be analyzed in isolation or that the ads can be categorized by these descriptions. Complaint Counsel asserts that the appropriate analysis is to look at the overall, net impression created by each advertisement through the interaction of different elements in the advertisement, including language and visual elements, rather than focusing on individual elements or phrases in isolation. (*See* CCFF Sections V.D – V.F for the net impression analysis of each challenged ad). The body copy in these excerpts describing the health benefits of antioxidants and representing that POM products were high in antioxidants were among the elements that resulted in a net impression in these ads that the POM products referenced therein were effective in treating, preventing, or reducing the risk of heart disease, prostate cancer, or erectile dysfunction. Complaint Counsel also notes that some of the ads cited in Findings 2521(a) and (c) are individual pages of a multi-page magazine wrap, and not individual ads. *See* Response to Finding 2252.

2522. The following ads also fall into the "general antioxidant" category and contain body copy that is similar or almost identical to the ads described above: CX0016; CX1426, Exh. I; CX0280; CX0279; CX0180; CX1426, Exh. K; CX0120; and CX0122.

Response to Finding No. 2522:

Complaint Counsel does not disagree that the ads cited in the proposed finding include body copy identical or very similar to the excerpts in Finding 2521, and that these excerpts were *part of* the body copy of the ads cited. However, Complaint Counsel disagrees that these descriptions can be analyzed in isolation or that the ads can be categorized by these descriptions. Complaint Counsel asserts that the appropriate analysis is to look at the overall, net impression created by each advertisement through the interaction of different elements in the advertisement, including language and visual

elements, rather than focusing on individual elements or phrases in isolation. (*See* CCFF Sections V.D – V.F for the net impression analysis of each challenged ad).

2523. As exemplified in the body copy quoted above, the overall net impression of "general antioxidant" category of ads is not that the Challenged Products are "clinically proven" to prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction. (*See* Appendix of Advertisements).

Response to Finding No. 2523:
Complaint Counsel disagrees with the proposed finding regarding the net impression of the advertisements cited. (*See* CCFF Sections V.D – V.F for the net impression analysis of each challenged ad). *See also* Responses to Findings in the cross-referenced Appendix.

2524. Dr. Butters testified that 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).

Response to Finding No. 2524:
The proposed finding is mischaracterizes the cited testimony. Dr. Butters said that a "superhero" was a work of fiction and not that the "superpower" ads were intended to be "a work of fiction." (Butters, Tr. 2906).

2525. Moreover, POM's ads in this category are truthful and adequately supported by competent and reliable scientific evidence. (*See supra* XII, XIV, XV, XVI).

Response to Finding No. 2525:
The proposed finding is incorrect. *See* Responses to Findings in the cross-referenced sections.

(c) Comparative Antioxidant

2526. The second sub-category, "comparative antioxidant", described POM Juice as surpassing other drinks in its antioxidant capacity. (*See* Appendix of Ads).

Response to Finding No. 2526:
Complaint Counsel does not disagree that POM's ads include some of the elements and phrases described above, among many others, but Complaint Counsel disagrees that these

elements can be analyzed in isolation or that the ads can be categorized by these elements. Complaint Counsel asserts that the appropriate analysis is to look at the overall, net impression created by each advertisement through the interaction of different elements in the advertisement, including language and visual elements, rather than focusing on individual elements or phrases in isolation. (*See* CCFF Sections V.D – V.F for the net impression analysis of each challenged ad). *See also* Responses to Findings in the cross-referenced Appendix.

2527. Examples of the body copy used in POM's "comparative antioxidant" ads include the following:

(a) [W]ith more naturally occurring antioxidant power than any other drink . . . Since our bodies don't produce enough antioxidants to do the job on their own, we need a little outside help. POM Wonderful Pomegranate Juice, with a higher level of antioxidants than any other drink, is a real Antioxidant Superpower. (CX0029 (Studies Show That 10 out of 10 People Don't Want To Die)); and

(b) Sip for sip, POM Wonderful 100% Pomegranate Juice has more polyphenol antioxidants than red wine, green tea and other juices. (CX0314_0005 (The proof is in the POM); CX0314_0009 (The proof is in the POM); CX0372_0003 (KA-POM!); CX0379_0003 (KA-POM!); CX0380_0003 (KA-POM!)).

Response to Finding No. 2527:

Complaint Counsel does not disagree that the body copy excerpts in the proposed finding were *part of* the body copy of the ads cited, but disagrees that these descriptions can be analyzed in isolation or that the ads can be categorized by these descriptions. Complaint Counsel asserts that the appropriate analysis is to look at the overall, net impression created by each advertisement through the interaction of different elements in the advertisement, including language and visual elements, rather than focusing on individual elements or phrases in isolation. (*See* CCFF Sections V.D – V.F for the net impression analysis of each challenged ad). Although Complaint Counsel is not specifically challenging Respondents' claims of superior antioxidant levels compared to other

beverages, the body copy in these excerpts describing the health benefits of antioxidants and representing that POM products were high in antioxidants were among the elements that resulted in a net impression in these ads that the POM products referenced therein were effective in treating, preventing, or reducing the risk of heart disease, prostate cancer, or erectile dysfunction. Complaint Counsel also notes that the ads cited in Finding 2527(b) are individual pages of multi-page magazine wraps, and not individual ads. *See* Response to Finding 2252.

2528. The following ads also fall into the "comparative antioxidant" category and contain body copy that is similar or almost identical to the ads described above: CX0314_0006 (The Antioxidant Superpower), CX0031 (Floss your artery).

Response to Finding No. 2528:

Complaint Counsel does not disagree that the ads cited in the proposed finding include body copy identical or very similar to the excerpts in Finding 2527, and that these excerpts were *part of* the body copy of the ads cited. However, Complaint Counsel disagrees that these descriptions can be analyzed in isolation or that the ads can be categorized by these descriptions. Complaint Counsel asserts that the appropriate analysis is to look at the overall, net impression created by each advertisement through the interaction of different elements in the advertisement, including language and visual elements, rather than focusing on individual elements or phrases in isolation. (*See* CCFF Sections V.D – V.F for the net impression analysis of each challenged ad). Although Complaint Counsel is not specifically challenging Respondents' claims of superior antioxidant levels compared to other beverages, the body copy in these excerpts describing the health benefits of antioxidants and representing that POM products were high in antioxidants were among the elements that resulted in a net impression in these ads that the POM products referenced therein were effective in treating, preventing, or

reducing the risk of heart disease, prostate cancer, or erectile dysfunction. Complaint Counsel also notes that CX0314_0006 is an individual pages of a multi-page magazine wrap, and not an individual ad. *See* Response to Finding 2252.

2529. As exemplified in the body copy quoted above, POM's ads in the "comparative antioxidant" category, the overall net impression of "comparative antioxidant" category of ads is not that the Challenged Products are "clinically proven" to prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction. (*See* Appendix of Advertisements).

Response to Finding No. 2529:
Complaint Counsel disagrees with the proposed finding regarding the net impression of the advertisements cited. (*See* CCFF Sections V.D – V.F for the net impression analysis of each challenged ad). *See also* Responses to Findings in the cross-referenced Appendix.

2530. Moreover, POM's ads in this category are truthful and adequately supported by competent and reliable scientific evidence. (*See supra* XII, XIV, XV, XVI).

Response to Finding No. 2530:
The proposed finding is incorrect. *See* Responses to Findings in the cross-referenced sections.

(d) Antioxidant Benefits

2531. The third sub-category, "antioxidant benefits" state that POM Juice and/or POMx Pills contain abundant antioxidants and that antioxidants can help fight or neutralize free radicals. (*See* Appendix of Ads).

Response to Finding No. 2531:
Complaint Counsel does not disagree that POM's ads include some of the elements and phrases described above, among many others, but Complaint Counsel disagrees that these elements can be analyzed in isolation or that the ads can be categorized by these elements. Complaint Counsel asserts that the appropriate analysis is to look at the overall, net impression created by each advertisement through the interaction of different elements in the advertisement, including language and visual elements, rather than

focusing on individual elements or phrases in isolation. (*See* CCFF Sections V.D – V.F for the net impression analysis of each challenged ad). *See also* Responses to Findings in the cross-referenced Appendix.

2532. Examples of the body copy used in POM's "antioxidant benefits" ads include the following:

(a) Not all antioxidants are created equal. POMx fights free radicals with a mighty 1000 mg in every pill. That's more concentrated antioxidants than any other pomegranate antioxidant supplement. There are antioxidants, and then there are POMx antioxidants. (CX0169 (The power of POM, in one little pill); CX1426, Exh. L (The power of POM, in one little pill));

(b) 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 POMx pill a day will help protect you against free radicals and keep you at your healthy best. (CX0328 (Your New Health Care Plan); CX0331 (Healthy, ~~Wealthy~~, and Wise); CX0337 (The First Bottle You Should Open in 2010); CX0280 (Live Long Enough to Watch your 401(k) Recover); CX0355 (The Only Antioxidant Supplement Rated X); CX1426, Exh. J (Healthy, ~~Wealthy~~, and Wise); CX0342 (Take Out a Life Insurance Supplement); CX0353(Take Out a Life Insurance Supplement); CX0350 (24 Scientific Studies Now In One Easy-To-Swallow Pill); CX0348 (24 Scientific Studies Now In One Easy-To-Swallow Pill); CX0351(The Only Antioxidant Supplement Rated X)); and

(c) With uniquely high levels of powerful antioxidants, POM Wonderful 100% Pomegranate Juice has demonstrated superior ability to neutralize harmful free radicals and to inhibit excess inflammation. (CX0314_0005 (The proof is in the POM); CX0314_0009 (The proof is in the POM); CX0372_0003 (KA-POM!); CX0379_0003 (KA-POM!); CX0380_0003 (KA-POM!)).

Response to Finding No. 2532:

Complaint Counsel does not disagree that the body copy excerpts in the proposed finding were *part of* the body copy of the ads cited, but disagrees that these descriptions can be analyzed in isolation or that the ads can be categorized by these descriptions. Complaint Counsel asserts that the appropriate analysis is to look at the overall, net impression created by each advertisement through the interaction of different elements in the advertisement, including language and visual elements, rather than focusing on individual

elements or phrases in isolation. (*See* CCFF Sections V.D – V.F for the net impression analysis of each challenged ad). The body copy in these excerpts describing the health benefits of antioxidants and representing that POM products were high in antioxidants were among the elements that resulted in a net impression in these ads that the POM products referenced therein were effective in treating, preventing, or reducing the risk of heart disease, prostate cancer, or erectile dysfunction. Complaint Counsel also notes that the ads cited in Finding 2532(c) are individual pages of multi-page magazine wraps and not individual ads. *See* Response to Finding 2252.

2533. These ads also fall into the "antioxidant benefits" category and contain body copy that is similar or almost identical to the ads described above: CX1426, Exh. M (Dreher Heart Newsletter); CX0034 (Amaze your cardiologist); and CX314_005 (The proof is in the POM).

Response to Finding No. 2533:

Complaint Counsel does not disagree that the ads cited in the proposed finding include body copy identical or very similar to the excerpts in Finding 2532, and that these excerpts were *part of* the body copy of the ads cited. However, Complaint Counsel disagrees that these descriptions can be analyzed in isolation or that the ads can be categorized by these descriptions. Complaint Counsel asserts that the appropriate analysis is to look at the overall, net impression created by each advertisement through the interaction of different elements in the advertisement, including language and visual elements, rather than focusing on individual elements or phrases in isolation. (*See* CCFF Sections V.D – V.F for the net impression analysis of each challenged ad). The body copy in these excerpts describing the health benefits of antioxidants and representing that POM products were high in antioxidants were among the elements that resulted in a net impression in these ads that the POM products referenced therein were effective in treating, preventing, or reducing the risk of heart disease, prostate cancer, or erectile

dysfunction. Complaint Counsel also notes that CX0314_0005 is an individual page of a multi-page magazine wrap, and not an individual ad. *See* Response to Finding 2252.

2534. Many of the "antioxidant benefit" ads discussed above conveyed a qualified message.

(a) For example, the science behind the antioxidant claims was described as "emerging science". (CX0328 (Your New Health Care Plan); CX0331 (Healthy, ~~Wealthy~~, and Wise); CX0337 (The First Bottle You Should Open in 2010); CX0280 (Live Long Enough to Watch your 401(k) Recover); CX0355 (The Only Antioxidant Supplement Rated X); CX1426, Exh. J (Healthy, ~~Wealthy~~, and Wise); CX0342 (Take Out a Life Insurance Supplement); CX0353 (Take Out a Life Insurance Supplement); CX0350 (24 Scientific Studies Now In One Easy-To-Swallow Pill); CX0348 (24 Scientific Studies Now In One Easy-To-Swallow Pill); CX0351 (The Only Antioxidant Supplement Rated X); CX0188 (Cheat death)); and

(b) Similarly, the ads stated that one POMx Pill "will help protect" against free radicals. (CX0328 (Your New Health Care Plan); CX0331 (Healthy, Wealthy, and Wise); CX0337 (The First Bottle You Should Open in 2010); CX0280 (Live Long Enough to Watch your 401(k) Recover); CX0355 (The Only Antioxidant Supplement Rated X); CX1426, Exh. J (Healthy, Wealthy, and Wise); CX0342 (Take Out a Life Insurance Supplement); CX0353 (Take Out a Life Insurance Supplement); CX0350 (24 Scientific Studies Now In One Easy-To-Swallow Pill); CX0348 (24 Scientific Studies Now In One Easy-To-Swallow Pill); CX0351 (The Only Antioxidant Supplement Rated X); CX0188 (Cheat death)).

Response to Finding No. 2534:
Complaint Counsel disagrees with the proposed finding. Moreover, Complaint Counsel disagrees that particular phrases or elements can be analyzed in isolation or that the ads can be categorized by use of these phrases. Complaint Counsel asserts that the appropriate analysis is to look at the overall, net impression created by each advertisement through the interaction of different elements in the advertisement, including language and visual elements, rather than focusing on individual elements or phrases in isolation. (*See* CCFF Sections V.D – V.F for the net impression analysis of each challenged ad).

2535. As exemplified in the body copy quoted above, the overall net impression of "antioxidant benefit" category of ads is not that the Challenged Products are "clinically proven" to

prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction. (*See* Appendix of Advertisements).

Response to Finding No. 2535:
Complaint Counsel disagrees with the proposed finding regarding the net impression of the advertisements cited. (*See* CCFF Sections V.D – V.F for the net impression analysis of each challenged ad). *See* Responses to Findings in the cross-referenced Appendix.

2536. Moreover, POM's ads in this category are truthful and adequately supported by competent and reliable scientific evidence. (*See supra* XII, XIV, XV, XVI).

Response to Finding No. 2536:
The proposed finding is incorrect and unsupported by the cited evidence. *See* Responses to Findings in the cross-referenced sections.

(e) Multi-Step

2537. The fourth sub-category, "multi-step" antioxidant ads, states that (a) emerging science suggests that free radicals may be damaging to health and may be implicated in a number of diseases; (b) POM Juice is high in antioxidants and have more antioxidants than other drinks; (c) antioxidants may help protect your body against free radicals; and therefore (d) POM Juice is beneficial and good for your health. (*See* Appendix of Ads).

Response to Finding No. 2537:
Complaint Counsel does not disagree that POM's ads include some of the elements and phrases described above, among many others, but Complaint Counsel disagrees that these elements can be analyzed in isolation or that the ads can be categorized by these elements. Complaint Counsel asserts that the appropriate analysis is to look at the overall, net impression created by each advertisement through the interaction of different elements in the advertisement, including language and visual elements, rather than focusing on individual elements or phrases in isolation. (*See* CCFF Sections V.D – V.F for the net impression analysis of each challenged ad). *See also* Responses to Findings in the cross-referenced Appendix.

2538. Examples of the body copy used in POM's "antioxidant benefits" ads include the following:

(b) What's it like to have a personal superhero? Find out by drinking delicious and refreshing POM Wonderful 100% Pomegranate Juice. It has more naturally occurring antioxidants than other drinks. Antioxidants fight free radicals, villainous little molecules that may cause premature aging, heart disease, stroke, Alzheimer's, even cancer. (CX0314_0006 (The Antioxidant Superpower));

(c) You need antioxidants. And POM Wonderful 100% Pomegranate Juice is loaded with them. It helps guard your body against free radicals, unstable molecules that emerging science suggests aggressively destroy healthy cells in your body and contribute to disease. (CX0188 (Cheat death)); and

(d) 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. (CX0033 (Life support)).

Response to Finding No. 2538:

Complaint Counsel does not disagree that the body copy excerpts in the proposed finding were *part of* the body copy of the ads cited, but disagrees that these descriptions can be analyzed in isolation or that the ads can be categorized by these descriptions. Complaint Counsel asserts that the appropriate analysis is to look at the overall, net impression created by each advertisement through the interaction of different elements in the advertisement, including language and visual elements, rather than focusing on individual elements or phrases in isolation. (*See* CCFF Sections V.D – V.F for the net impression analysis of each challenged ad). The body copy in these excerpts representing that scientific research has shown that free radicals can contribute to disease, that antioxidants can fight the effects of free radicals, and that POM products were high in antioxidants were among the elements that resulted in a net impression in these ads that the POM products referenced therein were effective in treating, preventing, or reducing the risk of heart disease, prostate cancer, or erectile dysfunction, and in some ads, that such effects were clinically proven. Complaint Counsel also notes that CX0314_0006 is an individual

page of a multi-page magazine wrap, and not an individual ad. *See* Response to Finding 2252.

2539. The following ads also fall into the "multi-step" category and contain body copy that is similar or almost identical to the ads described above: CX0016.

Response to Finding No. 2539:
Complaint Counsel does not disagree that the ad cited in the proposed finding includes body copy identical or very similar to the excerpts in Finding 2532, and that these excerpts were *part of* the body copy of the ads cited. However, Complaint Counsel disagrees that these descriptions can be analyzed in isolation or that the ads can be categorized by these descriptions. Complaint Counsel asserts that the appropriate analysis is to look at the overall, net impression created by each advertisement through the interaction of different elements in the advertisement, including language and visual elements, rather than focusing on individual elements or phrases in isolation. (*See* CCFF Sections V.D – V.F for the net impression analysis of each challenged ad). The body copy in this ad representing that scientific research has shown that free radicals can contribute to disease, that antioxidants can fight the effects of free radicals, and that POM products were high in antioxidants were among the elements that resulted in a net impression in this ad that POM Juice was effective in treating, preventing, or reducing the risk of heart disease, prostate cancer, or erectile dysfunction, and that such effects were clinically proven.

2540. Some of the "multi-step" ads are also accompanied by humorous, comical and frivolous images. For example, the "Life support" ad has an intravenous line ("IV") with a pomegranate bottle in place of IV solution. (CX0033).

Response to Finding No. 2540**:**

Complaint Counsel agrees that the cited ad depicts an IV line with a POM Juice bottle in place of IV solution, but disagrees with the conclusion that they were "humorous, comical and frivolous."

2541. Dr. Butters testified that the image is a "frivolous exaggeration" and that it is not possible that the IV imagery was conveying drugs and medicine. (Butters, Dep. at 165).

Response to Finding No. 2541:
The proposed finding mischaracterizes Dr. Butters's testimony. At his deposition, Dr. Butters was asked "Isn't it also possible that the symbolism of an IV is for drugs and medicine?" and he replied "I think *that's not impossible*. That did not occur to me that that could be what the IV bottle was conveying; that is, yes, people do get medications through IV bottles . . . ." (PX0350 (Butters, Dep. at 165) (emphasis added)). At trial, he also testified that in the proper context the visual of an IV drip bottle is a symbol for drugs and medicine. (Butters, Tr. 2947).

2542. Many of the "multi-step" ads discussed above also conveyed qualified messages.

(a) For example, the science behind the antioxidant claims was described as being "emerging science" and that such science "suggests" that free radicals destroy healthy cells. (CX0188 (Cheat death)); and

(b) The ads stated that antioxidants fight free radicals and that free radicals "may cause" certain diseases, (CX0314_0006 (The Antioxidant Superpower)), or "can cause" certain diseases" (CX0033 (Life support)), not that free radicals affirmatively do cause diseases.

Response to Finding No. 2542:
Complaint Counsel disagrees with the proposed finding. Moreover, Complaint Counsel disagrees that particular phrases or elements can be analyzed in isolation or that the ads can be categorized by use of these phrases. Complaint Counsel asserts that the appropriate analysis is to look at the overall, net impression created by each advertisement through the interaction of different elements in the advertisement, including language and visual elements, rather than focusing on individual elements or

phrases in isolation. (*See* CCFF Sections V.D – V.F for the net impression analysis of each challenged ad).

2543. As exemplified in the body copy quoted above, the overall net impression of "multi-step" antioxidant category of ads is not that the Challenged Products are "clinically proven" to prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction. (*See* Appendix of Advertisements).

Response to Finding No. 2543:
Complaint Counsel disagrees with the proposed finding regarding the net impression of the advertisements cited, but notes that it does not take the position that CX0033 ("Life Support") and CX0188 ("Cheat Death") make establishment claims. (*See* CCFF Sections V.D – V.F and Appendix A for the net impression analysis of each challenged ad). *See also* Responses to Findings in the cross-referenced Appendix.

2544. Moreover, POM's ads in this category are truthful and adequately supported by competent and reliable scientific evidence. (*See supra* XII, XIV, XV, XVI).

Response to Finding No. 2544:
The proposed finding is incorrect and unsupported by the cited evidence. *See* Responses to Findings in the cross-referenced sections.

H. The Handful of Media Interviews and/or Presentations Given By Respondents, Mrs. Resnick And Mr. Tupper, Are Not Actionable Advertising

2545. In the 11/9/11 Proposed Ad Stipulation, Complaint Counsel contend that four media interviews, three given by Mrs. Resnick (CX1426, Exhs. E-6 and F, CX472_0003) and one given by Mr. Tupper (CX1426, Exh. E-7), as well as a discussion with Mrs. Resnick at the University of Southern California ("USC") Annenberg School of Communication (CX472_0002), violate Section 5 and 12 of the FTC Act. (11/9/11 Johnson email).

Response to Finding No. 2545:
The proposed finding is unsupported because the evidence cited is not in the record, in violation of the Court's Order on Post-Trial Briefs. Proposed stipulations that Respondents declined to agree to are not evidence and irrelevant. Nevertheless, Complaint Counsel agrees that it is challenging four media interviews as example of

Respondents' conduct violating the FTC Act, but states that it is not challenging Mrs. Resnick's presentation, "How to Uncover the Hidden Gems in Your Business," Therefore the proposed finding as it relates to this presentation is irrelevant. (*See* CCFF Section V and Appendix A).

2546. The four media interviews and one discussion include:

(a) Mrs. Resnick's November 2008 television appearance on *The Martha Stewart Show* ("*Martha Stewart*") in which she shared personal recipes for a POMtini cocktail and Thanksgiving stuffing, (CX1426, E-6);

(b) Mrs. Resnick's February 2009 television appearance on *The Early Show* in which she shared some marketing ideas for POM and FIJI Water, (CX472_0003);

(c) an interview of Mrs. Resnick in *Newsweek* magazine, dated March 20, 2009, discussing the economy, her business acumen, and her book, *Rubies in the Orchard*, (CX1426, Exh. F);

(d) an April 2009 discussion with Mrs. Resnick at USC's Annenberg School of Communication with Dean Ernest J. Wilson III on "How to Uncover the Hidden Gems in Your Business", (CX472_0002); and

(e) a June 2008 television interview of Mr. Tupper on FOX Business discussing the newest "hot" wave in foods - the pomegranate - and the pomegranate juice industry, (CX1426, Exh E-7).

Response to Finding No. 2546:

The proposed finding is incomplete and incorrect. Complaint Counsel is not challenging (d), Mrs. Resnick's presentation, "How to Uncover the Hidden Gems in Your Business," as an example of Respondents' conduct violating the FTC Act, therefore the proposed finding as it relates to this presentation is irrelevant. (*See* CCFF Section V and Appendix A). In addition, the proposed finding is incomplete in its description of these media appearances. During these media appearances, Mrs. Resnick and Mr. Tupper also discussed the purported health benefits of the POM Products.

2547. As discussed below, neither Mrs. Resnick nor Mr. Tupper can be held liable under Section 5 and 12 of the FTC Act for these statements.

Response to Finding No. 2547:
The proposed finding is a legal conclusion, which is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs.

2548. First, the statements by Mrs. Resnick and Mr. Tupper are not advertising as defined by the FTC in *In the Matter of R.J. Reynolds Tobacco Co., Inc.,* 9206, 1988 WL 490114 (F.T.C. Mar. 4, 1988). (*See infra* XVII(H)(1-5)).

Response to Finding No. 2548:
The proposed finding is a legal conclusion. In addition, 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 Exs. E-6, E-7, and F) were "advertisements and promotional materials" that they disseminated or caused to be disseminated. (PX0364_0002, Answer ¶ 9).

2549. Second, the "main purposes" or "primary motivations" for the interviews given by Mrs. Resnick and Mr. Tupper were not to sell POM products. (*See infra* XVII(H)(1-5)).

Response to Finding No. 2549:
The proposed finding is unsupported by the cited evidence and the record as a whole. 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 Exs. E-6, E-7, and F) were "advertisements and promotional materials" that they disseminated or caused to be disseminated. (PX0364_0002, Answer ¶ 9). In addition, Mrs. Resnick testified that she believed she created a market for pomegranate juice through "public relations, advertising events, product placement, et cetera, all the arms of marketing." (CCFF ¶¶ 175-76). She also testified that public relations, which includes, among other elements, outreach to broadcast media like radio and television, is the "unsung hero of marketing." (*See* CCFF ¶¶ 261-62). In her book, *Rubies in the Orchard*, Mrs. Resnick explained, "[i]n 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." (CCFF ¶ 568).

2550. Third, the challenged statements by Mrs. Resnick and Mr. Tupper were their honest opinions in response to unsolicited questions posed by the interviewers and, therefore, are protected by the First Amendment. (*See infra* XVII(H)(1-5)).

Response to Finding No. 2550:
Complaint Counsel has no specific response, except to note that the proposed finding contains a legal conclusion.

2551. Last, Complaint Counsel has failed to introduce any evidence whatsoever that any of the statements by Mrs. Resnick or Mr. Tupper were material to consumers' decisions to purchase POM Juice. (*See infra* XVIII(A)).

Response to Finding No. 2551:
The proposed finding mischaracterizes the evidence in the record. CCFF Section VI provides ample evidence of the materiality of the challenged claims, including the claims made by Mrs. Resnick and Mr. Tupper set forth in CCFF Section V.F.2.

1. Lynda Resnick's Appearance on the Martha Stewart Show

2552. On November 20, 2008, Mrs. Resnick appeared on *Martha Stewart*. (CX1426, Exh. E-6). The substance of the interview, itself, makes clear that Mrs. Resnick's interview primarily focused on pomegranates, the company, POM, and the POMtini. (CX1426, Exh. E-6).

Response to Finding No. 2552:
The proposed finding is incomplete. In the *Martha Stewart* interview, Mrs. Resnick extolled "Wonderful" brand pomegranates as "the sweetest and [as] hav[ing] the health benefits," and as "the magic elixir of our age and of all ages." (CX1426, Compl. Ex. E-6 at 01:30-01:40; 02:50-02:57). Mrs. Resnick also urged viewers to "make [the men in their lives] drink eight ounces of pomegranate juice a day because what it does for prostate cancer is amazing," and touted that the pomegranate "helps circulation, it helps

Alzheimer's, it helps all sorts of things in the body" with "polyphenol antioxidants off the chart." (CX1426, Compl. Ex. E-6 at 02:50-03:20).

2553. Although the first segment of the two-part interview is set forth in a video marked as CX1426, Exh. E-6, the Complaint quoted the following 35 second transcription from the six minute and 15 second interview:

> **Mrs. Resnick:** . . . But, the Wonderfuls are [the pomegranates] ones that we grow because they're the sweetest and they have the health benefits.
>
> ***
>
> **Ms. Stewart:** But, the medical benefits even outweigh the mythical benefits?
>
> **Ms. Resnick:** Oh, they do, they do. I mean, it's 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—
>
> **Ms. Stewart:** Antioxidants.
>
> **Ms. Resnick:** Antioxidants. Polyphenol antioxidants off the chart.
>
> **Ms. Stewart:** Right.
>
> **Ms. 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.

(CX1426, Exh. E-6).

Response to Finding No. 2553:
Complaint Counsel does not disagree.

2554. At the end of the first segment, Martha Stewart states that when they return from the commercial break that she and Mrs. Resnick are going to make an amazing pomegranate cornbread stuffing. (CX1426, Exh. E-6). That next segment in which Mrs. Resnick and Martha Stewart make the stuffing and continue the interview is 6 minutes and 17 seconds. (Lynda Resnick Interview on *Martha Stewart* (November 20, 2008), available on You Tube at http://www.youtube.com/watch?v=IBejxwUTGAQ). The total length of Mrs. Resnick's interview on *Martha Stewart* is over 12 minutes.

Response to Finding No. 2554:
With respect to the first sentence of the proposed finding, Complaint Counsel does not disagree. The remainder of the proposed finding is unsupported because the YouTube video cited is not in the record, in violation of the Court's Order on Post-Trial Briefs.

2555. Complaint Counsel has presented no evidence that Mrs. Resnick or the other Respondents paid any money to *Martha Stewart* or anyone else for her participation in the interview or to allow her to speak about pomegranate juice.

Response to Finding No. 2555:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. However, Complaint Counsel notes that Mrs. Resnick sends Martha Stewart a case of pomegranates each year. (*See* CCFF ¶ 569). Although she was skeptical that this annual gift directly resulted in her invitation to appear on Martha Stewart's show and in a twelve-page spread on pomegranates in *Martha Stewart Living*, Mrs. Resnick did observe that "she know[s] that at least once a year [Martha Stewart] is reminded of how much she likes [pomegranates]." (CX0001_00025). Mrs. Resnick also stated in *Rubies in the Orchard* that: "not everyone has the chance to meet Martha Stewart, but anyone can send a product to someone who is influential—whether it's the editor of a local newspaper or the head of the chamber of commerce. . . . Having your product adopted by an influential person has its own rewards. After all, leaders have followers." (CX0001_00025).

2556. Complaint Counsel has presented no evidence that Mrs. Resnick's "main purpose" or "primary motivation" for participating in an interview on *Martha Stewart* was to sell POM.

Response to Finding No. 2556:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. *See also* Response to Finding 2549.

2557. During the interview, Ms. Resnick's reference to the health benefits of pomegranate juice was very, very short - only about 35 seconds out of the two segment interview, which

lasted 12 minutes and 30 seconds. (CX1426, Exh. E-6; Lynda Resnick Interview on *Martha Stewart* (November 20, 2008), available on You Tube at http://www.youtube.com/watch?v=IBejxwUTGAQ).

Response to Finding No. 2557:
The proposed finding is unsupported because the YouTube video cited is not in the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel has no specific response to the segment which is part of the record. (*See* CX1426, Ex. E-6).

2558. Mrs. Resnick's reference to the "medical benefits" of pomegranate juice during the course of her interview was strictly "reactive" and was directly in response to a question posed by Martha Stewart. (CX1426, Exh. E-6).

Response to Finding No. 2558:
The proposed finding mischaracterizes the evidence. In the segment, Ms. Stewart asked the open-ended question, "But, the medical benefits even outweigh the mythical benefits?" without any specific queries about Alzheimer's or prostate cancer. Thus, Mrs. Resnick's statements like "it is the magic elixir of our age and of all ages," "it helps Alzheimer's," 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" were not strictly "reactive," but rather at Mrs. Resnick's discretion. (*See* CCFF ¶ 570).

2559. Ms. Resnick's responses to questions concerning the "medical benefits" of pomegranate juice were purely statements of her opinion, which are protected under the First Amendment. (L. Resnick, Tr. 156; CX1375 (L. Resnick, Tropicana Dep. at 101)).

Response to Finding No. 2559:
Complaint Counsel has no specific response, except to note that the proposed finding contains a legal conclusion. In addition, the cited deposition testimony did not pertain specifically to Mrs. Resnick's *Martha Stewart* appearance, but to her statements in an aggregate of unspecified news and television interviews. (CX1375 (L. Resnick, Trop. Dep. at 101)).

2560. Mrs. Resnick staunchly believes that the opinions she expressed in her interview are completely true. (L. Resnick, Tr. 156; CX1375 (L. Resnick, Tropicana Dep. at101). Indeed, at the time of the *Martha Stewart* interview, Mrs. Resnick believed that POM juice is helpful for Alzheimer's and she still believes that today. (L. Resnick, Tr. 153-56).

Response to Finding No. 2560:
The proposed finding mischaracterizes the evidence. Mrs. Resnick also testified that she would not feel comfortable and confident telling consumers in an ad today that POM Juice can help prevent Alzheimer's because she "[didn't] think [POM's] research is really exhaustive enough." (CX1375 (L. Resnick, Dep. at 102)). Furthermore, the cited deposition testimony did not pertain specifically to Mrs. Resnick's *Martha Stewart* appearance, but to her statements in an aggregate of unspecified news and television interviews. (CX1375 (L. Resnick, Trop. Dep. at 101)).

2561. The substance of the interview, itself, evidence that neither Ms. Resnick's statements on *Martha Stewart* nor even her specific opinions on the benefits of pomegranate juice "proposed a commercial transaction." (CX1426, Exh. E-6).

Response to Finding No. 2561:
The proposed finding is a legal conclusion and is unsupported by the cited evidence. In addition to touting the health benefits of pomegranates and POM Juice, as noted in Response to Finding 2552, Mrs. Resnick specifically highlighted the purported superiority of the POM Wonderful brand with statements such as, "But, the Wonderfuls are the ones that we grow because they're the sweetest and they have the health benefits." (CX0473 (Compl. Ex. E-6 at 01:30)).

2562. During her appearance, Mrs. Resnick made no mention of the then-upcoming release of her book, *Rubies in the Orchard*. (CX1426, Exh. E-6).

Response to Finding No. 2562:
Complaint Counsel has no specific response.

2563. Although POM provided each audience member with a free, fresh pomegranate, (Lynda Resnick Interview on *Martha Stewart* (November 20, 2008), available on You Tube at http://www.youtube.com/watch?v=IBejxwUTGAQ).

Response to Finding No. 2563:
The proposed finding is unsupported because the YouTube video cited is not in the record, in violation of the Court's Order on Post-Trial Briefs.

2564. Moreover, 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.

Response to Finding No. 2564:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs.

2565. The Reibstein 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).

Response to Finding No. 2565:
The proposed finding is unsupported by the cited evidence or the record as a whole. The cited evidence does not assert that disease treatment or prevention claims would not be material to potential purchasers. (Reibstein, Tr. 2493; PX0223-0020). In addition, the Reibstein survey does not validly measure the materiality of the challenged claims for the POM products. (*See* CCFF ¶¶ 654, 657-61; CX1297 (Mazis, Report at 0008-10)).

2566. No liability can be based on Mrs. Resnick's appearance on *Martha Stewart* because (a) it was not advertising; (b) it is constitutionally protected speech; and (c) her opinions were not material to the consumer purchasing decisions.

Response to Finding No. 2566:
The proposed finding is a legal conclusion, which is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs.

2. Lynda Resnick's Appearance on the Early Show

2567. On February 19, 2009, Mrs. Resnick appeared on CBS' *The Early Show* in a segment titled "Cashing in on Ideas". (CX472_0003). The substance of the interview, itself, makes clear that the interview primarily focused on the history and story behind the company, POM, and Mrs. Resnick's marketing secrets. (CX472_0003).

Response to Finding No. 2567:

Complaint Counsel does not disagree to the extent that Mrs. Resnick appeared on *The Early Show* in February 2009, though Complaint Counsel disagrees as to the title of the segment. As noted in CCFF ¶ 574, the segment was called "Making it Happen: Turning Ideas into Ca$h." In addition, the proposed finding is incomplete in its description of the Mrs. Resnick's interview. Although, Mrs. Resnick did discuss the history and story behind POM and her marketing secrets, she also discussed the "health-giving properties" of POM Juice, including explaining that "once [POM] realized the health-giving benefits [of its product], that was [its] marketing direction." (CX0472 at 01:40, 02:36).

2568. Although the entire 3 minute and 52 second interview is set forth in a video marked as CX472_0003, the interview is not an exhibit to or excerpt in the Complaint. (*See* CX1426).

Response to Finding No. 2568:
Complaint Counsel does not disagree.

2569. Respondents' therefore surmise that Complaint Counsel challenge the following 20 second transcription:

> **Julie Chen:** And how did you start marketing [POM]? Because, like I see that bottle and I just want to drink it.
>
> **Mrs. Resnick:** I know. I know. . . And we decided to see if that was true. We started doing scientific, peer-reviewed research. And we found out, indeed, that the pomegranate has all these health-giving properties. There isn't a man in America that shouldn't drink 8oz. a day. Because it keeps you from getting prostate cancer or your PSA from rising. It's really an, amazing, amazing thing. And good for circulation too.

(CX472_0003).

Response to Finding No. 2569:

Complaint Counsel does not disagree that it is challenging the cited excerpt, but notes that the excerpts on which its challenge is based are set out more fully in CCFF ¶ 574, which is an excerpt of approximately 40 seconds.

2570. Complaint Counsel has proffered no evidence that Mrs. Resnick or the other Respondents paid any money to *The Early Show* or anyone else for her participation in the interview or to allow her to speak about pomegranate juice.

Response to Finding No. 2570:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs.

2571. Ms. Resnick's reference to the "health-giving properties" of pomegranates during the interview was very small, only about 20 seconds out of a 3 minute and 52 second segment. (CX472_0003).

Response to Finding No. 2571:
Complaint Counsel has no specific response, except to note that the excerpts on which its challenge is based are set out more fully in CCFF ¶ 574, which is an excerpt of approximately 40 seconds.

2572. Mrs. Resnick's reference to the "health-giving properties" of pomegranates was strictly "reactive" and directly in response to an unsolicited inquiry by the interviewer, Mrs. Chen, asking "how did [she] start marketing POM?" (CX472_0003).

Response to Finding No. 2572:
The proposed finding mischaracterizes the evidence. In responding to the interviewer's open-ended question, "how did you start marketing it because . . . I see that bottle, and I just want to drink it," it was in Mrs. Resnick's full discretion to, for example, urge viewers, "[t]here 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 01:20-02:07).

2573. Mrs. Resnick staunchly believes that the opinions she expressed in her interview are completely true. (CX1375 (L. Resnick, Tropicana Dep. at101)).

Response to Finding No. 2573:
Complaint Counsel has no specific response, but notes that the cited deposition testimony did not pertain specifically to Mrs. Resnick's *Early Show* appearance, but to her statements in an aggregate of unspecified news and television interviews. (CX1375 (L. Resnick, Trop. Dep. at 101)).

2574. Complaint Counsel has presented no evidence that Mrs. Resnick's "main purpose" or "primary motivation" for participating in an interview on *The Early Show* was to sell POM or her book, *Rubies in the Orchard*.

Response to Finding No. 2574:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. *See also* Response to Finding 2549.

2575. The substance of the interview, itself, evidences that the "main purpose" of the interview was to share with the viewer her successful marketing ideas and to provide tips on how to turn ideas into cash. (CX472_0003).

Response to Finding No. 2575:
The proposed finding is incomplete. Mrs. Resnick also extolled the purported "health-giving properties" of POM Juice, including with respect to prostate cancer and circulation. (*See* CCFF ¶ 574). *See also* Response to Finding 2572.

2576. The substance of the interview, itself, further evidence that neither Ms. Resnick's statements on *The Early Show* nor even her specific opinions on the benefits of pomegranate juice "proposed a commercial transaction." (CX472_0003).

Response to Finding No. 2576:
The proposed finding is a legal conclusion.

2577. The Reibstein 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).

Response to Finding No. 2577:
The proposed finding is unsupported by the cited evidence or the record as a whole. The cited evidence does not assert that disease treatment or prevention claims would not be material to potential purchasers. (Reibstein, Tr. 2493; PX0223-0020). In addition, the

Reibstein survey does not validly measure the materiality of the challenged claims for the POM Products. (CCFF ¶¶ 654, 657-61; CX1297 (Mazis, Report at 0008-10)).

2578. Even assuming *arguendo* that Mrs. Resnick's interview on *The Early Show* constitutes "advertising", Complaint Counsel has presented no evidence that showed any causal relationship between this interview and consumer purchasing decisions.

Response to Finding No. 2578:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Moreover, Mrs. Resnick in the interview explained the causal connection: ". . . 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." (*See* CX0472 at 02:36).

2579. Moreover, Ms. Resnick's responses to questions concerning pomegranate juice were purely statements of her opinion, which are protected under the First Amendment. (CX1375 (L. Resnick, Tropicana Dep. at 101)).

Response to Finding No. 2579:
Complaint Counsel has no specific response, except to note that the proposed finding contains a legal conclusion. In addition, the cited deposition testimony did not pertain specifically to Mrs. Resnick's *Early Show* appearance, but to her statements in an aggregate of unspecified news and television interviews. (CX1375 (L. Resnick, Trop. Dep. at 101)).

2580. No liability can be based on Mrs. Resnick's *The Early Show* 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.

Response to Finding No. 2580:
The proposed finding is a legal conclusion, which is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs.

3. Lynda Resnick's Newsweek Interview

2581. On March 20, 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?" (CX1426, Exh. F).

Response to Finding No. 2581:
The proposed finding is incomplete. The cited interview, which is titled "Striking Out On Your Own: Is now a good time to start a company? Absolutely, says Lynda Resnick, the founder of Fiji Water and POM Wonderful" was also posted on the pomwonderful.com website. In addition, the cited evidence is presented in the Complaint in full, as a print-out of the article as published on *Newsweek.com*. (CX1426_00032-35; CCFF ¶ 576).

2582. The content of the *Newsweek* publication, itself, evidences that 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).

Response to Finding No. 2582:
The proposed finding is incomplete. Mrs. Resnick also discussed the purported health benefits of POM Juice, including with respect to prostate cancer and erectile dysfunction. (CX1426_00034-35). *See also* Response to Finding 2581.

2583. Although the entire 2-page, 1500-word article is set forth in CX1426, Exh. F, the Complaint quoted, out of context, the following 150 words:

> [Interviewer:] Should I take vitamins?
>
> **[**L. 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—
>
> **[**L. 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.

[L. 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!

(CX1426, Exh. F).

Response to Finding No. 2583:
Complaint Counsel agrees that the text of the entire interview is appended to the Complaint as Exhibit F, but has no specific response to the remainder of the proposed finding.

2584. Mrs. Resnick staunchly believes that the opinions she expressed in her interview are completely true. (CX1375 (L. Resnick, Tropicana Dep. at 101)).

Response to Finding No. 2584:
Complaint Counsel has no specific response, but notes that the cited deposition testimony did not pertain specifically to Mrs. Resnick's *Newsweek.com* interview, but to her statements in an aggregate of unspecified news and television interviews. (CX1375 (L. Resnick, Trop. Dep. at 101)).

2585. Complaint Counsel has presented no evidence that Mrs. Resnick or the other Respondents paid any money to *Newsweek* or anyone else for her participation in the interview or to allow her to speak about pomegranate juice.

Response to Finding No. 2585:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs.

2586. Complaint Counsel has presented no evidence that Mrs. Resnick's "main purpose" or "primary motivation" for participating in an interview with *Newsweek* was to sell POM or her book, *Rubies in the Orchard*.

Response to Finding No. 2586:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. In addition, Respondents admitted in their Answer that the *Newsweek.com* interview with Mrs. Resnick (Complaint Ex. F) was among "advertisements and promotional materials" that they disseminated or caused to be disseminated. (PX0364_0002, Answer ¶ 9).

2587. The content of the *Newsweek* article, itself, evidences that the "main purpose" of the interview was to provide the viewer or reader with a wide-ranging discussion of herself and her views, interests and accomplishments. (CX1426, Exh. F).

Response to Finding No. 2587:
The proposed finding is unsupported by the cited evidence and the record as a whole.

See Response to Finding 2549.

2588. Ms. Resnick's references to the health benefits of pomegranate juice were very small, only about 150 words out of a 1500-word article. (CX1426, Exh. F).

Response to Finding No. 2588:
Complaint Counsel has no specific response.

2589. Mrs. Resnick's references to health benefits of pomegranate juice during the course of her interview were strictly "reactive" and in direct response to the unsolicited question, "Should I take vitamins?" posed by the interviewer. (CX1426, Exh. F).

Response to Finding No. 2589:
The proposed finding mischaracterizes the evidence. In response to the question, "Should I take vitamins?" Mrs. Resnick responded with her own inquiry, "I don't know your family history. How's your father?" (CX1426_00034). When the interviewer started to reply, "[h]e's in good health. Had a bout of prostate cancer," Mrs. Resnick interrupted with "[y]ou 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. . . . We just did a study at UCLA, on 43 men . . . It arrested their PSA." (CX1426_0034). In addition, Mrs. Resnick added, entirely unprompted, "[i]t's also 40 percent as effective as Viagra." (CX1426_0034).

2590. Ms. Resnick's responses to questions concerning pomegranate juice were purely statements of her opinion, which are protected under the First Amendment. (CX1375 (L. Resnick, Tropicana Dep. at 101)).

Response to Finding No. 2590:
Complaint Counsel has no specific response, except to note that the proposed finding contains a legal conclusion. In addition, the cited deposition testimony did not pertain specifically to Mrs. Resnick's *Martha Stewart* appearance, but to her statements in an aggregate of unspecified news and television interviews. (CX1375 (L. Resnick, Trop. Dep. at 101)). Also, POM posted the article on pomwonderful.com and admitted it was among the "advertisements and promotional materials" that they disseminated or caused to be disseminated." (CCFF ¶ 576; PX0364-0002, Answer ¶ 9).

2591. 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).

Response to Finding No. 2591:
The proposed finding is a legal conclusion. *See also* Response to Finding 2590.

2592. Indeed, Complaint Counsel has presented no evidence that the *Newsweek* interview was solely related to the economic interests of Mrs. Resnick and her audience.

Response to Finding No. 2592:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs.

2593. The Reibstein 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).

Response to Finding No. 2593:
The proposed finding is unsupported by the cited evidence or the record as a whole. The cited evidence does not assert that disease treatment or prevention claims would not be material to potential purchasers. (Reibstein, Tr. 2493; PX 0223-0020). In addition, the Reibstein survey does not validly measure the materiality of the challenged claims for the POM Products. (CCFF ¶¶ 654, 657-61; CX1297 (Mazis, Report at_0008-10)).

2594. Moreover, even assuming *arguendo* that Mrs. Resnick's interview with *Newsweek* constitutes "advertising", Complaint Counsel has presented no evidence that showed any causal relationship between this interview and consumer purchasing decisions.

Response to Finding No. 2594:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs.

2595. 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.

Response to Finding No. 2595:
The proposed finding is a legal conclusion, which is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs.

4. Discussion With Lynda Resnick at USC's Annenberg School of Communication

2596. On April 9, 2009, Mrs. Resnick joined Dean Ernest J. Wilson III at the USC Annenberg School of Communication for a discussion titled "How to Uncover the Hidden Gems in Your Business" (hereinafter, "Dean's Forum"). The substance of discussion, itself, makes clear that it was focused on entrepreneurship, the secrets of Mrs. Resnick's success with the Roll family of companies and demystifying the marketing and creative process. (CX472_0002).

Response to Finding No. 2596:
Complaint Counsel is not challenging the claims from this presentation as an example of Respondents' conduct violating the FTC Act, therefore the proposed finding is irrelevant. (*See* CCFF Section V and Appendix A).

2597. Although the entire Dean's Forum was almost an hour and is set forth in a video marked as CX472_0002, the discussion is not an exhibit to or excerpt in the Complaint. (*See* CX472_0002).

Response to Finding No. 2597:
Complaint Counsel is not challenging the claims from this presentation as an example of

Respondents' conduct violating the FTC Act, therefore the proposed finding is irrelevant.

(*See* CCFF Section V and Appendix A).

2598. Respondents' therefore speculate that Complaint Counsel challenge the following 10 seconds excerpted below:

> [Speaker:] I have one question I'd like to ask you . . . I wonder if you could share your thoughts a little bit especially with this audience about what you mean by the term communication. How does that fit into the picture?
>
> **[**L. Resnick:] Well, we are really everywhere . . . We had some pretty horrible PR nightmares. . . So the PETA decided that we were bad because I order for us to do our medical research, first you do the research in the test tube and then you test on animals. And then you go to humans. It's just the protocol. And we did some testing on our juice on rats and mice. And one rabbit study. But they were happy because that was because we were testing the Viagra quality of POM juice which is 40% as effective as Viagra . . . .

(CX472_0002).

Response to Finding No. 2598:
Complaint Counsel is not challenging the claims from this presentation as an example of

Respondents' conduct violating the FTC Act, therefore the proposed finding is irrelevant.

(*See* CCFF Section V and Appendix A).

2599. Complaint Counsel, however, has presented no evidence that Mrs. Resnick did not believe that that the opinions she expressed during the "Question and Answer" portion of the Dean's Forum or any portion of the Dean's Forum were not completely true.

Response to Finding No. 2599:

Complaint Counsel is not challenging the claims from this presentation as an example of

Respondents' conduct violating the FTC Act, therefore the proposed finding is irrelevant.

(*See* CCFF Section V and Appendix A).

2600. Complaint Counsel has presented no evidence that Mrs. Resnick or the other Respondents paid any money to USC or anyone else for her participation at the Dean's Forum to allow her to speak about pomegranate juice.

Response to Finding No. 2600:
Complaint Counsel is not challenging the claims from this presentation as an example of

Respondents' conduct violating the FTC Act, therefore the proposed finding is irrelevant.

(*See* CCFF Section V and Appendix A).

2601. Complaint Counsel has presented no evidence that Mrs. Resnick's "main purpose" or "primary motivation" for participating in the Dean's Forum was to sell POM or her book, *Rubies in the Orchard*.

Response to Finding No. 2601:
Complaint Counsel is not challenging the claims from this presentation as an example of

Respondents' conduct violating the FTC Act, therefore the proposed finding is irrelevant.

(*See* CCFF Section V and Appendix A).

2602. The content of the Dean's Forum, itself, evidences that the "main purpose" of the discussion was to provide the audience with a discussion regarding marketing, public relations and building successful brands. (CX472_0002).

Response to Finding No. 2602:
Complaint Counsel is not challenging the claims from this presentation as an example of

Respondents' conduct violating the FTC Act, therefore the proposed finding is irrelevant.

(*See* CCFF Section V and Appendix A).

2603. Ms. Resnick's references to the health benefits of pomegranate juice were very, very small, only about 10 seconds out of an hour-long discussion. (CX472_0002).

Response to Finding No. 2603:

Complaint Counsel is not challenging the claims from this presentation as an example of

Respondents' conduct violating the FTC Act, therefore the proposed finding is irrelevant.

(*See* CCFF Section V and Appendix A).

2604. Ms. Resnick's statements regarding the health benefits of pomegranate juice were purely statements of her opinion, which are protected under the First Amendment.

Response to Finding No. 2604:
Complaint Counsel is not challenging the claims from this presentation as an example of

Respondents' conduct violating the FTC Act, therefore the proposed finding is irrelevant.

(*See* CCFF Section V and Appendix A).

2605. The content of the Dean's Forum, itself, further evidence that neither Ms. Resnick's statements during the forum nor even her specific opinions on the benefits of pomegranate juice "proposed a commercial transaction." (CX472_0002).

Response to Finding No. 2605:
Complaint Counsel is not challenging the claims from this presentation as an example of

Respondents' conduct violating the FTC Act, therefore the proposed finding is irrelevant.

(*See* CCFF Section V and Appendix A).

2606. Indeed, Complaint Counsel has presented no evidence that the Dean's Forum was solely related to the economic interests of Mrs. Resnick and her audience.

Response to Finding No. 2606:
Complaint Counsel is not challenging the claims from this presentation as an example of

Respondents' conduct violating the FTC Act, therefore the proposed finding is irrelevant.

(*See* CCFF Section V and Appendix A).

2607. The Reibstein Survey shows that no mention of disease in Mrs. Resnick's discussion 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).

Response to Finding No. 2607:

Complaint Counsel is not challenging the claims from this presentation as an example of Respondents' conduct violating the FTC Act, therefore the proposed finding is irrelevant. (*See* CCFF Section V and Appendix A).

2608. Moreover, even assuming *arguendo* that Mrs. Resnick's discussion at the Dean's Forum constitutes "advertising", Complaint Counsel has presented no evidence that showed any causal relationship between this discussion and consumer purchasing decisions.

Response to Finding No. 2608:
Complaint Counsel is not challenging the claims from this presentation as an example of Respondents' conduct violating the FTC Act, therefore the proposed finding is irrelevant. (*See* CCFF Section V and Appendix A).

2609. No liability can be based on Mrs. Resnick's discussion at the Dean's Forum because (a) it was not advertising; (b) it is constitutionally protected speech; and (c) her opinions were not material to the consumer purchasing decisions.

Response to Finding No. 2609:
Complaint Counsel is not challenging the claims from this presentation as an example of Respondents' conduct violating the FTC Act, therefore the proposed finding is irrelevant. (*See* CCFF Section V and Appendix A).

5. Matt Tupper's Interview on Fox Business

2610. On June 17, 2008, Mr. Tupper appeared on FOX Business. The substance of the interview, itself, makes clear that the interview primarily focused on pomegranates - the newest super food, POM, and pomegranate product applications. (CX1426, Exh. E-7).

Response to Finding No. 2610:
The proposed finding is incomplete. The *Fox Business* interviewer began the interview noting that pomegranates, "the newest super food," had been "credited with helping to reduce the risk of heart disease." (CX0473 (Compl. Ex. E-7 at 00:04-00:20)). Stating at the outset that pomegranates have "been an important part of medicine throughout the ages," Mr. Tupper also discussed the purported health benefits of pomegranate juice for prostate cancer and cardiovascular disease, including atherosclerosis, as well as specific

scientific research pertaining to these subjects. (CX0473 (Compl. Ex. E-7 at 00:04-00:45)). He also discussed POM's "enormous investment" of "more than $25 million of scientific research" backing POM's products. (CX0473 (Compl. Ex. E-7 at 04:40-05:12)).

2611. Although the entire 6 minute and 5 second interview is set forth in a video marked as CX1426, Exh. E-7, Complaint Counsel appear to challenge the 100 second excerpt quoted in the Complaint:

* * *

Brian Sullivan: Alright, well, talk to us about the claims, heavy in anti-oxidants, credited with reducing heart disease. How much of a real benefit though are we talking about? And what's, you now, some of this food, you know we're showing some of your bottles here, but some of this food you say, well it will reduce your risk if you ingest , you know, 7 lbs. of it a day or something unnatural like that. How much do you have to have?

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.

* * *

Brian 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.

* * *

(CX1426, Exh. E-7).

Response to Finding No. 2611:
Complaint Counsel does not disagree that the cited excerpts are among Complaint Counsel's bases for challenging Mr. Tupper's *Fox Business* interview.

2612. Complaint Counsel has presented no evidence that Mr. Tupper did not believe that the opinions he expressed during his interview by Brian Sullivan were not completely true.

Response to Finding No. 2612:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs.

2613. Complaint Counsel has proffered no evidence that Mr. Tupper or the other Respondents paid any money to FOX Business or anyone else for his participation in the interview or to allow him to speak about pomegranate juice.

Response to Finding **No. 2613:**
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs.

2614. Complaint Counsel has presented no evidence that Mr. Tupper's "main purpose" or "primary motivation" for participating in an interview with FOX Business was to sell POM.

Response to Finding No. 2614:

The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. In addition, Respondents admitted in their Answer that the *Fox Business* interview with Mr. Tupper (Complaint Ex. E-7) was among "advertisements and promotional materials" that they disseminated or caused to be disseminated. (PX0364_0002, Answer ¶ 9). *See also* Response to Finding 2549.

2615. 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. (CX1426, Exh. E-7)

Response to Finding No. 2615:
Complaint Counsel has no specific response.

2616. 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?" (Tupper, Tr. 1061-62).

Response to Finding No. 2616:
The proposed finding mischaracterizes the evidence. Throughout the interview, in answering questions, Mr. Tupper gave lengthy responses about the purported health benefits of POM Juice and discussed POM's scientific research. For example, in response to the question, "How much do you have to have?" Mr. Tupper not only answered "the dose that's been shown to be effective is 8oz. a day," but also proceeded, unprompted, to state that "what's actually unique among pomegranates . . . is that pomegranate is the one fruit that's actually been tested in human beings by dozens of researchers across the globe" and to detail the results of studies on prostate cancer and cardiovascular disease. (CX0473 (Compl. Ex. E-7 at 00:45-02:00)).

2617. Mr. Tupper's responses to questions concerning pomegranate juice were purely statements of his opinion, which are protected under the First Amendment.

Response to Finding No. 2617:

The proposed finding is a legal conclusion, which is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs.

2618. The substance of the interview, itself, further evidence that neither Mr. Tupper's statements on FOX Business nor even his specific opinions on the benefits of pomegranate juice "proposed a commercial transaction." (CX1426, Exh. E-7).

Response to Finding No. 2618:
The proposed finding is a legal conclusion and is unsupported by the cited evidence. Mr. Tupper specifically highlighted the purported superiority of POM brand products, stating "[w]e'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." (CX1426_00035). In addition, responding to the comment, "these little POMs are pretty pricey. They're about five bucks a bottle, and that' s a latté-grade price tag," Mr. Tupper also stated "they're not cheap, but you get what you pay for." (CX0473 (Compl. Ex. E-7 at 03:08-03:23)).

2619. The Reibstein 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 reason for buying POM. (Reibstein, Tr. at 2493; PX02223-0020).

Response to Finding No. 2619:
The proposed finding is unsupported by the cited evidence or the record as a whole. The cited evidence does not assert that disease treatment or prevention claims would not be material to potential purchasers. (Reibstein, Tr. 2493; PX0223-0020). In addition, the Reibstein survey does not validly measure the materiality of the challenged claims for the POM products. (CCFF ¶¶ 654, 657-61; CX1297 (Mazis, Report at 0008-10)).

2620. Moreover, even assuming *arguendo* that Mr. Tupper's interview on FOX Business constitutes "advertising", Complaint Counsel has presented no evidence that showed any causal relationship between this interview and consumer purchasing decisions.

Response to Finding No. 2620:

The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs.

2621. No liability can 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 the consumer purchasing decisions.

Response to Finding No. 2621:
The proposed finding is a legal conclusion, which is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs.

I. Summary of the Evidentiary Record Regarding POM's advertisements

2622. In conclusion, Respondents summarize their factual findings regarding their advertisements as follows:

(a) Complaint Counsel, from their own actions, admissions, and from the testimony of their expert, Professor Mazis, have repeatedly narrowed the scope of the ads at issue to POM juice prints ads disseminated before December 2008 and POM juice website ads disseminated before August 2009. (*See supra* XVII(D)).

(b) Consequently, those ads remaining at issue, many of which Complaint Counsel focused heavily on at trial, were disseminated three to seven years ago and have not been disseminated since then. (*See supra* XVII(E)).

(c) Complaint Counsel has presented no evidence whatsoever that it is probable or likely that POM would disseminate these "older" types of advertisements again. (*See supra* XVII(E)).

(d) Moreover, there have been significant changed in POM's advertising since 2006 and Respondents' later advertisements convey qualified claims that are substantiated by competent and reliable scientific evidence. (*See supra* XVIII).

(e) Accordingly, Complaint Counsel failed to meet their burden of showing that Respondents' past wrongs are ongoing or likely to recur. As a general rule, "[p]ast wrongs are not enough for the grant of an injunction"; an injunction will issue only if the wrongs are ongoing or likely to recur. *F.T.C. v. Evans Products Co.*, 775 F.2d 1084, 1087 (9th Cir. 1985).

(f) Respondents assert that the Commission may rely on its own reasoned analysis to determine what claims, including implied ones, are conveyed only if those claims are "conspicuous, self-evident or reasonably clear from the face of the ad." (*Kraft*, 970 F.2d 311, 320 (7th Cir. 1972) *cert. denied*, 507 U.S. 909 (1993)).

(g) In this case, however, it is impossible for Complaint Counsel to "conclude with confidence" that POM's advertisements convey the "clinically proven" claims to prevent or treat disease, as alleged. (*See In re Thompson Medical Co.*, 104 F.T.C. 648, 789 (1984), *aff'd*, 791 F.2d 189 (D.C. Cir. 1986), *cert. denied*, 479 U.S. 1086 (1987)).

(h) Consequently, because the challenged implied claims may not be determined with confidence from the face of the challenged advertisements, extrinsic evidence must be examined, including consumer surveys and expert testimony. (*See* Appendix of Advertisements; *In re Stouffer Food Corp.*, 118 F.T.C. 746, 777 (1994) (citing *Kraft*, 970 F.2d at 318)).

(i) Here, even if the ALJ were to allow Complaint Counsel to proceed on a broader number of ads and statements, the net impression of POM's ads do not convey to a reasonable consumer the "clinically proven" claims that Complaint Counsel asserts are implied in the advertisements under Complaint Counsels' "net impression" analysis or any analysis. (*See* Appendix of Advertisements).

(j) Moreover, Complaint Counsel have failed to present any reliable extrinsic evidence or expert opinion on the challenged ads. (Mazis, Tr. 2752).

(k) Additionally, assuming *arguendo* that the presumption of materiality applies in favor of the Commission, such presumption was successfully rebutted by Respondents' expert witness, Professor Reibstein. His survey demonstrated that, even if the ads conveyed the messages that Complaint Counsel assign to them, any alleged disease claims made by Respondents were not material to the purchasing decisions of POM consumers. (*See infra* XVIII(A)).

(l) Additionally, Complaint Counsels' own rebuttal survey expert, Professor Mazis, in stark contrast to work he has performed previously for Complaint Counsel, (a) did not conduct any facial analysis of the ads or offer any expert opinion on them; (b) did not conduct any surveys on the ads and (c) did not provide any expert opinion on the exposure of the ads to consumers, despite testifying that such exposures were critical to having an effect on consumers. (*See infra* XVIII(B)).

(m) The statements made by individual respondents, Mrs. Resnick and Mr. Tupper, during media interviews, on which Complaint Counsel rely, do not constitute "advertisements" and were not intended to market the Challenged Products. (*See infra* XVII(H)).

(n) Consequently, Complaint Counsel cannot rely on these statements to the media to prove its case against POM. (*See infra* XVII(H)).

(o) The Challenged Advertisements are truthful and supported by competent reliable science. (*See infra* XIV, XV, XVI).

(p) None of the Challenged Advertisements convey that a Challenged Product is a substitute for conventional medical treatment. (Butters, Tr. 2819).

Response to Finding No. 2622:
Complaint Counsel refers to its Responses to Findings in the cross-referenced sections, above, in response to this summary.

XVIII. THE ASSERTED IMPLIED CLAIMS WERE NOT MATERIAL TO CONSUMERS

A. Any Presumption of Materiality Was Successfully Rebutted By Respondents' Exert Witness Professor David Reibstein

1. The Reibstein Survey Proves that Consumers Purchase POM Juice For Reasons Other Than Disease-Related Advertising Claims

2623. 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).

Response to Finding No. 2623:
Complaint Counsel disagrees with the proposed finding which is unsupported by the record as a whole. The proposed finding is based upon Dr. Reibstein's survey which fails to validly measure either the motivations of POM Juice purchasers or the materiality of the challenged claims. (CCFF ¶¶ 657-61; CX1297 (Mazis, Report at 0008-10)). It also has no relevance to either the materiality of the challenged POMx claims or the purchase motivations of POMx purchasers. (CCFF ¶ 654). Dr. Reibstein himself admits that the challenged claims regarding the treatment or prevention of heart disease, prostate cancer, and erectile dysfunction would likely be important to consumers. (CCFF ¶ 638). Moreover, according to the A&U study, approximately half of POM Juice purchasers bought it because it "helps promote heart health." and approximately 40% of males bought it because it "helps protect against prostate cancer" (Mazis, Tr. 2684-85). The Reibstein survey relied upon broad open-ended questions and as Dr. Stewart wrote in an

article published in the *Journal of Public Policy and Marketing*, "[R]esearch . . . demonstrates that consumers do not need to remember a specific claim for that claim to influence attitude or choice. The claim may not be stored in memory even though an evaluation of the brand has been made (Gibson 1983; Greenwald 1968; Lichtenstein and Srull 1985; Ross 1982; Srull 1989; Stout 1981; Young 1972). Thus, the claim may have an influence on consumer behavior even when it is not articulated by the consumer in response to an open-ended question. Because the . . . survey neither exposed respondents to the claims at issue nor measured any relative preference behavior (verbal or otherwise) following exposure, the results of the survey do not address . . . issues relevant to the question of materiality." (PX0223-0005; PX0357a06-0001-02; PX0357 (Stewart, Dep. at 190-92)).

2624. Only 1.74% (6 out of 344) of non-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).

Response to Finding No. 2624:
See Response to Finding 2623.

2625. Based on Questions E and H "Why Did You Purchase," less than 1% (7 out of 750) of pomegranate juice buyers (POM and non-POM) bought the juice because they believe it cures or prevents any specific disease. (Reibstein, Tr. 2493, 2495; PX0223-0010-0011, 0020).

Response to Finding No. 2625:
Complaint Counsel does not disagree that this was a finding of the Reibstein survey, but disagrees with the implication that the Reibstein survey validly measures either the materiality of the challenged claims or the motivations of POM Juice purchasers. *See* Response to Finding 2623.

2626. Based on Questions F1a and I1a "Why Would You Buy Again," less than 1% (2 out of 755) of pomegranate juice buyers who mentioned that they would buy pomegranate juice (any brand) again stated they would do so because they believe that pomegranate juice cures or prevents any specific disease. (Reibstein, Tr. 2493, 2495; PX0223-0011, 0020).

Response to Finding No. 2626:
Complaint Counsel does not disagree that this was a finding of the Reibstein survey, but disagrees with the implication that the Reibstein survey validly measures either the materiality of the challenged claims or the motivations of POM Juice purchasers. *See* Response to Finding 2623.

2627. Based on Questions G1a and J1a "Why Would You Recommend," less than 1% (4 out of the 750) of pomegranate juice buyers who mentioned that they would recommend pomegranate juice (any brand) to a friend stated they would do so because they believe pomegranate juice cures or prevents any specific disease. (Reibstein, Tr. 2493, 2495; PX0223-0012, 0020).

Response to Finding No. 2627:
Complaint Counsel does not disagree that this was a finding of the Reibstein survey, but disagrees with the implication that the Reibstein survey validly measures either the materiality of the challenged claims or the motivations of POM Juice purchasers. *See* Response to Finding 2623.

2628. Based on the results of Questions E, F1, G1, H1, I1 and J1, very few pomegranate juice buyers POM or non-POM bought, would buy again or would recommend pomegranate juice because they believe the juice cures or prevents any specific disease. (PX0223-0012; Reibstein, Tr. 2499, 2501).

Response to Finding No. 2628:
Complaint Counsel does not disagree that this was a finding of the Reibstein survey, but disagrees with the implication that the Reibstein survey validly measures either the materiality of the challenged claims or the motivations of POM Juice purchasers. *See* Response to Finding 2623.

2629. Based on the results of Questions E, F1, G1, H1, I1 and J1, there is no significant difference in the perception of whether pomegranate juice can cure or prevent disease between POM Juice buyers and non-POM Juice buyers. (Reibstein, Tr. 2499, 2501; PX0223-0010-0012, 0020).

Response to Finding No. 2629:
Complaint Counsel does not disagree that this was a finding of the Reibstein survey, but disagrees with the implications that the one can draw any reliable conclusions based on

such an analysis and that the Reibstein survey validly measures either the materiality of the challenged claims or the motivations of POM Juice purchasers. (Mazis, Tr. 2676-78; CX1297 (Mazis, Report at 0008-12); s*ee* Response to Finding 2623.

2630. A summary of the results of Questions E-J were set forth by Professor Reibstein in Figure 5 in his expert report. Figure 5 is set forth below:

Question	Percentage of POM Wonderful Juice Buyers whose response mentions a specific disease reference n=406	Percentage of Pomegranate Juice Buyers whose response mentions a specific disease reference n=344
E/H (Why did you purchase?)	1.0% (4/406)[6]	9% (3/344)[7]
F/I (Why would you purchase/not purchase again?)	5% (2/406)[8]	0% (0/344)
G/J (Why would/would not recommend?)	.3% (1/406)[9]	9% (3/344)[10]
NET	**1.48% (6/406)[11]**	**1.74% (6/344)**

Response to Finding No. 2630:

Complaint Counsel does not disagree that these were findings of the Reibstein survey but disagrees with the implication that the Reibstein survey validly measures either the materiality of the challenged claims or the motivations of POM Juice purchasers. *See* Response to Finding 2623.

[6] 4 respondents – 1200046, 1200183, 1200349, 1200618

[7] 3 respondents – 1200175, 1200543, 1201150

[8] 2 respondent – 1200284, 1200618

[9] 1 respondent - 1200229

[10] 3 respondents – 1200687, 1200836, 1200543

[11] Respondent 1200618 appears twice. In the NET he/she is only counted once.

2631. In response to Question E "Why Did You Purchase," only 1% of the 406 POM Juice buyers bought the product because they believe it cures or prevents any specific disease. (Reibstein, Tr. 2493, 2495; PX0223-0006, 0011; PX0233-0007, 0008).

Response to Finding No. 2631:
Complaint Counsel does not disagree that this was a finding of the Reibstein survey, but disagrees with the implication that the Reibstein survey validly measures either the materiality of the challenged claims or the motivations of POM Juice purchasers. *See* Response to Finding 2623.

2632. In response to Question E "Why Did You Purchase," less than 1% of the 344 non-POM Juice buyers bought the juice because they believe it cures or prevents any specific disease. (Reibstein, Tr. 2493, 2495; PX0223-0006, 0011; PX0233-0008).

Response to Finding No. 2632:
Complaint Counsel does not disagree that this was a finding of the Reibstein survey, but disagrees with the implication that the Reibstein survey validly measures either the materiality of the challenged claims or the motivations of POM Juice purchasers. *See* Response to Finding 2623.

2633. In response to Question E "Why Did You Purchase," 43.6% of the POM Juice buyers bought the juice because of "Taste." (Reibstein, Tr. 2496, 2553; PX0223-0006; PX0233-0008).

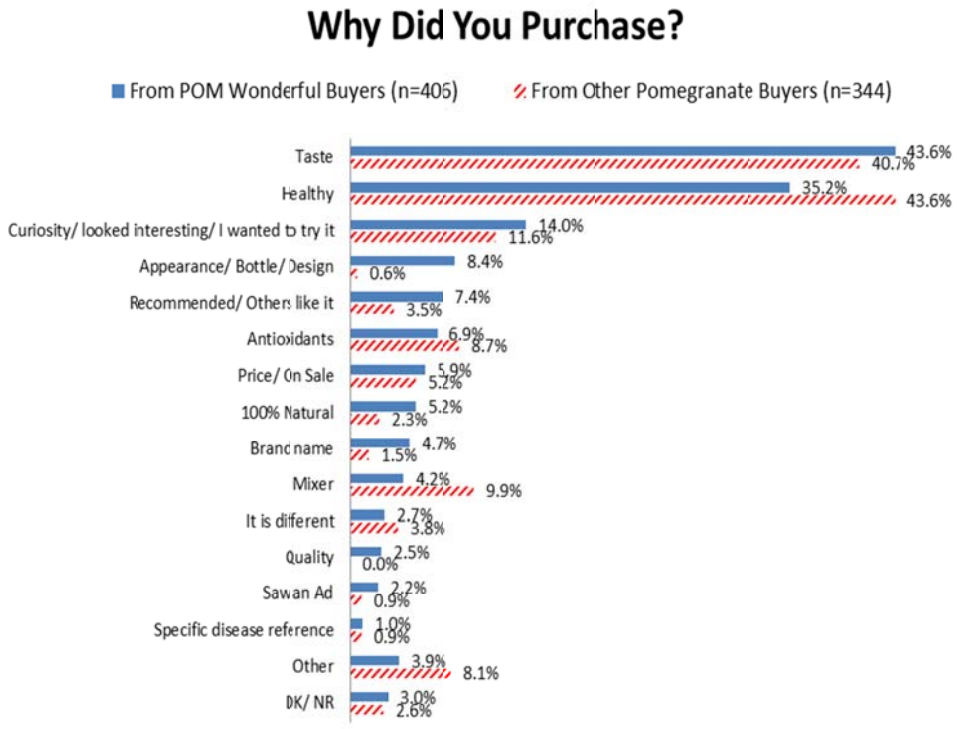
Response to Finding No. 2633:
Complaint Counsel does not disagree that this was a finding of the Reibstein survey, but disagrees with the implication that the Reibstein survey validly measures either the materiality of the challenged claims or the motivations of POM Juice purchasers. *See* Response to Finding 2623.

2634. In response to Question E "Why Did You Purchase," approximately 35% of POM Juice buyers bought the juice because they thought the product was "Healthy" versus 43.6% of non-POM Juice buyers. (Reibstein, Tr. 2496, 2553; PX0223-0006; PX0233-0008).

Response to Finding No. 2634:
Complaint Counsel agrees that this was a finding of the Reibstein survey, and agrees that health benefits are important reasons for purchase both for purchasers of POM Juice and

purchasers of other pomegranate juices. (CCFF ¶¶ 632-34, 641-43, 648-50, 655, 660; CX0370_0011-12; CX0292_0026; CX0136_0020). Dr. Reibstein failed to properly probe such healthy responses to ascertain what specific health benefits underlay healthy responses. (CCFF ¶¶ 660-61). The failure to do so was the "elephant in the room." (Mazis, Tr. 2669-70).

2635. The results of Question E "Why Did You Purchase" were set forth by Professor Reibstein in Figure 1 in his expert report. Figure 1 is set forth below:



Response to Finding No. 2635:
See Response to Finding 2634.

2636. In response to Question F1a "Why Would You Buy Again," only 0.5% of the POM Juice buyers would buy again because they believe it cures or prevents any specific disease. (Reibstein, Tr. 2497-98; PX0223-0007, 0011; PX0233-0012).

Response to Finding No. 2636:
Complaint Counsel does not disagree that this was a finding of the Reibstein survey, but disagrees with the implication that the Reibstein survey validly measures either the

materiality of the challenged claims or the motivations of POM Juice purchasers. *See* Response to Finding 2623.

2637. In response to Question F1a "Why Would You Buy Again," 0% of non-POM Juice buyers would buy again because they believe it cures or prevents any specific disease. (Reibstein, Tr. 2497-98; PX0223-0007; PX0233-0012).

Response to Finding No. 2637:
Complaint Counsel does not disagree that this was a finding of the Reibstein survey, but disagrees with the implication that the Reibstein survey validly measures either the materiality of the challenged claims or the motivations of POM Juice purchasers. *See* Response to Finding 2623.

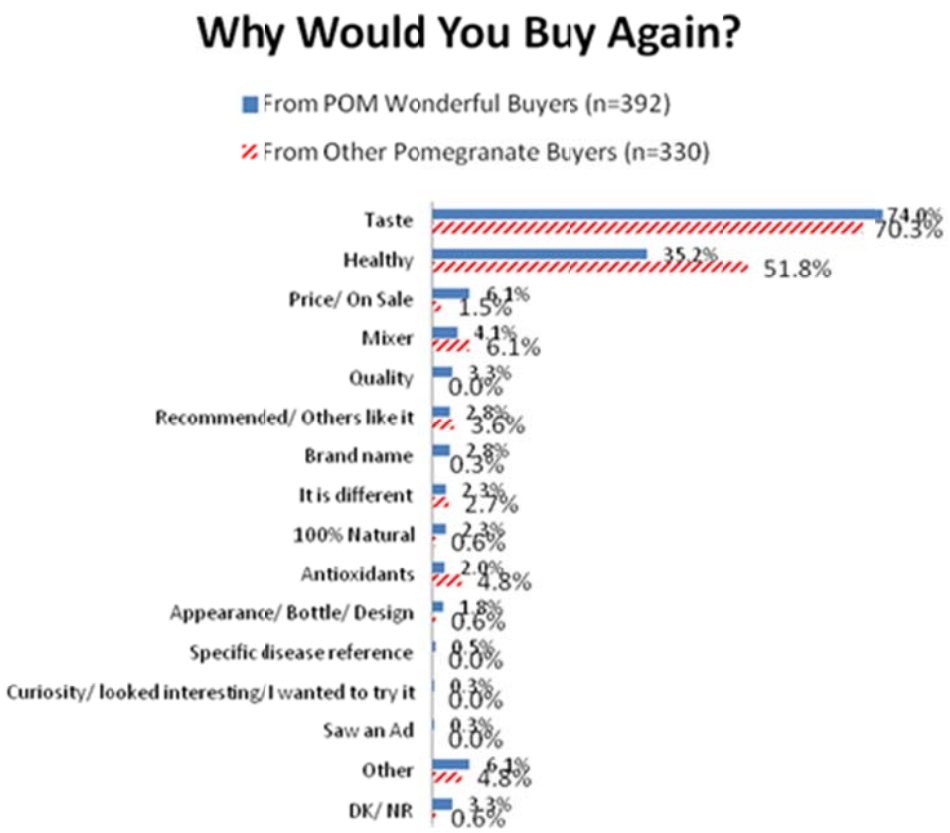
2638. In response to Question F1a "Why Would You Buy Again," 74% of the POM Juice buyers would buy again because of "Taste." (PX0223-0006; PX0233-0012).

Response to Finding No. 2638:
Complaint Counsel does not disagree that this was a finding of the Reibstein survey, but disagrees with the implication that the Reibstein survey validly measures either the materiality of the challenged claims or the motivations of POM Juice purchasers. *See* Response to Finding 2623.

2639. In response to Question F1a "Why Would You Buy Again," 35.2% of POM Juice buyers would buy again because they thought the product was "Healthy" versus 51.8% of non-POM Juice buyers. (PX0223-0007; PX0233-0012).

Response to Finding No. 2639:
Complaint Counsel agrees that this was a finding of the Reibstein survey, and agrees that health benefits are important reasons for purchase both for purchasers of POM Juice and purchasers of other pomegranate juices. (CCFF ¶¶ 632-34, 641-43, 648-50, 655, 660; CX0370_0011-12; CX0292_0026; CX0136_0020). Dr. Reibstein failed to properly probe such healthy responses to ascertain what specific health benefits underlay healthy responses. (CCFF ¶¶ 660-61). The failure to do so was the "elephant in the room." (Mazis, Tr. 2669-70).

2640. The results of Question F1a "Why Would You Buy Again" were set forth by Professor Reibstein in Figure 2 in his expert report. Figure 2 is set forth below:



Response to Finding No. 2640:
See Response to Finding 2639.

2641. In response to Question G1a "Why Would You Recommend," only 0.3% of the POM Juice buyers would recommend the juice because they believe it cures or prevents any specific disease. (Reibstein, Tr. 2498-99; PX0223-0008, 0012; PX0233-0018).

Response to Finding No. 2641:
Complaint Counsel does not disagree that this was a finding of the Reibstein survey, but disagrees with the implication that the Reibstein survey validly measures either the materiality of the challenged claims or the motivations of POM Juice purchasers. *See* Response to Finding 2623.

2642. In response to Question G1a "Why Would You Recommend," only 1% of the non-POM Juice buyers would recommend the juice because they believe it cures or prevents any specific disease. (PX0223-0008, 0012; Reibstein, Tr. 2498-99; PX0233-0018).

Response to Finding No. 2642:
Complaint Counsel does not disagree that this was a finding of the Reibstein survey, but disagrees with the implication that the Reibstein survey validly measures either the materiality of the challenged claims or the motivations of POM Juice purchasers. *See* Response to Finding 2623.

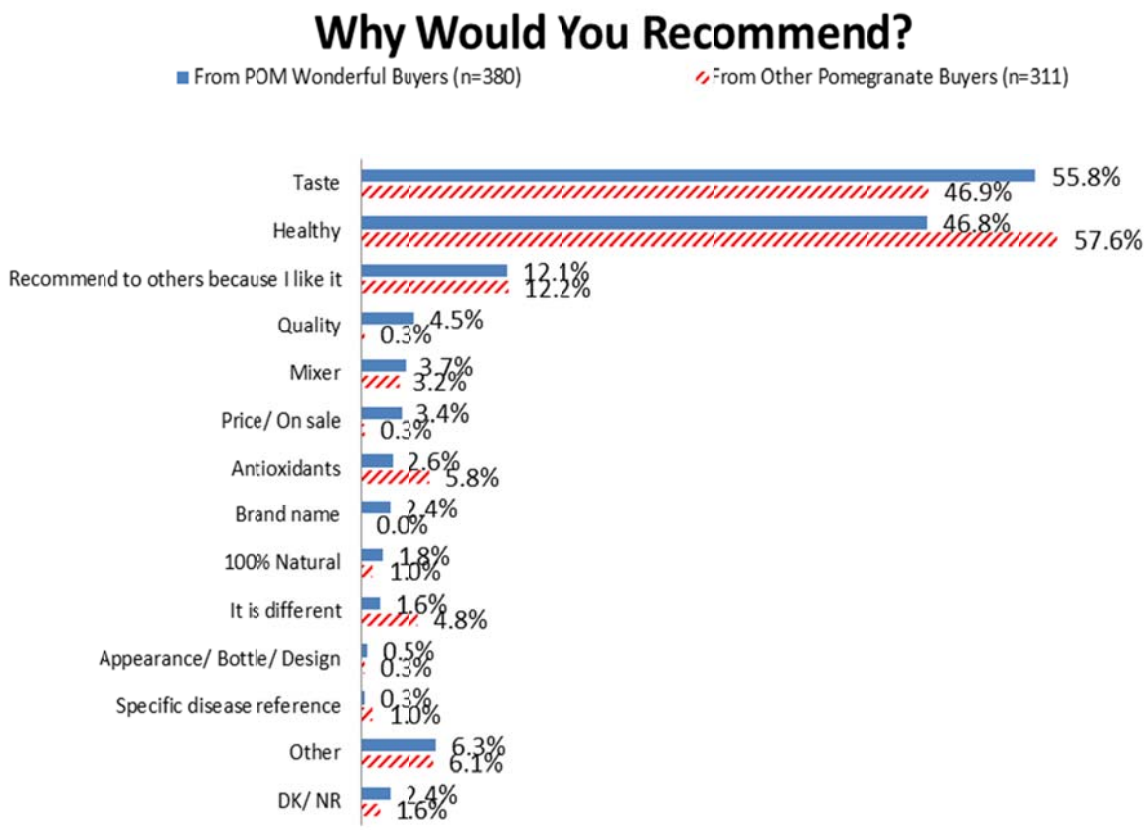
2643. In response to Question G1a "Why Would You Recommend," 55.8% of the POM Juice buyers would recommend the juice because of "Taste." (PX0223-0008; PX0233-0018).

Response to Finding No. 2643:
Complaint Counsel does not disagree that this was a finding of the Reibstein survey, but disagrees with the implication that the Reibstein survey validly measures either the materiality of the challenged claims or the motivations of POM Juice purchasers. *See* Response to Finding 2623.

2644. In response to Question G "Why Would You Recommend," 46.8% of POM Juice buyers would recommend the juice because they thought the product was "Healthy" versus 57.6% of non-POM Juice buyers. (PX0223-0008; PX0233-0018; Reibstein, Tr. 2499).

Response to Finding No. 2644:
Complaint Counsel agrees that this was a finding of the Reibstein survey, and agrees that health benefits are important reasons for purchase both for purchasers of POM Juice and purchasers of other pomegranate juices. (CCFF ¶¶ 632-34, 641-43, 648-50, 655, 660; CX0370_0011-12; CX0292_0026; CX0136_0020). Dr. Reibstein failed to properly probe such healthy responses to ascertain what specific health benefits underlay healthy responses. (CCFF ¶¶ 660-61). The failure to do so was the "elephant in the room." (Mazis, Tr. 2669-70).

2645. The results of Question G1a "Why Would You Recommend" were set forth by Professor Reibstein in Figure 3 in his expert report. Figure 3 is set forth below:



Response to Finding No. 2645:
See Response to Finding 2644.

2. The Reibstein Survey Proves That POM's Advertisements Had No Impact on Buyers Beliefs In the Curative or Preventive Attributes of Pomegranate Juice

2646. From the results of Questions E-K, POM's advertisements had no impact on buyers' beliefs that pomegranate juice can or will cure or prevent disease. (PX0223-0016-0020). A total of 12 unique respondents out of 750 total respondents, including non-POM Juice buyers, mentioned a specific disease as a reason for purchasing or recommending pomegranate juice. Among these respondents, only 4 of them have seen a POM advertisement at some point and 8 never have. (PX0223-0016-0020).

Response to Finding No. 2646:
The proposed finding's assertion that the Reibstein survey shows the impact of POM advertisements, and by implication the challenged ads, on consumer beliefs is unsupported by the record as a whole. Dr. Reibstein's analysis based on claimed recollection of ever having seen any POM Juice ad is flawed and his survey does not

show the impact of the challenged ads on consumers beliefs. (Mazis, Tr. 2678-81; CX1297 (Mazis, Report at 0009-11)). The impact of advertising on beliefs about a product is not an appropriate measure of materiality or ad claim communication. (CX1297 (Mazis, Report at 0009)).

2647. The data from the Reibstein Survey shows that the small portion of pomegranate juice buyers who believe in the curative or preventive attributes of pomegranate juice is very similar between the group of respondents who had seen a POM advertisement and ones who have not. (PX0223-0016-0020).

Response to Finding No. 2647:
The proposed finding is unsupported by the record as a whole. The Reibstein survey does not measure consumer beliefs; to the extent that it measures purchase motivations, it is seriously flawed and inadequate; and Dr. Reibstein's analysis based on claimed recollection of ever having seen any POM Juice ad is flawed. (Mazis, Tr. 2678-81, 2731; CX1297 (Mazis, Report at 0008-11); PX0359 (Mazis, Dep. at 54-56)).

2648. Based on Question K1 "Have You Seen a POM Ad," 41.9% of POM Juice buyers, 36.9% of the non-POM Juice buyers, and 39.6% of people (297 out of 750) who consumed pomegranate juice in the last 6 months had ever seen a POM advertisement. (PX0223-0009, 0016; PX0233-0028; Reibstein, Tr. 2536).

Response to Finding No. 2648:
Complaint Counsel does not disagree that this was a finding of the Reibstein survey, but disagrees with the implication that the Reibstein survey validly measured exposure to POM ads or to the challenged POM ads. Answers regarding whether survey respondents ever saw a POM Juice ad are unreliable and there is no basis for concluding which if any of the survey respondents saw any of the challenged POM Juice ads. (Mazis, Tr. 2679-80; CX1297 (Mazis, Report at 0010-11); Reibstein, Tr. 2536-38; *see also* PX0356 (Reibstein, Dep. at 97, 133-34)).

2649. Based on Question K1a, none of the respondents who saw a POM advertisement responded that they remember the advertisement making a specific disease claim. (PX0223-0009; PX0233-0029).

Response to Finding No. 2649:

Complaint Counsel does not disagree that this was a finding of the Reibstein survey, but disagrees with the implication that the Reibstein survey validly measured the ad communication of the challenged ads. (CX1297 (Mazis, Report at 0010-11); Mazis, Tr. 2691-93). *See also* Response to Finding 2648. Dr. Reibstein did not show survey respondents any of POM's advertisements. (Reibstein, Tr. 2494). The ads airing at the time of the survey were not making the challenged claims. (CX1297 (Mazis, Report at 0010-11); Mazis, Tr. 2691). Of the approximately, 40% of POM Juice purchasers in the Reibstein survey who claimed to have ever seen a POM ad, approximately 25% gave indicia of having seen one of the POM television ads running at the time of the survey. (Mazis, Tr. 2692-93; Reibstein, Tr. 2536-45).

2650. Based on Questions E and H "Why Did You Purchase," among the respondents who bought pomegranate juice and who have seen a POM advertisement, only 0.7% (2 out of 297 total) bought the juice because they believe it cures or prevents any specific disease whereas 42.8% (127 out of 297 total) bought the juice because they think it is "Healthy." (PX0223-0016-0017; Reibstein, Tr. 2507).

Response to Finding No. 2650:

Complaint Counsel agrees that this was a finding of the Reibstein survey, and agrees that health benefits are important reasons for purchase both for purchasers of POM Juice and purchasers of other pomegranate juices. (CCFF ¶¶ 632-34, 641-43, 648-50, 655, 660; CX0370_0011-12; CX0292_0026; CX0136_0020). Dr. Reibstein failed to properly probe such healthy responses to ascertain what specific health benefits underlay healthy responses. (CCFF ¶¶ 660-61). The failure to do so was the "elephant in the room." (Mazis, Tr. 2669-70).

2651. Based on Questions E and H "Why Did You Purchase," among the respondents who bought pomegranate juice and who did not see a POM advertisement, less than 2% bought the juice because they believe it cures or prevents any specific disease whereas

approximately 36% bought the juice because they think it is "Healthy." (PX0223-0016-0017).

Response to Finding No. 2651:
See Response to Finding 2650.

2652. Based on Questions F1a and I1a "Why Would You Buy Again," among the respondents who bought pomegranate juice and stated they would purchase pomegranate juice again and who have seen a POM advertisement, only 0.4% (1 out of 285 total) would purchase the juice again because think it cures or prevents any specific disease and 46.3% (132 out of 285 total) said they would purchase again because they think it is "Healthy." (PX0223-0017-0018; PX0233-0012).

Response to Finding No. 2652:
See Response to Finding 2650.

2653. Based on Questions F1a and I1a "Why Would You Buy Again," among the respondents who bought pomegranate juice and who did not see a POM advertisement, only 0.3% (1 out of 349 total) said they would purchase the juice again because think it cures or prevents any specific disease whereas 37.8% (132 out of 349 total) said they would purchase again because they think it is "Healthy." (PX0223-0017-0018; PX0233-0012).

Response to Finding No. 2653:
See Response to Finding 2650.

2654. Based on Questions G1a and J1a "Would you Recommend," among the respondents who bought pomegranate juice and stated that they would recommend pomegranate juice to a friend and who have seen a POM advertisement, only 0.4% (1 out of 279 total) said they would recommend the juice because they think it cures or prevents any specific disease whereas 55.6% (155 out of 279 total) said they would recommend the juice because they think it is "Healthy." (PX0223-0018-0019; PX0233-0012).

Response to Finding No. 2654:
See Response to Finding 2650.

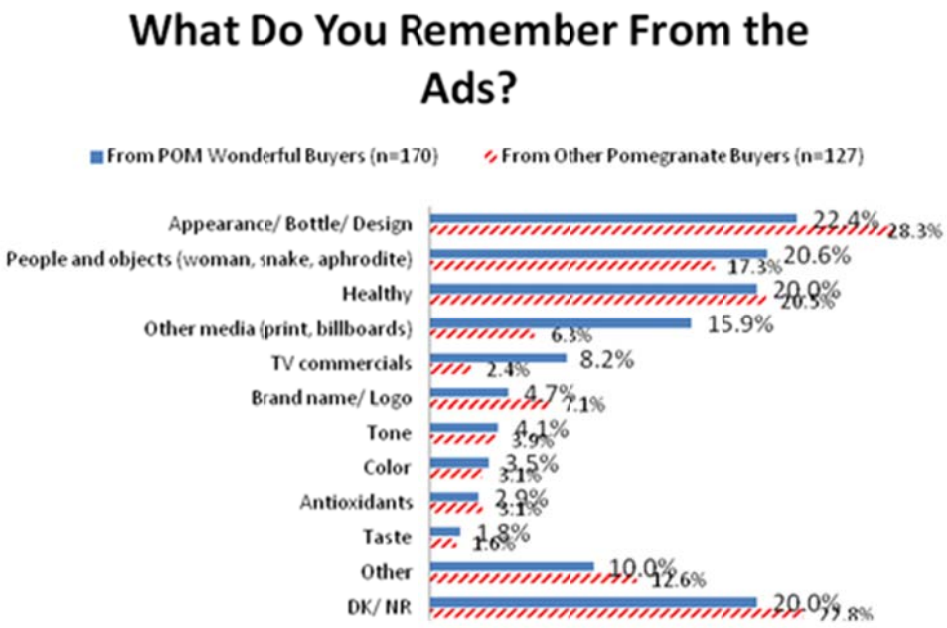
2655. Based on Questions G1a and J1a "Would you Recommend," among the respondents who bought pomegranate juice and stated that they would recommend pomegranate juice to a friend and who have not seen a POM advertisement, only 0.9% (3 out of 328 total) said they would recommend the juice because think it cures or prevents any specific disease whereas 47.3% (155 out of 328 total) said they would recommend the juice because they think it is "Healthy." (PX0223-0019; PX0233-0012).

Response to Finding No. 2655:
See Response to Finding 2650.

2656. The amount of money POM spent on its research was not a factor in why respondents purchased POM Juice. (Reibstein, Tr. 2508).

Response to Finding No. 2656:
The proposed finding is unsupported by the record evidence as a whole. The Reibstein survey was seriously flawed and inadequate as a measure of the purchase motivations of POM Juice purchasers, asking only asked broad open-ended questions with no probing. (PX0359 (Mazis, Dep. at 54-56); CX1297 (Mazis, Report at 0009-10); Mazis, Tr. 2731).

2657. A summary of the results of Questions K1a were set forth by Professor Reibstein in Figure 4 in his expert report. Figure 4 is set forth below:



Response to Finding No. 2657:
Complaint Counsel does not disagree that these were findings of the Reibstein survey, but disagrees with the implication that the Reibstein survey validly measured the ad communication of the challenged ads. (CX1297 (Mazis, Report at 0010-11); Mazis, Tr. 2691-93). *See also* Response to Finding 2649.

3. The Methodology of the Reibstein Survey Is Scientifically Valid

2658. The Reibstein Survey was conducted by an independent market research company, Horizon Consumer Science ("HCS") under Professor Reibstein's direction. (PX0223-0003).

Response to Finding No. 2658:
Complaint Counsel has no specific response.

2659. HCS maintains an on-line panel of over one million subjects. From this population, a stratified sample of 2,164 was drawn from the U.S. population. (PX0223-0004).

Response to Finding No. 2659:
Complaint Counsel has no specific response.

2660. The Reibstein Survey was designed to reveal (i) a buyer's motivation for purchasing pomegranate juice; (ii) whether having previously seen POM Juice advertisements in the normal sequence of view ads, and not in an artificial setting, the ads affected the buyer's motivations for buying pomegranate juice; and (iii) whether the buyer's awareness of the legal issues around the case might have affected their motivation for buying pomegranate juice. (PX0223-0005; Reibstein, Tr. 2487; PX0356 (Reibstein Dep. at 11, 39, 51)).

Response to Finding No. 2660:
Complaint Counsel does not disagree that the proposed finding lists Dr. Reibstein's stated objectives but disagrees with the implications that the Reibstein survey validly measures the materiality of the challenged claims, the motivations of POM Juice purchasers, or the impact of POM advertisements on consumer beliefs. *See* Responses to Findings 2523 and 2646.

2661. To qualify for the survey, respondents had to meet the following criteria: (i) purchased pomegranate juice in the last 6 months; (ii) had not completed any online survey within the past 3 months for any beverage products; (iii) did not work in any of the following industries: advertising, public relations, beverages, marketing or market research; and (iv) was over 18 years old. This was accomplished through a serious of screening questions. (PX0223-0004; PX0237-0001-0002; PX0356 (Reibstein, Dep. at 50, 57-58)).

Response to Finding No. 2661:
Complaint Counsel has no specific response.

2662. The 2,164 chosen panelists completed the online survey and 750 of them met the qualification criteria and actually conducted the survey. (PX0223-0004).

Response to Finding No. 2662:
Complaint Counsel has no specific response.

2663. The Reibstein Survey surveyed two groups, 406 respondents who purchased POM Juice in the past 6 months and 344 respondents who purchased brands of pomegranate juice other than POM in the past 6 months. (PX0223-0004; Reibstein, Tr. 2494).

Response to Finding No. 2663:
Complaint Counsel has no specific response.

2664. In order to find out what motivated the sample of 406 POM Juice consumers to buy POM Juice, the Reibstein Survey asked three primary open-ended questions as set forth in Questions E through G. (PX0223-0005).

Response to Finding No. 2664:
Complaint Counsel has no specific response.

2665. Question E asked "Why did you purchase POM Wonderful 100% Pomegranate Juice? *Please include as many specific details*." (PX0237-0002; PX0223-0006).

Response to Finding No. 2665:
Complaint Counsel has no specific response.

2666. Question F asked "Would you consider purchasing POM Wonderful 100% Pomegranate Juice again? (SELECT ONE ONLY) 1. Yes a. Why? *Please include as many specific details as to why you would?* 2. No. a. Why not? *Please include as many specific details as to why you would not?* 3. Don't know." (PX0237-0002; PX0223-0007).

Response to Finding No. 2666:
Complaint Counsel has no specific response.

2667. Question G asked "Would you recommend POM Wonderful 100% Pomegranate Juice to a friend? (SELECT ONE ONLY) 1. Yes a. Why? *Please include as many specific details as to why you would?* 2. No. a. Why not? *Please include as many specific details as to why you would not?* 3. Don't know." (PX0237-0002; PX0223-0008).

Response to Finding No. 2667:
Complaint Counsel has no specific response.

2668. In order to find out what motivated the sample of 344 non-POM Juice pomegranate juice consumers to buy POM Juice, the Reibstein Survey asked three primary open-ended questions as set forth in Questions H through J. (PX0223-0005).

Response to Finding No. 2668:
Complaint Counsel has no specific response.

2669. Question H asked "You indicated that you have purchased pomegranate juice. *Please include as many specific details* as to why you purchased it. *Please* be *as detailed as possible.*" (PX0237-0002; PX0223-0006).

Response to Finding No. 2669:
Complaint Counsel has no specific response.

2670. Question I asked "Would you consider purchasing pomegranate juice again? (SELECT ONE ONLY) 1. Yes a. Why? *Please include as many specific details as to why you would again*? 2. No. a. Why not? *Please include as many specific details as to why you* would *not again*? 3. Don't know." (PX0237-0003).

Response to Finding No. 2670:
Complaint Counsel has no specific response.

2671. Question J asked "Would you recommend pomegranate juice to a friend? (SELECT ONE ONLY) 1. Yes a. Why? *Please include as many specific details as to why* you *would?* 2. No. a. Why not? *Please include as many specific details as to why you would not?* 3. Don't know." (PX0237-0003).

Response to Finding No. 2671:
Complaint Counsel has no specific response.

2672. Questions E-J were asked in open-ended format, which reduces any biasing of the respondents. (PX0223-0005; PX0356 (Reibstein Dep. at 84-85)).

Response to Finding No. 2672:
Complaint Counsel has no specific response.

2673. Question K asked respondents "Have you ever seen a POM Wonderful 100% Pomegranate Juice advertisement? (SELECT ONLY ONE) 1. Yes. A. Please include as many specific details as to what you remember about the ad. *Please be as detailed as possible*. 2. No 3. Don't know." (PX0237-0003; PX0223-0016; Reibstein, Tr. 2507, 2567).

Response to Finding No. 2673:
Complaint Counsel has no specific response.

2674. The Reibstein Survey employed two types of controls. The first control was to draw a sample of non-POM Juice buyers and ask them the same questions as the POM Juice buyers to see if these buyers had different motivations for purchasing pomegranate juice. The second control was to compare the responses of people who had seen POM advertisements against those who had not seen any POM advertisement. (PX0223-0004, 0005; Reibstein, Tr. 2488-89, 2493; PX0356 (Reibstein, Dep. at 73-74)).

Response to Finding No. 2674:
Complaint Counsel does not disagree that Dr. Reibstein employed two purported controls, but disagrees with the implication that the analyses based upon these purported controls has any validity. (Mazis, Tr. 2676-81; CX1297 (Mazis, Report at 0009-11)).

2675. Respondents to the Reibstein survey were not shown any POM advertisements because there is no need to show respondents advertisements to determine what motivated them to purchase pomegranate juice. (Reibstein, Tr. 2494, 2525).

Response to Finding No. 2675:
Complaint Counsel has no specific response other than to note that there is a need to show respondents advertisements, if one is seeking to measure claim communication, and that there is a need to provide the "claim" and ask about its importance, if one is measuring the materiality of the claim. (Mazis, Tr. 2693-94; PX0359 (Mazis, Dep. at 154); CCFF ¶ 658). As Dr. Stewart wrote in an article published in the *Journal of Public Policy and Marketing*, "Because the . . . survey neither exposed respondents to the claims at issue nor measured any relative preference behavior (verbal or otherwise) following exposure, the results of the survey do not address . . . issues relevant to the question of materiality." (PX0357a06-0001-02; PX0357 (Stewart, Dep. at 190-92)).

2676. The Reibstein Survey included in the category "Specific disease reference" responses such as pomegranate juice is good for bowel movements or helpful in fighting urinary tract infections. (Reibstein, Tr. 2505; PX0223-0011).

Response to Finding No. 2676:
Complaint Counsel has no specific response.

2677. The Reibstein Survey was conducted in or about October 2010. (PX0356 (Reibstein Dep. at 12); Mazis, Tr. 2759).

Response to Finding No. 2677:
Complaint Counsel has no specific response.

2678. The results of the Reibstein Survey are statistically significant because there were more than 300 respondents in each group. (PX0223-0004; Reibstein, Tr. 2495-96).

Response to Finding No. 2678:
The proposed finding is unsupported by the cited evidence. Dr. Reibstein did not claim that he found statistically significant results, but rather explained that a 300 person sample size would allow a result to reach statistical significance. (PX0223-0004;

Reibstein, Tr. 2495-96). To the contrary, he claimed to have not found statistically significant results. (PX0223-0015, 0020; Reibstein, Tr. 2493, 2499, 2502).

2679. The survey respondents were compensated solely by the provision of contributions to a charity for their participation in the Reibstein Survey. (PX0223-0004).

Response to Finding No. 2679:
The proposed finding is unsupported by the record as a whole. Dr. Reibstein's report misstates that survey respondents were compensated by the provision of contributions to a charity for their participation in the survey, and he later learned that survey respondents, in fact, received "points which they could subsequently use to purchase things." (PX0356 (Reibstein, Dep. at 67)).

B. Complaint Counsel's Survey Expert Failed to Rebut Respondents' Credible Evidence Disproving the Materiality of the Challenged Claims

1. Professor Michael Mazis Offered No Opinion on the Materiality of the Challenged Claims But Concedes That a Claim is Material Only If It Affects a Consumer Purchasing Decisions

2680. It was not within the scope of Professor Mazis's assignment to examine the materiality of the Challenged Claims. (PX0296).

Response to Finding No. 2680:
The proposed finding mischaracterizes Complaint Counsel's use of Dr. Mazis as a rebuttal witness to respond to Dr. Reibstein, including to the Reibstein survey and to Dr. Reibstein's assertion in his report that the A&U study is not "reliable or relevant." (CX1297 (Mazis, Report at 0001-02, 0012-13); PX0223 (Reibstein, Report at 0003)). As such, Dr. Mazis was not asked to affirmatively opine on whether the challenged claims would be material. (Mazis, Tr. 2651-2751; CX1297 (Mazis, Report at 0001-15); PX0359 (Mazis, Dep. at 1-243)). Dr. Mazis also expressed his opinion that the A&U study demonstrated that the challenged heart disease and prostate cancer claims are material. (Mazis, Tr. 2688-89, 2760; CX1297 (Mazis, Report at 0012-13)).

2681. Professor Mazis offered no expert opinion on the materiality of the Challenged Claims in his export report, deposition or trial testimony. (PX0296; Mazis, Tr. 2651-2761; PX0359 (Mazis, Dep. at 1-242)).

Response to Finding No. 2681:
See Response to Finding 2680.

2682. Professor Mazis was only asked by Complaint Counsel to evaluate the "scientific adequacy" of the Reibstein Survey. (PX0296-0002; PX0359 (Mazis, Dep. at 119)).

Response to Finding No. 2682:
The proposed finding mischaracterizes the cited evidence. Dr. Mazis was also asked to "evaluate the scientific adequacy of the . . . report written by" Dr. Reibstein. (PX0296 (Mazis, Report at 0002)). In his report, Dr. Reibstein refers to his review of "Other Studies," which were in Respondents' possession, including the A&U study. (PX0223 (Reibstein, Report at 0003)); CX1297 (Mazis, Report at 0012-13). Dr. Mazis reviewed the A&U study, and determined that it was highly relevant to this proceeding and that it demonstrated that the challenged heart disease and prostate cancer claims are material. (Mazis, Tr. 2688-89, 2760; CX1297 (Mazis, Report at 0012-13)).

2683. Professor Mazis's expert opinions offered in this case were limited solely to the "scientific adequacy" of the Reibstein Survey. (PX0296-0002).

Response to Finding No. 2683:
See Response to Finding 2682.

2684. Professor Mazis was neither asked by Complaint Counsel nor did he design or conduct a consumer survey regarding the Challenged Claims or any POM advertising. (PX0359 (Mazis, Dep. at 128, 232; Mazis, Tr. 2736).

Response to Finding No. 2684:
See Response to Finding 2680.

2685. Professor Mazis provided no expert opinion based on a facial analysis of POM's advertisements. (PX0296; Mazis, Tr. 2651-2761; PX0359 (Mazis, Dep. at 1-242).

Response to Finding No. 2685:
See Response to Finding 2680.

2686. Professor Mazis provided no expert opinion on the impact of POM's advertisements on consumers. (PX0296; Mazis, Tr. 2651-2761; PX0359 (Mazis, Dep. at 1-242).

Response to Finding No. 2686:
See Response to Finding 2680. In addition, Dr. Mazis did express the opinion that the Reibstein Survey does not allow one to draw conclusions about the impact of POM's advertisements. (Mazis, Tr. 2671, 2690-95; CX1297 (Mazis, Report at 0009-11).

2687. Professor Mazis provided no expert opinion on the "indirect effects" of POM's advertisements. (PX0296; Mazis, Tr. 2651-2761; PX0359 (Mazis, Dep. at 1-242).

Response to Finding No. 2687:
See Response to Finding 2680.

2688. Professor Mazis provided no expert opinion on POM's advertisements based on the psychological and consumer behavior theory of "categorization." (PX0296; Mazis, Tr. 2651-2761; PX0359 (Mazis, Dep. at 1-242).

Response to Finding No. 2688:
See Response to Finding 2680.

2689. Professor Mazis conceded that there is no evidence in the record in this case regarding whether "it's probable that any POM Juice or POMx advertisement was likely to affect anyone's belief about POM." (Mazis, Tr. 2753).

Response to Finding No. 2689:
The proposed finding mischaracterizes the cited testimony. Dr. Mazis said that he did not think that there was any such evidence in the record, not that there was no such evidence. (Mazis, Tr. 2753). Dr. Mazis stated, "the impact of advertising on beliefs about a product is not an appropriate measure of materiality or ad claim communication." (CX1297 (Mazis, Report at 0009)).

2690. Professor Mazis agreed that a statement is material if it is likely to affect a consumer's choice to purchase a product. (PX0296-0008; Mazis, Tr. 2699-2700, 2727).

Response to Finding No. 2690:
Complaint Counsel agrees.

2691. According to Professor Mazis, "the appropriate measure of materiality" is "the potential impact of the challenged claim on purchase or usage behavior." (Mazis, Tr. 2700).

Response to Finding No. 2691:
Complaint Counsel agrees.

2692. Professor Mazis testified that "an advertising claim may involve information important to consumers, but to be material is has to be important to their decision to buy." (Mazis, Tr. 2672-2673, 2700-2701, 2727).

Response to Finding No. 2692:
Complaint Counsel has no specific response.

2693. Professor Mazis testified that a product may have a certain effect but that may not be the reason the consumer purchases the product. (Mazis, Tr. 2700-2701).

Response to Finding No. 2693:
Complaint Counsel has no specific response.

2694. Professor Mazis testified that a survey on materiality does not need to show the survey participants actual advertisements. (Mazis, Tr. 2725).

Response to Finding No. 2694:
The proposed finding is incomplete. Dr. Mazis went on to testify that in order to do a survey on materiality "you don't have to show them the ad, but you have to give them a statement about what the claim was and you have to ask them how important they think that claim would be in their potential purchase decision." (Mazis, Tr. 2728).

2695. Professor Mazis has never done a materiality survey on behalf of the FTC or any federal agency. (PX0359 (Mazis, Dep. at 99); Mazis, Tr. 2721).

Response to Finding No. 2695:
Complaint Counsel has no specific response other than to note that Dr. Mazis has designed and conducted a materiality survey in private litigation, that he has critiqued a materiality survey in an FTC proceeding, and that the Commission ultimately agreed with his opinion. (PX0359 (Mazis, Dep. at 100-02); Mazis, Tr. 2671-72, 2675-76).

2. There is No Evidence in the Record Showing that Consumers Were Exposed to POM's Advertisements on Multiple Occasions

2696. The general rule is that it takes three good exposures to an advertisement for the message of the advertisement to be effective on consumers. And it takes many exposures to constitute three good exposures. (Stewart, Tr. 3228-3229).

Response to Finding No. 2696:
The proposed finding mischaracterizes Dr. Stewart's testimony and is irrelevant. Dr. Stewart did not testify that there is a general rule that it takes three good exposures to an advertisement for the message of the advertisement to be effective on consumers Rather, he agreed that "there is a general rule of thumb that suggests that three exposures [to an ad] is an optimal number of exposures." (Stewart, Tr. 3228). Moreover, the number of ad exposures is irrelevant. *See* Response to Finding 38.

2697. Professor Mazis testified that a "couple of exposures to an ad" are "probably . . .not going to affect people's belief about a product." (Mazis, Tr. 2752).

Response to Finding No. 2697:
The proposed finding is incomplete and irrelevant. Dr. Mazis testified "sometimes one exposure can influence people, influence people's beliefs, but . . . if you have repetition, that tends to influence people a lot more." (Mazis, Tr. 2752). Dr. Mazis also stated, "the impact of advertising on beliefs about a product is not an appropriate measure of materiality or ad claim communication." (CX1297 (Mazis, Report at 0009)).

2698. Professor Mazis testified that he has no idea how many times any POM Juice or POMx advertisements were run by POM. (Mazis, Tr. 2752).

Response to Finding No. 2698:
See Response to Finding 2697.

2699. Professor Mazis testified that no surveys have been introduced to show how many times any POM Juice or POMx advertisements were run by POM. (Mazis, Tr. 2752).

Response to Finding No. 2699:
Complaint Counsel has no specific response but notes that the dissemination of 43 challenged ads is discussed in CCFF Section V.B.4, V.D-F.

2700. There is no evidence in the record regarding the number of exposures consumers had to any particular POM advertisement. (Mazis, Tr. 2752).

Response to Finding No. 2700:
See Responses to Findings 2697 and 2699.

2701. There is no evidence in the record regarding whether any POM advertisement making a disease claim of any kind had more than a single run. (Mazis, Tr. 2752).

Response to Finding No. 2701:
The proposed finding mischaracterizes the cited testimony. Dr. Mazis said that he did not know of evidence regarding how many times any POM or POMx ad was run but he did not say that there was no such evidence. (Mazis, Tr. 2752-53). There is evidence in the record that some of the challenged advertisements ran multiple times. (CCFF ¶¶ 341, 349, 372, 415, 419). Moreover, the number of ad exposures is irrelevant. *See* Response to Finding 2697.

2702. Complaint Counsel informed Professor Mazis that the FTC was only challenging POM Juice print advertisements that ran at least 22 months prior to the execution of the Reibstein Survey and POM Juice website entries in the 14 months prior to the execution of the Reibstein Study. (PX0296-0010; Mazis, Tr. 2753-2754). This is because the participants in the Reibstein Survey may have forgotten the advertisements. In his expert report, Professor Mazis said that "[e]ven if consumers could recall POM Juice advertising, they would be expected to recall more recent advertising, which is not being challenged by the FTC." (PX0296-0010).

Response to Finding No. 2702:
The proposed finding mischaracterizes the cited evidence in asserting that "Complaint Counsel informed Professor Mazis that the FTC was only challenging POM Juice print advertisements that ran at least 22 months prior to the execution of the Reibstein Survey and POM Juice website entries in the 14 months prior to the execution of the Reibstein Study." *See* Response to Finding 2238.

3. Professor Mazis Was Repeatedly Impeached at Trial

2703. Professor Mazis admitted that he wrote an article called the Use of Consumer Surveys in FTC Advertising Cases. (Mazis, Tr. 2754). He testified that, in that article, he suggested, as one way of proving that ads were not material, a survey asking why the participants buy the advertised product, using three open-ended questions. The open-ended questions Professor Mazis used as examples of how to prove non-materiality 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?'" (Mazis, Tr. 2755-56). Professor Mazis stated that, while these open-ended questions might understate the importance of calcium in selecting

cheese, they would nevertheless have "probative value" in showing that the ads in question were not material. (Mazis, Tr. 2756).

Response to Finding No. 2703:
Complaint Counsel agrees that Dr. Mazis testified as such but disagrees with the implication that Dr. Mazis affirmatively recommended using open-end questions without follow-up probing as an approach to proving immateriality. (Mazis, Tr. 2756-57). On redirect, he stated, that in the article he next said "Of course, consumers might rely on an ad making a calcium claim, but they might not volunteer 'calcium' in response to these open-ended questions." (Mazis, Tr. 2758). There is no inconsistency in his statements.

2704. Professor Mazis's testimony at the hearing was inconsistent with what he said in his deposition. In his deposition, Professor Mazis testified that Dr. Reibstein concluded that a very small percentage of POM Juice buyers believed the product was beneficial to any disease and that "the statement is true because Dr. Reibstein found that in his study. So I'm not disagreeing with what he found. I'm just disagreeing with the methodology he used to find that out." (PX0359 (Mazis, Dep. at 66)). At the hearing, however, Professor Mazis claimed that when he testified in his deposition that Dr. Reibstein's "statement" that only a tiny percentage of POM Juice buyers believe the product helps a disease "is true," he really meant that the statement isn't true, but that Dr. Reibstein only "said it was true." (Mazis. Tr. 2703-04).

Response to Finding No. 2704:
The proposed finding mischaracterizes Dr. Mazis's testimony as inconsistent. At both his deposition and at trial, Dr. Mazis in essence said that Dr. Reibstein "did this study and he came up with certain conclusions based on his data. . . . I don't see anything wrong with how he reported it, . . . but his study is so flawed that the conclusions that he reaches aren't tenable." (Mazis. Tr. 2705; *compare* Mazis, Tr. 2702-06 *with* PX0359 (Mazis, Dep. at 66-67)).

2705. Professor Mazis's testimony at the hearing was inconsistent with what he said in his deposition. At the hearing, Professor Mazis criticized Dr. Reibstein for using six months as the period in which participants bought the product. He testified that, "if he were Dr. Reibstein" he would never have divided the survey participants into two groups - those that bought POM pomegranate juice in the last six months and those that did not. (Mazis, Tr. 2719-20). In his deposition, however, Professor Mazis said exactly the opposite. He said "from Dr. Reibstein's point of view" and "if I were Dr. Reibstein", the relevant

universe for the survey would be "people who purchased pomegranate juice in the last six months," which would be divided into two subgroups – "people who purchased POM Juice and people who didn't purchase POM Juice." (PX0359 (Mazis, Dep. at 230-31)). Confronted with his inconsistent deposition testimony, at the hearing, Professor Mazis testified that, in his deposition, he was only speaking "from Dr. Reibstein's point of view" and "based on Dr. Reibstein's approach." He further testified that when he testified at the hearing that he would never divide the participants into the two six month groups, he was not speaking from Dr. Reibstein's point of view, but only from his own point of view. [Mazis, Tr. 2724-25).

Response to Finding No. 2705:
The proposed finding mischaracterizes the cited testimony as inconsistent. At his deposition, Dr. Mazis stated that he was answering the question only from Dr. Reibstein's point of view, "I'm thinking about this now from Dr. Reibstein's point of view, you know, based – if I were Dr. Reibstein, which is the only way I can really answer the question, if I'm in his shoes . . . ." (PX0359 (Mazis, Dep. at 230)).

4. Professor Mazis Is Biased Against Respondents Because of His Long Employment and Consulting Relationship with Complaint Counsel

2706. Over the years, Professor Mazis has 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. (PX0296 at 0003; Mazis, Tr. 2656, 2697).

Response to Finding No. 2706:
Complaint Counsel agrees that the proposed finding is supported by the cited evidence but disagrees with the implication that Dr. Mazis is biased against Respondents. Complaint Counsel notes that Dr. Mazis has served as an expert witness for numerous private litigants, including both plaintiffs and defendants. (Mazis, Tr. 2656-57). In fact, in 2008 Respondents hired Dr. Mazis as an expert consultant in a Lanham Act case against Welch's. (PX0359 (Mazis, Dep. at 233-35)).

2707. Professor Mazis was employed by the FTC from July, 1977 through August, 1979. (PX096a001 at 0001; Mazis, Tr. 2653). During that time he was Chief of Marketing and Consumer Research in the Office of Policy and Planning. (Mazis, Tr. 2696).

Response to Finding No. 2707:
Complaint Counsel has no specific response other than to disagree with the implication that Dr. Mazis is biased against Respondents. *See* Response to Finding 2706.

2708. Beginning in the mid 1990's, Professor Mazis worked a day-a-week for the FTC, at its offices in Washington D.C., for five to six years. (PX0359 (Mazis, Dep. at 22-24).

Response to Finding No. 2708:
Complaint Counsel has no specific response other than to disagree with the implication that Dr. Mazis is biased against Respondents. *See* Response to Finding 2706.

2709. Professor Mazis served as the FTC's principal marketing witness in several cases, including *FTC v. Novartis* in 1997, *FTC v. Trans Union* in 1998, *FTC v. Mercury Marketing* in 2003 and *FTC v. Telebrands* in 2004. (PX096a at 0012).

Response to Finding No. 2709:
Complaint Counsel has no specific response other than to disagree with the implication that Dr. Mazis is biased against Respondents. *See* Response to Finding 2706.

2710. In the past four years, Professor Mazis has been a testifying expert witness in 24 legal proceedings. (PX096a002 at 0001-0002; Mazis, Tr. 2697-98).

Response to Finding No. 2710:
Complaint Counsel has no specific response other than to disagree with the implication that Dr. Mazis is biased against Respondents. *See* Response to Finding 2706.

5. Professor Mazis's Objections to the Reibstein Survey Are Baseless

2711. Professor Mazis's two principal criticisms of the Reibstein Survey were that Dr. Reibstein's questions were not relevant to either the issues of advertising communication or the FTC's standard regarding materiality and that Dr. Reibstein's methodology was flawed because he asked only open-ended questions with no follow-up questions probing further the respondents' answers. (Mazis, Tr. 2720; PX0296-0004,0007,0009).

Response to Finding No. 2711:
Complaint Counsel has no specific response, other than to note that the proposed findings in this section do not demonstrate that Dr. Mazis's objections to the Reibstein survey are baseless.

2712. Professor Mazis does not consider himself an expert on what the FTC considers material, how the FTC determines materiality or what survey evidence the FTC considers relevant in assessing materiality. (Mazis, Tr. 2720-21; PX0359 (Mazis, Dep. at 98)).

Response to Finding No. 2712:
Complaint Counsel has no specific response other than to note that Dr. Mazis has a working understanding of materiality, that he has written or been an editor of published academic articles discussing materiality in an FTC proceeding, that he has designed and conducted a materiality survey in private litigation, that he has critiqued a materiality survey in an FTC proceeding, and that the Commission ultimately agreed with his opinion. (PX0359 (Mazis, Dep. at 100-02); Mazis, Tr. 2671-72, 2675-76, 2754-55; PX0357 (Stewart, Dep. at 190-92); PX0357a06-0001-02).

2713. Professor Mazis wrote an article called the Use of Consumer Surveys in FTC Advertising Cases. (Mazis, Tr. 2754). He testified that, in that article, he suggested, as one way of proving that ads were not material to consumers, a survey asking why the participants buy the advertised product, using three open-ended questions. The open-ended questions Professor Mazis used as examples of how to prove non-materiality 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?'" (Mazis, Tr. 2755-56). No follow up questions were asked. Professor Mazis stated that, while these open-ended questions might understate the importance of calcium in selecting cheese, they would nevertheless have "probative value" in showing that the ads in question were not material. (Mazis, Tr. 2756).

Response to Finding No. 2713:
See Response to Finding 2703.

2714. Professor Mazis is not an attorney trained in the legal concepts governing materiality.

Response to Finding No. 2714:
Complaint Counsel has no specific response.

2715. Professor Mazis agreed that open-ended questions make it "significantly less likely that the respondents will be led into giving a particular answer." (Mazis, Tr. 2732).

Response to Finding No. 2715:
Complaint Counsel has no specific response.

2716. Professor Mazis testified that in his opinion the Reibstein Survey was not a "causal study" (Mazis, Tr. 2734-36, 2741). But Professor Mazis also testified that non-causal

studies do not need a control. (PX0359 (Mazis, Dep. at 207)). Despite this fact, Professor Mazis criticized the Reibstein Survey for not allegedly having a "true" control. (Mazis, Tr. 2741).

Response to Finding No. 2716:
The proposed finding mischaracterizes Dr. Mazis's testimony and is unsupported by the cited evidence. Dr. Mazis did not "criticize[] the Reibstein Survey for not allegedly having a 'true' control." (Mazis, Tr. 2740-41). Dr. Mazis criticized the analysis that Dr. Reibstein attempted based upon his purported controls (people who drank POM against the people who didn't drink POM and people who drank POM and had seen an ad against the people who had not seen an ad). (Mazis, Tr. 2740-41).

2717. Professor Mazis has no evidence that "any substantial number of the people in the non-POM drinking group actually were former users of POM who quit." (Mazis, Tr. 2718).

Response to Finding No. 2717:
Complaint Counsel has no specific response.

2718. Professor Mazis declined to rule out the Reibstein Survey "as probative evidence." (Mazis, Tr. 2709).

Response to Finding No. 2718:
Complaint Counsel has no specific response other than to note that Dr. Mazis also testified that the Reibstein survey "is so flawed that the conclusions that he reaches aren't tenable. They're not reliable conclusions." (Mazis, Tr. 2705).

6. Professor David Stewart Offered No Opinion on the Materiality of the Asserted Implied Claims

2719. It was not within the scope of Professor Stewart's assignment, and he did not opine in his export report, deposition or trial testimony, on the materiality of the asserted implied claims, including how consumers perceive them. (Stewart, Tr. 3226; CX1295; PX0357 (Stewart, Dep. at 1-194)).

Response to Finding No. 2719:
The proposed finding mischaracterizes Dr. Stewart's testimony regarding consumers perceptions. Dr. Stewart testified that his "opinion on how consumers understand or

interpret the messages of the POM ads" was "only as it relates to Professor Butters' testimony." (Stewart, Tr. 3226). Complain Counsel also notes that Dr. Stewart did write an article published in the *Journal of Public Policy and Marketing* in which he explained, "[R]esearch . . . demonstrates that consumers do not need to remember a specific claim for that claim to influence attitude or choice. The claim may not be stored in memory even though an evaluation of the brand has been made (Gibson 1983; Greenwald 1968; Lichtenstein and Srull 1985; Ross 1982; Srull 1989; Stout 1981; Young 1972). Thus, the claim may have an influence on consumer behavior even when it is not articulated by the consumer in response to an open-ended question. Because the . . . survey neither exposed respondents to the claims at issue nor measured any relative preference behavior (verbal or otherwise) following exposure, the results of the survey do not address . . . issues relevant to the question of materiality." (PX0357a06-0001-02; PX0357 (Stewart, Dep. at 190-92)).

2720. Professor Stewart does not know of any evidence in the record on how consumers perceive POM's challenged advertisements. (Stewart, Tr. 3226-27).

Response to Finding No. 2720:

The proposed finding mischaracterizes Dr. Stewart's testimony. He did not say that he does not know of any evidence in the record on how consumers perceive POM's challenged advertisements. (Stewart, Tr. 3226-27). During cross-examination, asked whether he knew of "any evidence on how consumers perceive the ads" he replied "I don't have any direct, specific evidence beyond what I've testified to today." (Stewart, Tr. 3226). Dr. Stewart had testified during his direct testimony about creative strategies and the Bovitz Survey which are evidence as to how consumers perceive POM's challenged ads. (Stewart, Tr. 3185-98, 3202-22). He also agreed that he did not have

any extrinsic evidence of how consumers "perceived the ads at the level of a net impression." (Stewart, Tr. 3226-27).

C. Complaint Counsel's Attempt to Identify An "Intent" Sufficient to Obtain a Presumption or Rebuff Respondents' Survey Expert on Materiality Was Unsuccessful

1. The Consumer Research Relied Upon By Complaint Counsel Do Not Show the Challenged Claims Were Material to Consumers

(a) The A&U Study is Methodologically Flawed and Unreliable

2721. In June 2009, a study was conducted by OTX Corporation of 200 current POM Juice users, 200 other pomegranate juice users, and 200 non-pomegranate juice users who were asked closed-ended questions regarding the reasons they buy pomegranate juice ("A&U Study"). (PX0224-0002, 0004; Reibstein, Tr. at 2517).

Response to Finding No. 2721:
The proposed finding is unsupported by the cited evidence which shows that 200 was the intended "minimum" for each of those three groups. (PX0224-0004). There, in fact, were 218 current POM Juice users, 269 other pomegranate juice users, and 291 non-pomegranate juice users who were surveyed by OTX on behalf of POM to determine purchase motivations. (PX0224-0011).

2722. The A&U Survey does not address whether POM is advertisements were material to the purchase decision of the respondents. (Mazis, Tr. 2743).

Response to Finding No. 2722:
Complaint Counsel agrees that, apart from a typographical error ("POM is" should be "POM's"), the proposed finding accurately cites Dr. Mazis's testimony, but the implied conclusion is irrelevant. The A&U study was designed to help "POM Wonderful . . . better understand attitudes and usage of POM Wonderful and its competitors" including "purchase behavior" and reasons for purchase and to "potentially be used to help inform marketing and communications programs." (CX0370_0002-03, 0011-12). It was not designed to evaluate what ads would be of interest to consumers. (CX0370_0001-51).

Dr. Mazis testified that 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 material. (Mazis, Tr. 2688-89, 2760).

2723. The A&U Study used closed-ended questions in that it provided respondents with a list of 5 choices as to why they drink pomegranate juice. (PX0227-0006; Reibstein, Tr. at 2518-2520).

Response to Finding No. 2723:
The proposed finding is incomplete. POM and OTX designed the A&U study to provide respondents with 5 specific choices as well as the option of giving other answers that were not listed. (PX0227-0006; Mazis, Tr. 2681-82).

2724. By providing respondents with a list of choices respondents were cued to select from attributes that they may not otherwise have thought of. (Reibstein, Tr. at 2518).

Response to Finding No. 2724:
Complaint Counsel has no specific response other than to note that Mrs. Resnick testified that for the 2009 timeframe, during which POM commissioned the A&U study, she would "traditionally" personally look at a consumer research questionnaire and "see if it if it was precise enough and would yield the answers we wanted." (CX1359 (L. Resnick, Dep. at 76-77); CCFF ¶ 640).

2725. Utilizing closed-end questions also results in the exclusion of potential answers that were not included on the list of choices because survey respondents often feel compelled to select one of the answers provided on the list of choices. (Reibstein, Tr. at 2519).

Response to Finding No. 2725:
The proposed finding mischaracterizes Dr. Reibstein's testimony. He did not state that respondents "often feel compelled to select one of the answers provided on the list of choices." (Reibstein, Tr. 2519). He stated that other potential answers "end up going away because they don't really have an option." (Reibstein, Tr. 2519-20). In the context of the A&U study, his statement is unsupported by the record as a whole because survey

respondents were also provided the option of giving other answers that were not listed. (PX0227-0006; Mazis, Tr. 2681-83).

2726. Utilizing closed-end questions 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. (Reibstein, Tr. at 2519).

Response to Finding No. 2726:
See Response to Finding 2725, which is identical.

2727. Question B1 asked respondents why they drink pomegranate juice and provided a limited number of choices, none of which were "don't know or "no opinion." (PX0227-006).

Response to Finding No. 2727:
The proposed finding mischaracterizes the evidence because survey respondents were also given the opportunity to give other answers and their choices were unlimited. (PX0227-0006; Mazis, Tr. 2681-82). Again, Mrs. Resnick testified that for the 2009 timeframe, during which POM commissioned the A&U study, she would "traditionally" personally look at a consumer research questionnaire and "see if it if it was precise enough and would yield the answers we wanted." (CX1359 (L. Resnick, Dep. at 76-77); CCFF ¶ 640).

2728. Respondents who selected "health" from the list of 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?" Respondents were provided a list of only 11 reasons. (PX0227-0006).

Response to Finding No. 2728:
The proposed finding is unsupported by the cited evidence and is incomplete. Male survey respondents were given a list of nine specific choices together with the opportunity to give other health reasons that were not listed. (PX0227-0006; Mazis, Tr. 2682-83). Female survey respondents were given a list of ten specific choices together with the opportunity to give other health reasons that were not listed. (PX0227-0006; Mazis, Tr. 2682-83). Again, Mrs. Resnick testified that for the 2009 timeframe, during

which POM commissioned the A&U study, she would "traditionally" personally look at a consumer research questionnaire and "see if it if it was precise enough and would yield the answers we wanted." (CX1359 (L. Resnick, Dep. at 76-77); CCFF ¶ 640).

2729. The results from Questions B1 and B2 as well as any closed-ended questions are unreliable and inflated because the questions to those set of choices to the exclusion of others are leading in that the respondents are given a limited number of choices and/or cued to select from attributes that they might otherwise have thought of. (Reibstein, Tr. at 2518-2520).

Response to Finding No. 2729:
Complaint Counsel does not disagree as to the nature of Dr. Reibstein's testimony, but his conclusion is unsupported by the record as a whole. Surveys done in the ordinary course of business, as this one was done for POM, almost always rely upon close-ended questions and most surveys done for litigation employ both closed-ended and open-ended questions. (Mazis Tr. 2664-65). The results from the A&U study were reliable. (Mazis Tr. 2688). The results of the A&U study factored into POM's decision making. (CX1378 (Kuyoomjian, OS Dep. at 216)).

2730. When questions are open-ended as in the Reibstein Survey, other reasons for purchase are given that are not listed in the A&U Study. (PX0223-0006; PX0227-0006).

Response to Finding No. 2730:
Complaint Counsel does not disagree that survey respondents in the Reibstein survey expressed purchase motivations such as "brand name," "mixer," and "[h]ad trouble with my bowl [sic] movements" (PX0223-0006, 0011), but notes that survey respondents had the opportunity to give such answers in the A&U study if they thought that they were important and some survey respondents did give "other" answers which are not detailed in the survey report. (CX0370_0011-12; PX0227-0006; Mazis, Tr. 2681-83).

2731. In the A&U Survey, 88-91% of the respondents answered that they bought pomegranate juice because it had antioxidants (PX0224-0012), which contrasts significantly with the Reibstein Survey, which showed that less than 10% of respondents purchase for that

reason, and which were based on open-ended questions. (Reibstein, Tr. at 2519; PX0223-0006).

Response to Finding No. 2731:
The proposed finding is unsupported by the record as a whole. In the A&U study, 77% of current POM Juice drinkers (85% of survey respondents bought pomegranate juice for health reasons and of those 91% said that they bought it because it had antioxidants) and 68% of other pomegranate juice drinkers (77% of survey respondents bought pomegranate juice for health reasons and of those 88% said that they bought it because it had antioxidants) answered that they bought pomegranate juice because it had antioxidants. (PX0224-0011-12).

2732. By using the phrase "antioxidant-rich fruit juices" in two of the screening questions and the phrase "antioxidant-rich fruit" in the Intro, the A&U Study cued respondents on the issue of antioxidants even before asking them why they buy pomegranate juice. (PX0227-0003-0004; Reibstein, Tr. at 2519).

Response to Finding No. 2732:
Complaint Counsel does not disagree that references to "antioxidant-rich" fruit and fruit juices may have cued some respondents on the issue of antioxidants, but disagrees as to the significance of this flaw. Dr. Mazis did not believe that the few references to antioxidants in the A&U study's screener was a big issue in this case. (Mazis, Tr. 2687). Although Dr. Mazis acknowledged that those references to "antioxidants" in the A&U study's screener could inflate the "contains naturally occurring antioxidants" responses, and could potentially have some impact on how many gave a "healthy/good for my health" response, he did not think that the references to antioxidants would inflate the responses to the other specific health benefits such as "helps promote heart health" or "helps protect against prostate cancer" and he testified that those references certainly would not affect the relative ranking of the specific health attributes. (Mazis, Tr. 2686-88). Again, Mrs. Resnick testified that for the 2009 timeframe, during which POM

commissioned the A&U study, she would "traditionally" personally look at a consumer research questionnaire and "see if it if it was precise enough and would yield the answers we wanted." (CX1359 (L. Resnick, Dep. at 76-77); CCFF ¶ 640).

2733. The A&U Study was methodologically flawed and unreliable because the sample size of 200 POM Juice users was too small to reach statistical significance. (Reibstein, Tr. at 2520).

Response to Finding No. 2733:
The proposed finding is unsupported by Dr. Reibstein's cited testimony and the record as a whole. Although Dr. Reibstein asserted that the A&U study samples were "very small" and that there was therefore "uncertainty about the particular numbers," he did not assert that the study was therefore "methodologically flawed and unreliable" or that the sample was "was too small to reach statistical significance." (Reibstein, Tr. 2520). The A&U study's sample of 218 current POM Juice drinkers was sufficient and a fairly normal sample size. (Mazis, Tr. 2689-90).

2734. The A&U Study was conducted in two markets, one in which POM advertised and another in which POM ran no advertising. More respondents in the non-POM advertising markets (15%) thought POM's pomegranate juice was healthier than other brands than in the POM advertising markets (10%). (PX0224-0024; Reibstein, Tr. at 2521).

Response to Finding No. 2734:
The proposed finding's assertion that the A&U study "was conducted in two markets" is unsupported by the cited evidence. The A&U study was conducted in five markets in which POM specifically ran advertising as well as throughout the rest of the country. (PX0227-0001; Reibstein, Tr. 2521; PX0356 (Reibstein, Dep. at 161-62)). As to this finding's second sentence, it is incomplete and irrelevant. Asked why they bought the POM brand most often, somewhat more respondents in those markets where POM did not specifically advertise said because "It's healthier than other brands," as opposed to other answers such as "I trust this brand." (PX0224-0001). Complaint Counsel also

notes that much of Respondents' challenged marketing, including magazines, Internet, point of sale, and public relations, was national and not market specific. (CCFF ¶¶ 230 (direct mail); 231 (GNC stores); 232 (website); 253 (online banner ads); 329, 336, 341, 344, 349, 357, 363-364, 368, 372, 397-398, 409, 415, 419, 425 (print ads); 385 (hangtags); 570, 572, 574, 576 (media appearances)).

2735. To eliminate the effect of yea-saying, inattention, the halo effect, or other noise, and to get the true impact of advertisements on the test group, the responses to the control group are subtracted from the responses to the test group. (Stewart, Tr. 3238; Mazis, Tr. 2735-2736).

Response to Finding No. 2735:

The proposed finding is overbroad, misleading, and unsupported by the cited testimony of Drs. Stewart and Mazis. Dr. Mazis agreed that in the context of an ad communication study which is a causal study closed-ended questions require the use of some type of control mechanism and the responses to the control questions are subtracted from responses to the test questions. (Mazis, Tr. 2733-36). Dr. Mazis made clear that this was not true as a general proposition and was limited to the context of causal studies like ad communication tests. (Mazis, Tr. 2733-34). Dr. Mazis also testified that the Reibstein survey and the A&U study are not communication studies or causal studies and that one would not take such an approach with such studies. (Mazis, Tr. 2734-38). Dr. Stewart agreed that in the context of a "causal study" one "would generally like to have a control" and one would "deduct the control group response from the test group response," but he did not say that one should use such an approach in a non-causal study. (Stewart, Tr. 3238).

2736. When the responses of the control group of people non-POM Juice drinker is subtracted from the responses of the test group of POM Juice drinkers, the percentage of POM Juice drinkers who mentioned "promotes heart health" is only 8%. (PX0224-0012).

Response to Finding No. 2736:

The proposed finding is unsupported by the cited evidence which merely lists the survey results. Because the A&U study is a non-causal study it is neither necessary nor appropriate to subtract the results for non-POM Juice drinkers. *See* Response to Finding 2735. If 100% of POM Juice Drinkers and 100% of drinkers of other pomegranate juices were motivated by pomegranate juice benefitting heart disease there would be a zero percentage difference between the two groups, but one would not conclude that heart disease was unimportant to the POM Juice purchasers. (Mazis, Tr. 2760-61).

2737. When the responses of the control group of people non-POM Juice drinker is subtracted from the responses of the test group of POM Juice drinkers, the percentage of POM Juice drinkers who mentioned "helping prevent prostate cancer" is only 7%. (PX0224-0012).

Response to Finding No. 2737:
The proposed finding is unsupported by the cited evidence which merely lists the survey results. *See* Response to Finding 2736.

2738. Professor Mazis testified that the A&U Study does not state whether "POM ads were material to [consumers'] purchase decision[s]." (Mazis, Tr. 2743).

Response to Finding No. 2738:
Complaint Counsel does not disagree that Dr. Mazis agreed that nothing in the A&U Survey shows that POM ads caused the people who drink POM to have viewpoints on various health conditions, so it does not tell us whether "POM **ads** were material to the purchase decision," (emphasis added) (Mazis, Tr. 2743), but Complaint Counsel notes that Dr. Mazis testified that the A&U study shows that consumers would find a **claim** that drinking POM Juice treats, prevents or reduces the risk of heart disease to be material and that they would find a **claim** that drinking POM Juice treats, prevents or reduces the risk of prostate cancer to be material. (Mazis, Tr. 2688-89, 2760).

2739. Professor Mazis testified that he understood that many of the figures in the A&U Study did not reach a 90% confidence level, but that he did not have a full understanding of what was done and he did not think it was done properly. (Mazis, Tr. 2751-2752).

Response to Finding No. 2739:
Complaint Counsel does not disagree that Dr. Mazis did not fully understand the use in the A&U study report of various letters to signify statistically significant differences at a 90% confidence level and that he did not know whether such annotations were done properly. (Mazis, Tr. 2751-52).

2740. Professor Mazis agreed that the A&U Study asked only closed-ended questions. (Mazis, Tr. 2681).

Response to Finding No. 2740:
Complaint Counsel has no specific response.

2741. Professor Mazis agreed that closed-end questions have the potential to direct participants to certain aspects of an advertisement, so that participants may respond to such questions based upon yea-saying, inattention, preconceptions or other noise. (Mazis, Tr. 2733).

Response to Finding No. 2741:
The proposed finding is misleading and incomplete. The cited testimony related to the use of closed-end questions in an advertising communication study. (Mazis, Tr. 2733-34). Dr. Mazis previously explained that although close-ended questions may lead to some upward bias, in a study like the A&U study, one accounts for this by looking at the relative ranking of responses. (Mazis Tr. 2663-64).

2742. Professor Mazis testified that "open-ended questions make it significantly less likely that the participant will be led into giving a particular answer." (Mazis, Tr. 2732).

Response to Finding No. 2742:
Complaint Counsel has no specific response other than to note that Dr. Mazis also testified that a disadvantage of open-ended questions is that sometimes you get answers that are too general to be useful or probative. (Mazis, Tr. 2660-61).

2743. Professor Mazis testified that the A&U Study was flawed because it "primed" the survey participants 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 participants may have been focused on health and health issues. (Mazis, Tr. 2686-2687, 2739-2740).

Response to Finding No. 2743:

The proposed finding is incomplete. Dr. Mazis did not believe that the few references to antioxidants in the A&U study's screener was a big issue in this case. (Mazis, Tr. 2687). Although Dr. Mazis acknowledged that those references to "antioxidants" in the A&U study's screener could inflate the "contains naturally occurring antioxidants" responses, and could potentially have some impact on how many gave a "healthy/good for my health" response, he did not think that the references to antioxidants would inflate the responses to the other specific health benefits such as "helps promote heart health" or "helps protect against prostate cancer" and he testified that those references certainly would not affect the relative ranking of the specific health attributes. (Mazis, Tr. 2686-88).

2744. Professor Mazis criticized the A&U Study as lacking a "true control" (Mazis, Tr. 2740-2741) but also testified that a control was not necessary in the A&U Study because it was not what he called a "causal study." (Mazis, Tr. 2734-2736, 2741).

Response to Finding No. 2744:

The proposed finding mischaracterizes the cited testimony and is unsupported by the cited evidence. Dr. Mazis did not "criticize[] the A&U for not allegedly having a 'true control.'" (Mazis, Tr. 2740-41). Dr. Mazis agreed that neither the Reibstein survey nor the A&U study had a control and he criticized the analysis that Dr. Reibstein attempted based upon his purported controls (people who drank POM versus the people who didn't drink POM and people who drank POM and had seen an ad versus the people who had not seen an ad). (Mazis, Tr. 2740-41).

2745. Professor Mazis agreed with a quote from *Telebrands* that responses to control questions "measure the number of participants who answered based upon yea-saying, inattention, the halo effect, or other 'noise'" and "[t]o eliminate the effect of such external factors, the responses to the control or masking questions are subtracted from the responses to the test questions." (Mazis, Tr. 2735-2736).

Response to Finding No. 2745:

The proposed finding is incomplete in that Dr. Mazis limited his answer to ad communication studies like the one in *Telebrand*s. (Mazis, Tr. 2735-36).

2746. Professor Mazis conceded that, with respect to the results in the A&U Study, he did not subtract the results to the control questions from the results to the test questions (Mazis, Tr. 2735-2738) because the A&U Study was not what he calls a "causal" survey, and only "causal" surveys require the subtraction outlined in *Telebrands*. (Mazis, Tr. 2733-2737).

Response to Finding No. 2746:
The proposed finding mischaracterizes the cited testimony and is unsupported by the record as a whole in that it suggests that the A&U study had test questions and control questions and that Dr. Mazis agreed that it did. (Mazis, Tr. 2735-38).

2747. Professor Mazis testified that asking participants the "cause" of their purchase was not a "causal study." (Mazis, Tr. 2734-2735).

Response to Finding No. 2747:
Complaint Counsel has no specific response other than to note that Dr. Mazis explained that a "causal study is a study in which there's a manipulation where you're trying to assess why a particular factor causes something. It's an experimental study." (Mazis, Tr. 2735).

2748. Professor Mazis testified that on page 12 of the A&U Study that there is no statistically significant difference among the three groups of respondents regarding the "helps protect against prostate cancer" response. (Mazis, Tr. 2742). He further testified that "[t]hose numbers are quite similar. And I'm sure other information out in the marketplace, on the Internet and other places certainly influenced all of those people, but it doesn't really say anything about what the influence of specific POM claims would be on consumers exposed to those claims." (Mazis, Tr. 2743).

Response to Finding No. 2748:
Complaint Counsel does not disagree about the nature of Dr. Mazis' testimony but disagrees with the implication that the similarity in purchase motivations between POM Juice drinkers and drinkers of other juices is relevant. If 100% of POM Juice Drinkers and 100% of drinkers of other pomegranate juices were motivated by pomegranate juice benefitting heart disease there would be a zero percentage difference between the two

groups, but one would not conclude that heart disease was unimportant to the POM Juice purchasers. (Mazis, Tr. 2760-61).

2749. Professor Mazis agreed that, even though the A&U Study found that a very substantial number of the three groups of respondents said that they thought that POM Juice and other juices help protect against urinary tract infections, neither of the three groups could have gotten that information from a POM advertisement if POM never advertised such information. (Mazis, Tr. 2747-48).

Response to Finding No. 2749:
Complaint Counsel has no specific response.

2750. Professor Mazis agreed that, even though the A&U Study found that approximately 49% of respondents said that POM and the other juices provided immunity from colds and flu, none of those respondents could have gotten that information from a POM advertisement if POM never advertised such information. (Mazis, Tr. 2748).

Response to Finding No. 2750:
Complaint Counsel has no specific response.

2751. Despite his criticisms of the A&U Study, Professor Mazis testified that he finds the A&U Study more reliable than the Reibstein Survey on the likely importance of the challenged claims on consumers' purchase or use decisions. (Mazis, Tr. 2689).

Response to Finding No. 2751:
The proposed finding mischaracterizes Dr. Mazis's testimony in that it states that he had multiple criticisms of the A&U study. Dr. Mazis acknowledged that the A&U study had a flaw, albeit not a big issue, in that there were a few references to "antioxidants" early in the study. (Mazis, Tr. 2686-88). *See also* Response to Finding 2743. Dr. Mazis then testified that he did not think there were any other flaws in the A&U study and that "it was a pretty reasonable study." (Mazis, Tr. 2688). Again, Mrs. Resnick testified that for the 2009 timeframe, during which POM commissioned the A&U study, she would "traditionally" personally look at a consumer research questionnaire and "see if it if it was precise enough and would yield the answers we wanted." (CX1359 (L. Resnick, Dep. at 76-77); CCFF ¶ 640). Complaint Counsel agrees that Dr. Mazis testified that he finds the A&U Study more reliable than the Reibstein Survey "on the likely importance .

. . the challenged claims would have to consumers' purchase or use decisions." (Mazis, Tr. 2689).

(b) The Bovitz Survey Is Methodological Flawed, Unreliable and Does Not Address Consumers' Purchasing Decisions

2752. Professor Mazis did not consider and offered no expert opinion in his expert report on the survey conducted by the Bovitz Research Group comparing consumers' perception of ten (10) billboard advertisements from POM's *Super Hero* and *Dressed* Bottle advertising campaigns (the "Bovitz Survey"). (PX0296-0003).

Response to Finding No. 2752:
Complaint Counsel has no specific response.

2753. In the Bovitz Survey, a total of 150 target consumers and 100 POM users were recruited and exposed to each campaign (PX0225-0002-0003).

Response to Finding No. 2753:
Complaint Counsel has no specific response other than to clarify that a total of 300 target consumers and 200 POM consumers were recruited, and 150 target consumers and 100 POM users were exposed to each of the two campaigns that POM wanted to evaluate. (PX0225-0004; CCFF ¶ 579).

2754. Respondents to the Bovitz Survey were not asked why they purchase POM Juice. (PX0236-0001-0015; Reibstein, Tr. at 2509).

Response to Finding No. 2754:
Complaint Counsel has no specific response except to note that the Bovitz Survey was designed and commissioned by POM to evaluate the effectiveness of the then-running "Super Hero" advertising campaign compared to POM's earlier "Dressed Bottle" campaign, including the main message communication and the communication of benefits. (CCFF ¶ 579; PX0225-0012-14). It was not designed to evaluate consumers' purchase motivations. (PX0225-0001-47).

2755. The Bovitz Survey is unreliable for measuring consumers' motivations for purchasing POM Juice because respondents were not asked why they purchase POM Juice. (Reibstein, Tr. at 2509, 2513).

Response to Finding No. 2755:
See Response to Finding 2754.

2756. The Bovitz Survey is methodologically flawed and unreliable because respondents were shown specific advertisements in a tightly controlled environment, which is not how consumers normally view advertisements. (Reibstein, Tr. at 2509-2510).

Response to Finding No. 2756:
Complaint Counsel agrees that Dr. Reibstein stated this but disagrees with his conclusion. The Bovitz Survey used a forced exposure methodology (*i.e.,* showing the advertisement for which you want to ascertain the consumer take away to the survey respondents) which is the proper method for advertising communication surveys. (CCFF ¶ 581; PX0359 (Mazis, Dep. at 136-39)). Dr. Reibstein clarified that he was criticizing the forced-exposure nature of the Bovitz Survey as an approach to evaluating the overall impact of advertising and not as a way of measuring ad communication. (Reibstein, Tr. 2578-79).

2757. The Bovitz Survey is methodologically flawed and unreliable because it had no control and, thus respondents might have had preconceived perceptions about pomegranate juice before being exposed to POM's billboard advertisements. (Reibstein, Tr. at 2510-2511).

Response to Finding No. 2757:
Complaint Counsel agrees that Dr. Reibstein testified as such but disagrees with his conclusion. It is appropriate to draw conclusions about advertising communication from open-ended questions without the use of any controls. (CCFF ¶ 587). Moreover, the open-ended main ideas expressed by the survey respondents most relevant to the allegations in this matter ("helps/lowers blood pressure," "good for prostates," and "$25 million spent on research/research based") do not overlap across the test ads. (PX0295a15_0017-18, 45-46). Thus, the other tested POM ads effectively functioned as control ads for the main ideas articulated below, demonstrating that these main ideas were caused by the ads themselves and not other factors extraneous to the ads. *See* Responses to Findings 2760, 2764. Similarly, for the open-ended question about the

benefits of drinking POM Juice, the "Super Hero" ads effectively functioned as control ads for the "Dressed Bottle" ads. *See* Response to Finding 2765. With respect to the closed-ended questions in the Bovitz Survey, Complaint Counsel did do an analysis using an attribute as a control for noise. (CCFF ¶¶ 592-95).

2758. As measured by survey Question E, the Bovitz Survey imposed strict qualification requirements, including the fact that individuals had to engage in a health-conscious lifestyle and/or hold attitudes toward improving their overall health. (PX0225-0003; PX0236-0002).

Response to Finding No. 2758:
Complaint Counsel agrees and notes that the screening requirements were appropriate given the target audience for POM Juice advertising. (CCFF ¶ 582). Complaint Counsel also notes that Mrs. Resnick was involved in the design and approval of the questionnaire for this campaign research and that she used the Bovitz Survey to determine that POM would continue using the then-running "Super Hero" advertising campaign. (CCFF ¶¶ 580, 596).

2759. The Bovitz Survey is methodologically flawed and unreliable because Question E creates a bias towards extremely health-focused people, which is not representative of the overall consumer population. (Reibstein, Tr. at 2511-2512).

Response to Finding No. 2759:
See Response to Finding 2758.

2760. The Bovitz Survey is methodologically flawed and unreliable because the sample size of only 100 POM users and 150 target consumers was too small to reach statistical significance at the 95% confidence level. (Reibstein, Tr. at 2512-2513).

Response to Finding No. 2760:
First, Complaint Counsel wishes to clarify, that as Dr. Reibstein testified, the Bovitz Survey had a universe of 500 individuals, made up of 200 POM users and 300 target consumers. (Reibstein, Tr. 2512-2513; PX0295a15_0006). Second, Complaint Counsel agrees that Dr. Reibstein testified that the Bovitz Survey's "sample was concerningly small . . . . In the ideal, . . . you want to be 95 percent certain of your answers on a

percentage basis . . . . The sample size makes it not reliable," but he is mistaken. The Bovitz Survey is not too small to reach statistically significant differences at the 95% confidence level. There are annotations throughout the Bovitz Survey report noting statistically significant results at the 95% confidence level. Among other things they show: (a) the 14% of the general target audience and the 17% of POM Juice users shown the "Decompress" test ad who said the ad's main idea was "helps/lowers blood pressure" were statistically significantly different at a 95% confidence level than the 0% who gave that answer when exposed to two other tested ads. (PX0295a15-0018, 0046); (b) the 43% of the general target audience and the 48% of POM Juice users shown the "I'm off to save PROSTATES!" test ad who said the ad's main idea was "good for prostates" were statistically significantly different at a 95% confidence level than the 0% who gave that answer when exposed to two other tested ads (PX0295a15-0017, 0045); and (c) the 22% of the general target audience and the 33% of POM Juice users shown the "HOLY HEALTH! $25 million in medical research" test ad who said the ad's main idea was "$25 million spent on research/research based" were statistically significantly different at a 95% confidence level than the 0% who gave that answer when exposed to two other tested ads. (PX0295a15-0010, 0017, 0045). Again, Mrs. Resnick was involved in the design and approval of the questionnaire for this campaign research and she used the Bovitz Survey to determine that POM would continue using the then-running "Super Hero" advertising campaign. (CCFF ¶¶ 580, 596).

2761. The Bovitz Survey is unreliable for determining consumers' perceptions of POM's billboard advertising because of the sample size was too small. (Reibstein, Tr. at 2513).

Response to Finding No. 2761:

Complaint Counsel agrees that Dr. Reibstein testified as such but disagrees with his conclusions. Contrary to Respondents' assertion, the Bovitz sample is not too small to

reach statistically significant differences at the 95% confidence level. *See* Response to Finding 2760. In *Novartis Corp.*, the Administrative Law Judge and the Commission relied upon two advertising communication studies that were conducted in the ordinary course of business, as was the Bovitz study, each of which only involved 300 survey respondents (100 per ad). (PX0359a02-0026-28, 0054, 0054 (also available at *Novartis Corp.*, 127 F.T.C. 580, 617-21, 665, 682-83)).

2762. The Bovitz Survey is unreliable for determining consumers' perceptions of POM's billboard advertising because of the tightly controlled environment in which the respondents were exposed to the billboard advertisements. (Reibstein, Tr. at 2513-2514).

Response to Finding No. 2762:
Complaint Counsel agrees that Dr. Reibstein testified as such but disagrees with his conclusion. The Bovitz Survey used a forced exposure methodology (*i.e.,* showing the advertisement for which you want to ascertain the consumer take away to the survey respondents) which is the proper method for advertising communication surveys. (CCFF ¶ 581; PX0359 (Mazis, Dep. at 136-39)). Again, Mrs. Resnick was involved in the design and approval of the questionnaire for this campaign research and she used the Bovitz Survey to determine that POM would continue using the then-running "Super Hero" advertising campaign. (CCFF ¶¶ 580, 596).

2763. The Bovitz Survey is unreliable for determining whether what was observed within the survey applies to a normal advertising viewing context. (Reibstein, Tr. at 2513-2514).

Response to Finding No. 2763:
See Response to Finding 2762.

2764. Question 9 of the Bovitz Survey states: "Other than trying to get you to buy the product, what do you think is the main idea these ads are trying to get across to you?" (PX0236-0009). When asked this general question, 5% of the respondents answered that the billboard advertisements conveyed a message about helping/lowering blood pressure. (PX0235-0011).

Response to Finding No. 2764:

The proposed finding mischaracterizes the Bovitz Survey's findings and is incomplete. Fourteen percent of the general target audience and seventeen percent of POM Juice users in the Bovitz Survey who were shown the "Decompress" test ad said the ad's main idea was "helps/lowers blood pressure." (PX0295a15_0011, 18, 46; Stewart, Tr. 3213-14). Not a single survey respondent shown any of five other POM Juice ads tested responded that the main idea of the ad that they saw was "helps/lowers blood pressure." (PX0295a15_0017-18, 45-46).

2765. Question 10 of the Bovitz Survey states: "Based on the ads you just saw, what are the specific benefits, if any, of drinking POM Wonderful?" (PX0236-0009). When asked this leading question, 21% of the health-conscious respondents answered that the billboard advertisements conveyed a message about helping/lowering blood pressure. (PX0235-0011).

Response to Finding No. 2765:

The proposed finding mischaracterizes the Bovitz Survey's findings and is incomplete. The question, "Based on the ads you just saw, what are the specific benefits, if any, of drinking POM Wonderful?" is a non-leading, open-ended question. (CCFF ¶ 589). Of the survey respondents exposed to the five "Dressed Bottle" ads, which included the images and headlines of the challenged "Decompress" print ads, 21% said that a benefit of drinking POM Juice was "helps/lowers blood pressure." (PX0295a15_0011, 0020, 0048; Stewart, Tr. 3216-17). Not a single respondent shown the "Super Hero" campaign ads said that a benefit of POM Juice was that it "helps/lowers blood pressure." (PX0295a15_0010, 0020, 0048).

2766. In regard to the 5% of respondents who answered in response to Question 9 that the billboard advertisements conveyed a message about helping/lowering blood pressure, the Bovitz Survey is unreliable because the sample size is too small and the tightly controlled environment is not the normal advertising viewing context. (Reibstein, Tr. at 2516).

Response to Finding No. 2766:

See Responses to Findings 2756, 2760-62, 2764.

2767. In regard to the 21% of respondents who answered in response to Question 10 that the billboard advertisements conveyed a message about helping/lowering blood pressure, the Bovitz Survey are unreliable because the sample size is too small and the question is leading and biasing in that it directs respondents to select a "specific benefit" which pressures them to identify a particular benefit from the list of choices even if they had not perceived one of those benefits being conveyed to them. (Reibstein, Tr. at 2515-2516).

Response to Finding No. 2767:
The proposed finding's assertion that "Question 10 [of] the Bovitz Survey . . . directs respondents to select a 'specific benefit' . . . from the list of choices" is unsupported by the cited evidence. (Reibstein, Tr. 2515-2516). Question 10 is an open-ended question that does not present a list of choices. (CX0369_0009). The question, "Based on the ads you just saw, what are the specific benefits, if any, of drinking POM Wonderful?" is a non-leading, open-ended question. (CCFF ¶ 589). Of the survey respondents exposed to the five "Dressed Bottle" ads, which included "Decompress" test ad, 21% said that a benefit of drinking POM Juice was "helps/lowers blood pressure." (PX0295a15_0011, 20, 48; Stewart, Tr. 3216-17). Not a single respondent shown the "Super Hero" campaign ads said that a benefit of POM Juice was that it "helps/lowers blood pressure." (PX0295a15_0020, 48). With respect to this finding's other assertions, *see* Responses to Findings 2756, 2760-62.

2768. With respect to consumers' perception of the "Decompress" billboard advertisement, the Bovitz Survey is unreliable because the sample size is small and the question is leading and biasing in that it directs respondents to select a "specific benefit" which pressures them to identify a particular benefit from the list of choices even if they had not perceived one of those benefits being conveyed to them. (Reibstein, Tr. at 2515-2516).

Response to Finding No. 2768:
The proposed finding's assertion that "the question . . . directs respondents to select a 'specific benefit' . . . from the list of choices" is unsupported by the cited evidence. (Reibstein, Tr. 2515-16). With respect to this finding's other assertions, *see* Responses to Findings 2760-61, 2766-67.

2769. Over 90% of respondents answered that the billboard advertisements were about general health versus a specific disease. (Reibstein, Tr. at 2516-2517; PX0225-0012-0013).

Response to Finding No. 2769:
The proposed finding is incomplete and unsupported by the record as a whole. Of those shown the Super Hero campaign 55% said a benefit of drinking POM Juice was "good for prostates" in response to an open-ended question, as opposed to 51% who said "antioxidants" and 33% who gave a generic "healthy" answer. (PX0225-0014). Of those shown the Dressed Bottle campaign, 38% said a benefit of drinking POM Juice was "good for your heart" and 21% said "helps/lowers blood pressure" in response to an open-ended question, as opposed to 37% who said "antioxidants" and 21% who gave a generic "healthy" answer. (PX0225-0014).

2770. The Complaint Counsel is not challenging POM's billboard advertisements in this case. (Stewart, Tr. 3208; Reibstein, Tr. at 2574).

Response to Finding No. 2770:
Complaint Counsel is not challenging POM's billboard advertisements in this case but disagrees with the implication that the Bovitz Survey's results are not applicable to non-billboard advertisements using identical headlines and imagery. (CCFF ¶¶ 584-85, 596).

2771. The Bovitz Survey exposed respondents only to POM's billboard advertising. (Reibstein, Tr. at 2573,2575; Stewart, Tr. 3207, 3209; PX0225-0005-0006).

Response to Finding No. 2771:
Complaint Counsel has no specific response.

(c) The AccentHealth Study Is Methodological Flawed and Unreliable

2772. Professor Mazis did not consider the AccentHealth Study in preparing his expert report and proffered no opinion on it in his expert report. (PX0296-0003).

Response to Finding No. 2772:
Complaint Counsel has no specific response.

2773. In December 2008, Roper Public Affairs and Media, a division of Gfk Custom Research, was commissioned by AccentHealth to conduct a survey of POM's advertising in select AccentHealth offices (the "AccentHealth Study"). (PX0235-0006).

Response to Finding No. 2773:
Complaint Counsel has no specific response.

2774. The AccentHealth Study surveyed patients as they left their urologists' offices, asking them about a wall mounted poster in the waiting area of the doctor's office that featured a POM advertisement. (PX0234-0001; PX0235-0006).

Response to Finding No. 2774:
Complaint Counsel has no specific response.

2775. The AccentHealth Study was methodologically flawed and unreliable because the patient was intercepted immediately after leaving his urologist's office, heightening whatever issues the patient had about helping his prostate. (Reibstein, Tr. at 2522; PX0223-0021).

Response to Finding No. 2775:
Complaint Counsel has no specific response except to note that POM placed magazine wrap ads in urologists' offices in the same "heightened" issue environment. (CCFF ¶ 226).

2776. The AccentHealth Study was methodologically flawed and unreliable because it had no control and, thus survey respondents might have believed that POM Juice was good for their prostate before seeing the wall-mounted poster advertisement in their urologist's office. (Reibstein, Tr. at 2522; PX0223-0021).

Response to Finding No. 2776:
Complaint Counsel has no specific response.

2777. Because of the methodological flaws of the AccentHealth Study, the results of the AccentHealth Study are biased. (Reibstein, Tr. at 2522).

Response to Finding No. 2777:
Complaint Counsel has no specific response.

2778. The AccentHealth Study was conducted by AccentHealth who has a vested interest in convincing businesses to place advertisements in doctors' offices. Thus, AccentHealth had the motivation to skew the results of the AccentHealth Study by designing the study such that the results would show that the advertisement it selected to be surveyed had a positive impact on patient's perceptions of helping their prostates. (Reibstein, Tr. at 2522).

Response to Finding No. 2778:

Complaint Counsel has no specific response.

2. POM's Consumer Comment Logs Do Not Show that the Challenged Claims Were Material to Consumers' Purchasing Decisions

2779. POM maintains a consumer comment log. Once a consumer comment is received by POM, it is given a unique "ID" number. The consumer comment is then listed in sequential order by ID number on the consumer comment log. POM has received at least 24,470 consumer comments over the years and its consumer comment log is at least 2,297 pages. (CX0454; CX0455; CX0456).

Response to Finding No. 2779:
Complaint Counsel has no specific response.

2780. From the nearly 25,000 consumer comments, POM provided Complaint Counsel the 53 consumer comment log entries that referenced a specific disease, health study or POM advertisement. An only a few of those53 log entries referenced any health-related advertising claim made by POM. (CX0454; CX0455; CX0456).

Response to Finding No. 2780:
This finding mischaracterizes what POM provided Complaint Counsel. Respondents provided Complaint Counsel with a 2,333 page consumer comment log; not just 53 log entries. (CX0485_0001-2333). This log shows that POM was aware that some 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; that consumers believed that POM products could treat, prevent, or reduce the risk of heart disease, arterial plaque, or high blood pressure; that some 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. (CCFF ¶¶ 616-17).

D. Professor Reibstein Was Extremely Well Qualified To Provide the Opinions He Offered In This Case

2781. Dr. Reibstein is a tenured Professor of Marketing at the University of Pennsylvania in The Wharton School. Dr. Reibstein has taught courses in marketing management,

marketing strategy and marketing metrics to MBA Program and Executive MBA Program students; marketing research courses to MBA Program students; and other marketing courses to undergraduate students. Many of these courses involve the use and design of surveys. (Reibstein, Tr. at 2482; PX0356a01-0002-0003).

Response to Finding No. 2781:
Complaint Counsel has no specific response other than to disagree with the implication that Dr. Reibstein was well qualified to offer opinions relevant to this case. 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. (CCFF ¶ 652).

2782. Dr. Reibstein has been a visiting professor at Stanford Business School, Harvard Business School and Purdue University where he taught marketing courses. Dr. Reibstein has taught courses in marketing strategy and advanced industrial marketing strategy at INSEAD, a top business school in Europe. (Reibstein, Tr. at 2483; PX0356a01-0002, 0003).

Response to Finding No. 2782:
Complaint Counsel has no specific response other than to disagree with the implication that Dr. Reibstein was well qualified to offer opinions relevant to this case. *See* Response to Finding 2782.

2783. Dr. Reibstein received Doctor of Industrial Administration from the Herman C. Krannert Graduate School of Industrial Administration at Purdue University with major in marketing and a minor in behavioral science. (Reibstein, Tr. at 2481). Dr. Reibstein's doctoral dissertation was titled "An Empirical Study of Brand Choice and Switching Behavior." (PX0356a01-0001). Dr. Reibstein attended the Master of Business Administration Program at the Graduate Business School at Tulane University. (Reibstein, Tr. at 2480-81; PX0356a01-0001). Dr. David Reibstein received a B.S. in Business Administration and a B.Z. in Statistics and Political Science from the University of Kansas. (Reibstein, Tr. at 2480; PX0356a01-0001).

Response to Finding No. 2783:
Complaint Counsel has no specific response other than to disagree with the implication that Dr. Reibstein was well qualified to offer opinions relevant to this case. *See* Response to Finding 2782.

2784. Dr. Reibstein has been awarded an Honorary Master of Science by The Wharton School at the University of Pennsylvania. (PX0356a01-0001).

Response to Finding No. 2784:
Complaint Counsel has no specific response other than to disagree with the implication that Dr. Reibstein was well qualified to offer opinions relevant to this case. *See* Response to Finding 2782.

2785. From 1985 to 1989, Dr. Reibstein was the Director of the Wharton/PIMS Strategy Research Center at the University of Pennsylvania. (PX0356a01-0002). From 1987 to 1992, Dr. Reibstein was the Vice Dean and Director of The Wharton Graduate Division at the University of Pennsylvania. (Reibstein, Tr. at 2482; PX0356a01-0002).

Response to Finding No. 2785:
Complaint Counsel has no specific response other than to disagree with the implication that Dr. Reibstein was well qualified to offer opinions relevant to this case. *See* Response to Finding 2782.

2786. Dr. Reibstein was the Executive Director for the Marketing Science Institute, an organization of 72 company-members. The Marketing Science Institute works closely with its members to identify the major marketing issues confronting them. The Marketing Science Institute prepares reports on various marketing issues which are disseminated to its members and the general business community. The Marketing Science Institute sets the research agenda for marketing academia globally. (Reibstein, Tr. at 2483-84; PX0356a01-0002).

Response to Finding No. 2786:
Complaint Counsel has no specific response other than to disagree with the implication that Dr. Reibstein was well qualified to offer opinions relevant to this case. *See* Response to Finding 2782.

2787. Throughout his teaching career, Dr. Reibstein has received numerous awards recognizing him for excellence in teaching. (PX0356a01-0003).

Response to Finding No. 2787:
Complaint Counsel has no specific response other than to disagree with the implication that Dr. Reibstein was well qualified to offer opinions relevant to this case. *See* Response to Finding 2782.

2788. Dr. Reibstein has published extensively in prestigious peer-reviewed marketing journals, including many articles on marketing and marketing research. Those journals include, among others, the Journal of Consumer Research, Journal of Marketing Research, Marketing Science and the Harvard Business Review. (Reibstein, Tr. at 2484; PX0356a01-0004-0007).

Response to Finding No. 2788:
Complaint Counsel has no specific response other than to disagree with the implication that Dr. Reibstein was well qualified to offer opinions relevant to this case. *See* Response to Finding 2782.

2789. Dr. Reibstein has written over 7 books and numerous chapters in books on marketing and marketing research. (Reibstein, Tr. at 2484; PX0356 (Reibstein, Dep. at 14; (PX0356a01-0007,0008).

Response to Finding No. 2789:
Complaint Counsel has no specific response other than to disagree with the implication that Dr. Reibstein was well qualified to offer opinions relevant to this case. *See* Response to Finding 2782.

2790. Dr. Reibstein authored the book "Marketing Metrics: 50+ Metrics Every Executive Should Master (2006)" which was named as the "Best Business Book: Marketing" by Strategy & Business in 2007. (PX0356a01-0004).

Response to Finding No. 2790:
Complaint Counsel has no specific response other than to disagree with the implication that Dr. Reibstein was well qualified to offer opinions relevant to this case. *See* Response to Finding 2782.

2791. Dr. Reibstein has spoken or presented at over 100 conferences on marketing and marketing research. (PX0356 (Reibstein, Dep. at 14; (PX0356a01-0008-0013).

Response to Finding No. 2791:
Complaint Counsel has no specific response other than to disagree with the implication that Dr. Reibstein was well qualified to offer opinions relevant to this case. *See* Response to Finding 2782.

2792. Dr. Reibstein is the Chairman elect of the American Marketing Association. (Reibstein, Tr. at 2484; Reibstein, Dep. at 14).

Response to Finding No. 2792:
Complaint Counsel has no specific response other than to disagree with the implication that Dr. Reibstein was well qualified to offer opinions relevant to this case. *See* Response to Finding 2782.

2793. Dr. Reibstein has designed, executed and supervised market research studies for over 30 years, including studies concerning consumer behavior. (Reibstein, Tr. at 2485-86).

Response to Finding No. 2793:
Complaint Counsel has no specific response other than to disagree with the implication that Dr. Reibstein was well qualified to offer opinions relevant to this case. *See* Response to Finding 2782.

2794. Dr. Reibstein has designed, executed or supervised hundreds of surveys during his career. (Reibstein, Tr. at 2485-86).

Response to Finding No. 2794:
Complaint Counsel has no specific response other than to disagree with the implication that Dr. Reibstein was well qualified to offer opinions relevant to this case. *See* Response to Finding 2782.

2795. Dr. Reibstein has performed consulting research for a variety of companies where is work focuses on understanding why it is that customers buy, what motivates customers to buy, and the interface with customer behavior and a company's marketing activities, price, product, place, and promotion. (Reibstein, Tr. at 2484-2485; PX0356 (Reibstein, Dep. at 14-15)).

Response to Finding No. 2795:
Complaint Counsel has no specific response other than to disagree with the implication that Dr. Reibstein was well qualified to offer opinions relevant to this case. *See* Response to Finding 2782.

2796. Dr. Reibstein's consulting work for companies involves collecting and processing information to better inform the company about what has or might influence customers to make the purchase decisions they do, and in the manner they do to reduce uncertainty in the decisions they make. Dr. Reibstein's consulting work also involves determining the messages consumers take from certain advertising. (PX0356 (Reibstein, Dep. at 16)).Dr. Reibstein has also provided extensive management education in the field of marketing to more than 300 companies over his career. (Reibstein, Tr. at 2485).

Response to Finding No. 2796:
Complaint Counsel has no specific response other than to disagree with the implication that Dr. Reibstein was well qualified to offer opinions relevant to this case. *See* Response to Finding 2782.

2797. Dr. Reibstein has also provided extensive management education in the field of marketing to more than 300 companies over his career. (Reibstein, Tr. at 2485).

Response to Finding No. 2797:
Complaint Counsel has no specific response other than to disagree with the implication that Dr. Reibstein was well qualified to offer opinions relevant to this case. *See* Response to Finding 2782.

2798. Dr. Reibstein serves on the board of the Marketing Accountability Standards Board. This board sets the standards on what are the most important marketing metrics and how to measure them both in the United States and globally. (Reibstein, Tr. at 2485).

Response to Finding No. 2798:
Complaint Counsel has no specific response other than to disagree with the implication that Dr. Reibstein was well qualified to offer opinions relevant to this case. *See* Response to Finding 2782.

2799. Pomegranates are naturally safe, Pomegranate, Punica granatum, is a fruit-bearing plant native to high-altitude regions of Central Asia. Humans have consumed pomegranates for thousands of years as a safe and nutritious food. The FDA identifies pomegranate as being "generally recognized as safe" for human consumption. See generally 32 U.S.C. § 231(s); 21 C.F.R. § 182.20.

Response to Finding No. 2799:
The first two sentences of the proposed finding are not supported by any reference to the record in violation of the Court's Order on Post-Trial Briefs. With respect to the third sentence, *see* Response to Finding 1002.

Respectfully Submitted,

Date: February 7, 2012

/s/ Serena Viswanathan

Serena Viswanathan
Heather Hippsley
Tawana E. Davis
Devin W. Domond
Janet M. Evans
Mary L. Johnson
Elizabeth K. Nach
Michael F. Ostheimer
Elise D. Whang
Andrew D. Wone

Federal Trade Commission
Bureau of Consumer Protection
Division of Advertising Practices
600 Pennsylvania Ave., N.W.
NJ-3212
Washington, D.C. 20580
Telephone: (202) 326-3090
Facsimile: (202) 326-3259

Counsel Supporting the Complaint

RESPONDENTS' APPENDIX OF ADVERTISEMENTS

1. For ease of reference, Respondents include this separate Appendix of Advertisements, which is an advertisement-by-advertisement analysis of the exhibits listed in the chart set forth in paragraph 2252 of the RFF, with the exception of the "outlier" ads, website materials, press releases, and the interviews of Mrs. Resnick and Mr. Tupper, which have been thoroughly addressed in the RFF XVII(D)(4).

Response to Appendix Finding No. 1:
Complaint Counsel has no specific response, other than its Responses to the Findings in the cross-referenced section and paragraph in Respondents' Findings of Fact.

2. Additionally, as set for the in the Proposed Findings of Fact, each of the ads analyzed below also fall into one or more of the three categories: (a) specific study; (b) "backed by" and (c) antioxidant, and are supported by competent and reliable scientific evidence. (*See* RFF XVII(G)(1)).

Response to Appendix Finding No. 2:
Complaint Counsel has no specific response, other than its Response to the Findings in the cross-referenced section in Respondents' Findings of Fact.

24 SCIENTIFIC STUDIES NOW IN ONE EASY-TO SWALLOW PILL - (CX0348)

3. Complaint Counsel claim that on April 1, 2010, POM ran an advertisement with the headline "24 Scientific Studies" with the body copy that appears on (CX0348_0001, attached hereto as Ex. 1)

Response to Appendix Finding No. 3:
Complaint Counsel agrees.

4. Complaint Counsel failed to present any other definitive information regarding this ad's dissemination.

Response to Appendix Finding No. 4:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Moreover, this finding is incorrect. *See* CX0348_0002, CX0474, and CX0371 for additional evidence on dissemination.

5. 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.

Response to Appendix Finding No. 5:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel has presented evidence in CCFF Section VI.E that Respondents have continued to run advertising claims that they had been told were deceptive or misleading.

6. 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.

Response to Appendix Finding No. 6:
The proposed finding mischaracterizes the record and is incorrect. *See* Responses to Findings 2238, 2245 in Respondents' Findings of Fact (Complaint Counsel is challenging POM Juice print ads disseminated prior to approximately June 2009 and POM Juice websites as they appeared prior to approximately February 2010). Moreover, the proposed finding is irrelevant because the ad at issue is for POMx.

7. 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. (CX0348_0001).

Response to Appendix Finding No. 7:
Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 419, 422, 424).

8. Complaint Counsel's assertion that the ad 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. (CX0348_0001).

Response to Appendix Finding No. 8:
Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 419, 422, 424).

9. 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.

Response to Appendix Finding No. 9:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 419, 422, 424).

10. 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. (CX0348_0001). Even the language of the ad itself uses such qualifiers as "emerging science suggests," "help protect," "promising results," "initial UCLA study," "hopeful results" and "preliminary study." (CX0348_0001).

Response to Appendix Finding No. 10:
Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 419, 422, 424).

11. 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 "reduces the risk," like a healthy diet of fruits and vegetables and exercise "reduces the risk" of disease. (CX0348_0001).

Response to Appendix Finding No. 11:
Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 419, 422, 424).

12. 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).

Response to Appendix Finding No. 12:
The proposed finding is unsupported by the cited testimony. Dr. Butters did not define "treat" as a substitute for conventional medical treatment. He defined "treat" as medical treatment and then asserted that he didn't see any ad stating or implying that POM Products "treated any disease." Complaint Counsel also disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 419, 422, 424).

13. 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 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)).

Response to Appendix Finding No. 13:
Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 419, 422, 424). However, Complaint Counsel agrees that "proven" does not mean that "everyone in the study" benefitted.

14. Mrs. Resnick testified that the purpose of including the amount of money related to medical research in the advertising was 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. 249-53).

Response to Appendix Finding No. 14:
Complaint Counsel agrees.

15. Professor Butters testified that this advertisement conveys "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).

Response to Appendix Finding No. 15:
Complaint Counsel has no specific response.

16. Professor Butters also testified that the ad also communicates 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).

Response to Appendix Finding No. 16:
Complaint Counsel does not disagree as to the nature of Dr. Butters's testimony but disagrees with his unsupported conclusion.

17. Further, Professor Butters testified that the ad never states that it 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)).

Response to Appendix Finding No. 17:
This finding is unsupported by the cited evidence, which does not mention comparing a drug to how a healthy diet of fruits and vegetables and exercise maintain health and reduce the risk of disease.

18. Professor Butters also testified that the advertisement 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)).

Response to Appendix Finding No. 18:
Complaint Counsel does not disagree as to the nature of Dr. Butters's testimony but disagrees with his unsupported conclusion.

19. Viewing the "24 Scientific Studies" ad as a whole, including the interaction of the words and visual imagery, the overall net impression of the ad is that POMx Pills are healthy and that they may help with prostate health. (PX0350 (Butters, Dep. at 141); (PX0158-0033)).

Response to Appendix Finding No. 19:
The proposed finding is unsupported by the cited evidence. Dr. Butters's cited deposition testimony is about a different ad and is not about the overall net impression of any POMx ad. Complaint Counsel does not disagree that Dr. Butters's report made broad conclusions about the net impression of POM ads in general, but disagrees with his conclusions, including specifically as to this ad. Moreover, the cited page of his expert report does not state that POMx Pills may help with prostate health.

20. 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)).

Response to Appendix Finding No. 20:
The proposed finding mischaracterizes the testimony of Dr. Stewart, who in the cited testimony simply said that he was not asked to do a net impression analysis of the challenged ads and that he did not know whether the Commission had evidence of how consumers perceive the ads at the level of a net impression. Moreover, Complaint Counsel presented evidence as to the meaning of POM advertisements. (*See* CCFF Sections V.C – V.G).

21. 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.

Response to Appendix Finding No. 21:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Moreover, Complaint Counsel presented evidence as to the meaning of POM advertisements. (*See* CCFF Sections V.C – V.G).

22. 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).

Response to Appendix Finding No. 22:

The proposed finding is irrelevant. *See* Response to Finding 38 in Respondents' Findings of Fact.

24 SCIENTIFIC STUDIES NOW IN ONE EASY-TO SWALLOW PILL - (CX0350)

23. Complaint Counsel claim that on April 26, 2010, POM ran an advertisement with the headline "24 Scientific Studies" with the body copy that appears on CX0350_0001 attached hereto as Ex. 2.

Response to Appendix Finding No. 23:
Complaint Counsel agrees.

24. Complaint Counsel failed to present any other definitive information regarding this ad's dissemination.

Response to Appendix Finding No. 24:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Moreover, this finding is incorrect. (*See* CX0350_0002, CX0474, and CX0371 for additional evidence on dissemination).

25. 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.

Response to Appendix Finding No. 25:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel has presented evidence in CCFF Section VI.E that Respondents have continued to run advertising claims that they had been told were deceptive or misleading.

26. 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.

Response to Appendix Finding No. 26:
The proposed finding mischaracterizes the record and is incorrect. (*See* Responses to Findings 2238, 2245 in Respondents' Findings of Fact (Complaint Counsel is challenging POM Juice print ads disseminated prior to approximately June 2009 and POM Juice websites as they appeared prior to approximately February 2010). Moreover, the proposed finding is irrelevant because the ad at issue is for POMx.

27. 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. (CX0350_0001).

Response to Appendix Finding No. 27:
See Response to Appendix Finding 7.[1]

28. Complaint Counsel's assertion that the ad 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 conveyed in this ad is not conspicuous, self-evident, or reasonably clear from the face of the ad. (CX0350_0001).

Response to Appendix Finding No. 28:
See Response to Appendix Finding 8.

29. 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.

Response to Appendix Finding No. 29:
See Response to Appendix Finding 9.

30. 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. (CX0350_0001). Even the language of the ad itself uses such qualifiers as "emerging science suggests," "help protect," "promising results," "initial UCLA study," "hopeful results" and "preliminary study." (CX0350_0001).

Response to Appendix Finding No. 30:
See Response to Appendix Finding 10.

31. 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

[1] This ad, CX0350, is substantively identical to CX0348, except that CX350 claims that POMx is made from the only pomegranates "backed by "$34 million" rather than "$32 million" in medical research. (*Compare* CX0350_0001 *with* CX0348_0001). Because the ads are substantively identical, and because Respondents have proposed identical findings for CX0348 (Appendix Findings 3-22) and CX0350 (Appendix Findings 23-42), Complaint Counsel adopts and restates its responses from the prior ad here, as appropriate.

action, but "reduces the risk," like a healthy diet of fruits and vegetables and exercise "reduces the risk" of disease. (CX0350_0001).

Response to Appendix Finding No. 31:
See Response to Appendix Finding 11.

32. 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).

Response to Appendix Finding No. 32:
See Response to Appendix Finding 12.

33. 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 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)).

Response to Appendix Finding No. 33:
See Response to Appendix Finding 13.

34. Mrs. Resnick testified that the purpose of including the amount of money in medical research in the advertising was 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. 249-53).

Response to Appendix Finding No. 34:
See Response to Appendix Finding 14.

35. Butters testified that this advertisement conveys "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).

Response to Appendix Finding No. 35:
See Response to Appendix Finding 15.

36. Professor Butters also testified that the ad also communicates 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).

Response to Appendix Finding No. 36:
See Response to Appendix Finding 16.

37. Further, Professor Butters testified that the ad never states that it will treat a disease and that reasonable consumers cannot infer from this advertisement that POMx Pills treats disease, prevents or reduces 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)).

Response to Appendix Finding No. 37:
See Response to Appendix Finding 17.

38. Professor Butters also testified that the advertisement 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)).

Response to Appendix Finding No. 38:
See Response to Appendix Finding 18.

39. Viewing the "24 Scientific Studies" ad as a whole, including the interaction of the words and visual imagery, the overall net impression of the ad is that POMx Pills are healthy and that they may help with prostate health. (PX0350 (Butters, Dep. at 141); (PX0158-0033)).

Response to Appendix Finding No. 39:
See Response to Appendix Finding 19.

40. 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)).

Response to Appendix Finding No. 40:
See Response to Appendix Finding 20.

41. 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.

Response to Appendix Finding No. 41:
See Response to Appendix Finding 21.

42. 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).

Response to Appendix Finding No. 42:
See Response to Appendix Finding 22.

100% PURE pomegranate juice to the rescue! - (CX0380_0006; CX0372_0004)

43. Complaint Counsel claim that, on September 10, 2009, POM ran an advertisement with the headline "100% PURE pomegranate juice to the rescue!" with this body copy:

> Will POM Wonderful 100% purity be enough to help save your health? Does its lack of added sugar, colorants and cheap filler juice make it superior to its competitors? Can POM products' $32 million in medical research truly make a difference in the current state of your health?* Do superheroes wear tights?
>
> *visit POM Wonderful.com/health/research to review published studies

(CX0380_0006; CX0372_0004, attached hereto as Ex. 3).

Response to Appendix Finding No. 43:
The proposed finding mischaracterizes the exhibits at issue as individual ads, when in fact they should be considered together as multi-page "magazine wrap" or "cover wrap" ads. CX0372_0001-04 is one ad (indicated by the same job number PJ2007 across all pages). Documents that Respondents produced as dissemination schedules show that POM used unique project numbers starting with "PJ" to indicate individual ads. (CX0436; CX0437). CX0380_0005-07 lacks a job number but was produced as part of the same document as CX0380_0001-06 by Respondents and on its face appears to be a Time Magazine cover. *See* Response to Finding 2252 in Respondents' Findings of Fact. Complaint Counsel agrees that these pages were disseminated as part of CX0380_0005-07 and CX0372_0001-04.

44. Complaint Counsel failed to present any definitive information regarding this ad's dissemination.

Response to Appendix Finding No. 44:
The proposed finding is incorrect. *See* Response to Finding 2252 (CX0372_0001-04 dated 9/10/2009; CX0380_0005-07 produced as a single document with a similar magazine wrap dated 9/10/2009).

45. 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.

Response to Appendix Finding No. 45:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel has presented evidence in CCFF Section VI.E that Respondents have continued to run advertising claims that they had been told were deceptive or misleading.

46. Mrs. Resnick testified that she does not remember seeing "100% pure pomegranate juice to the rescue" as an ad but the headline sounds familiar to her. The ad may never have happened. If the ad did run, she does not think that POM ran this ad much. (L. Resnick, Tr. 118-20).

Response to Appendix Finding No. 46:
The proposed finding mischaracterizes the cited evidence. Mrs. Resnick was testifying about a different exhibit (meeting notes, CX0410) and about headlines for billboard ads, not about this ad specifically.

47. Complaint Counsel's assertion that the ad conveys the message that (a) POM Juice "prevents," "treats," or "reduces the risk" of certain diseases; or (b) POM Juice is "clinically proven" to "prevent," "treat," or "reduce the risk" of certain diseases is not conspicuous, self-evident, or reasonably clear from the face of the ad. (CX0380_0006; CX0372_0004).

Response to Appendix Finding No. 47:
The proposed finding is incomplete, as these were not single page ads, but part of multi-page magazine wraps. *See* Response to Appendix Finding 43. Complaint Counsel disagrees with the proposed finding regarding the net impression of the entirety of these advertisements (described in Response to Appendix Finding 43). (CCFF ¶¶ 381, 384).

48. 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.

Response to Appendix Finding No. 48:
The proposed finding is incomplete, as these were not single page ads, but part of multi-page magazine wraps. *See* Response to Appendix Finding 43. Complaint Counsel

disagrees with the proposed finding regarding the net impression of the entirety of these advertisements (described in Response to Appendix Finding 43). (CCFF ¶¶ 381, 384).

49. 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; or (b) drinking eight ounces of POM Juice is "clinically proven" to prevent, treat or reduce the risk of certain diseases. (CX0380_0006; CX0372_0004).

Response to Appendix Finding No. 49:
The proposed finding is incomplete, as these were not single page ads, but part of multi-page magazine wraps. *See* Response to Appendix Finding 43. Complaint Counsel disagrees with the proposed finding regarding the net impression of the entirety of these advertisements (described in Response to Appendix Finding 43). (CCFF ¶¶ 381, 384).

50. 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, 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. (CX0380_0006; CX0372_0004).

Response to Appendix Finding No. 50:
The proposed finding is incomplete, as these were not single page ads, but part of multi-page magazine wraps. *See* Response to Appendix Finding 43. Complaint Counsel disagrees with the proposed finding regarding the net impression of the entirety of these advertisements (described in Response to Appendix Finding 43). (CCFF ¶¶ 381, 384).

51. 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).

Response to Appendix Finding No. 51:
The proposed finding is unsupported by the cited testimony. Dr. Butters did not define "treat" as a substitute for conventional medical treatment. He defined "treat" as medical treatment and then asserted that he didn't see any ad stating or implying that POM Products "treated any disease." The proposed finding is incomplete, as these were not

single page ads, but part of multi-page magazine wraps. *See* Response to Appendix Finding 43. Complaint Counsel disagrees with the proposed finding regarding the net impression of the entirety of these advertisements (described in Response to Appendix Finding 43). (CCFF ¶¶ 381, 384).

52. 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 certain diseases 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)).

Response to Appendix Finding No. 52:
The proposed finding is incomplete, as these were not single page ads, but part of multi-page magazine wraps. *See* Response to Appendix Finding 43. Complaint Counsel disagrees with the proposed finding regarding the net impression of the entirety of these advertisements (described in Response to Appendix Finding 43). (CCFF ¶¶ 381, 384). However, Complaint Counsel agrees that "proven" does not mean that "everyone in the study" benefitted.

53. 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).

Response to Appendix Finding No. 53:
Complaint Counsel does not disagree that Dr. Butters's report made broad conclusions about the net impression of POM ads in general, but disagrees with his conclusions, including specifically as to these ads.

54. 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)).

Response to Appendix Finding No. 54:
The proposed finding mischaracterizes the testimony of Dr. Stewart, who in the cited testimony simply said that he was not asked to do a net impression analysis of the challenged ads and that he did not know whether the Commission had evidence of how consumers perceive the ads at the level of a net impression. Moreover, Complaint Counsel presented evidence as to the meaning of POM advertisements. (*See* CCFF Sections V.C – V.G).

55. Further, Complaint Counsel presented no evidence that the claims in Respondents' ads reasonably conveyed that the Challenged Products are "clinically proven" to prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction.

Response to Appendix Finding No. 55:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. The proposed finding is incomplete, as these were not single page ads, but part of multi-page magazine wraps. *See* Response to Appendix Finding 43. Moreover, Complaint Counsel presented evidence on the meaning of these and other POM advertisements. (*See* CCFF ¶¶ 381, 384 and Sections V.C – V.G).

56. 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).

Response to Appendix Finding No. 56:
The proposed finding is irrelevant. *See* Response to Finding 38 in Respondents' Findings of Fact.

Amaze your urologist - (CX1426_00036, Exh. G; CX0468_0001)

57. Complaint Counsel claim that POM ran an advertisement with the headline "Amaze your urologist" with this body copy:

> The Antioxidant Superpower. Learn More. (CX1426_0036, Exh. G; CX0468_0001, attached hereto as Ex. 4).

Response to Appendix Finding No. 57:
Complaint Counsel is not challenging the claims from this ad as an example of

Respondents' conduct violating the FTC Act; therefore the proposed finding is irrelevant.

(*See* CCFF Section V and Appendix A).

58. Complaint Counsel failed to present any definitive information regarding this ad's dissemination.

Response to Appendix Finding No. 58:
Complaint Counsel is not challenging the claims from this ad as an example of

Respondents' conduct violating the FTC Act; therefore the proposed finding is irrelevant.

(*See* CCFF Section V and Appendix A).

59. 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.

Response to Appendix Finding No. 59:
Complaint Counsel is not challenging the claims from this ad as an example of

Respondents' conduct violating the FTC Act; therefore the proposed finding is irrelevant.

(*See* CCFF Section V and Appendix A).

60. 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. (CX1426_0036, Exh. G; CX0468_0001).

Response to Appendix Finding No. 60:
Complaint Counsel is not challenging the claims from this ad as an example of

Respondents' conduct violating the FTC Act; therefore the proposed finding is irrelevant.

(*See* CCFF Section V and Appendix A).

61. 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.

Response to Appendix Finding No. 61:
Complaint Counsel is not challenging the claims from this ad as an example of

Respondents' conduct violating the FTC Act; therefore the proposed finding is irrelevant.

(*See* CCFF Section V and Appendix A).

62. 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. (CX1426_0036, Exh. G; CX0468_0001).

Response to Appendix Finding No. 62:
Complaint Counsel is not challenging the claims from this ad as an example of

Respondents' conduct violating the FTC Act; therefore the proposed finding is irrelevant.

(*See* CCFF Section V and Appendix A).

63. 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 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. (CX1426_0036, Exh. G; CX0468_0001).

Response to Appendix Finding No. 63:
Complaint Counsel is not challenging the claims from this ad as an example of

Respondents' conduct violating the FTC Act; therefore the proposed finding is irrelevant.

(*See* CCFF Section V and Appendix A).

64. 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).

Response to Appendix Finding No. 64:
Complaint Counsel is not challenging the claims from this ad as an example of

Respondents' conduct violating the FTC Act; therefore the proposed finding is irrelevant.

(*See* CCFF Section V and Appendix A).

65. 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 prostate cancer 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)).

Response to Appendix Finding No. 65:
Complaint Counsel is not challenging the claims from this ad as an example of

Respondents' conduct violating the FTC Act; therefore the proposed finding is irrelevant.

(*See* CCFF Section V and Appendix A).

66. Mr. Perdigao testified that he does not know when this advertisement ran or what internet sites the advertisement ran on. He 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)).

Response to Appendix Finding No. 66:
Complaint Counsel is not challenging the claims from this ad as an example of

Respondents' conduct violating the FTC Act; therefore the proposed finding is irrelevant.

(*See* CCFF Section V and Appendix A).

67. 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).

Response to Appendix Finding No. 67:
Complaint Counsel is not challenging the claims from this ad as an example of

Respondents' conduct violating the FTC Act; therefore the proposed finding is irrelevant.

(*See* CCFF Section V and Appendix A).

68. 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)).

Response to Appendix Finding No. 68:
Complaint Counsel is not challenging the claims from this ad as an example of

Respondents' conduct violating the FTC Act; therefore the proposed finding is irrelevant.

(*See* CCFF Section V and Appendix A).

69. 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)).

Response to Appendix Finding No. 69:
Complaint Counsel is not challenging the claims from this ad as an example of

Respondents' conduct violating the FTC Act; therefore the proposed finding is irrelevant.

(*See* CCFF Section V and Appendix A).

70. 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.

Response to Appendix Finding No. 70:
Complaint Counsel is not challenging the claims from this ad as an example of

Respondents' conduct violating the FTC Act; therefore the proposed finding is irrelevant.

(*See* CCFF Section V and Appendix A).

71. 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).

Response to Appendix Finding No. 71:
Complaint Counsel is not challenging the claims from this ad as an example of

Respondents' conduct violating the FTC Act; therefore the proposed finding is irrelevant.

(*See* CCFF Section V and Appendix A).

Antioxidant Superpill - (CX1426_0038-0042, Exh. I)

72. Complaint Counsel claim that POM ran an advertisement with the headline "Antioxidant Superpill" with the body copy that appears on CX1426_0038-0042, Exh. I, attached hereto as Ex. 5.

Response to Appendix Finding No. 72:
Complaint Counsel agrees.

73. Complaint Counsel failed to present any definitive information regarding this ad's dissemination.

Response to Appendix Finding No. 73:
The proposed finding is incorrect. The package insert, copyrighted 2007, was produced by Respondents from their own files with a notation "POMx Brochure, Monthly and Trial, 1st Shipment, June 2007 – present (ongoing)." (CX0428_0001). Moreover, Respondents admit this package insert was disseminated in their Answer and further admit in these findings that there is evidence that it ran. (PX0364-0003; Respondents' Finding 2252 (chart)).

74. 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.

Response to Appendix Finding No. 74:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel has presented evidence in CCFF Section VI.E that Respondents have continued to run advertising claims that they had been told were deceptive or misleading.

75. 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).

Response to Appendix Finding No. 75:
Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (*See* CCFF ¶¶ 430-34).

76. Complaint Counsel's assertion that the ad 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).

Response to Appendix Finding No. 76:
Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (*See* CCFF ¶¶ 430-34).

77. 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.

Response to Appendix Finding No. 77:
This finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (*See* CCFF ¶¶ 430-34).

78. 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).

Response to Appendix Finding No. 78:
Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (*See* CCFF ¶¶ 430-34).

79. 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 "reduces the risk," like a healthy diet of fruits and vegetables and exercise "reduces the risk" of disease. (CX1426_0038-0042, Exh. I).

Response to Appendix Finding No. 79:
Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (*See* CCFF ¶¶ 430-34).

80. 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).

Response to Appendix Finding No. 80:
The proposed finding is unsupported by the cited testimony. Dr. Butters did not define "treat" as a substitute for conventional medical treatment. He defined "treat" as medical treatment and then asserted that he didn't see any ad stating or implying that POM Products "treated any disease." Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (*See* CCFF ¶¶ 430-34).

81. 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 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)).

Response to Appendix Finding No. 81:
Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (*See* CCFF ¶¶ 430-34). However, Complaint Counsel agrees that "proven" does not mean that "everyone in the study" benefitted.

82. 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)).

Response to Appendix Finding No. 82:
The proposed finding mischaracterizes the testimony of Dr. Stewart who stated in the cited testimony only that he was not asked to do a net impression analysis of the challenged ads and that he did not know whether the Commission had evidence of how consumers perceive the ads at the level of a net impression. Moreover, Complaint Counsel presented evidence as to the meaning of this and other POM advertisements. (*See* CCFF ¶¶ 430-34 and Sections V.C – V.G).

83. 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.

Response to Appendix Finding No. 83:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Moreover, Complaint Counsel presented evidence on the meaning of this and other POM advertisements. (*See* CCFF ¶¶ 430-34 and Sections V.C – V.G).

84. 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).

Response to Appendix Finding No. 84:
The proposed finding is irrelevant. *See* Response to Finding 38 in Respondents' Findings of Fact.

Cheat death - (CX0188)

85. Complaint Counsel claim that, on April 1, 2008, POM ran an advertisement with the headline "Cheat death" with this body copy:

> You need more than luck to live longer. You need antioxidants. And POM Wonderful 100% Pomegranate Juice is loaded with them. It helps guard your body against free radicals, unstable molecules that emerging science suggests aggressively destroy healthy cells in your body and contribute to disease. POM Wonderful 100% Pomegranate Juice is supported by $23 million of medical scientific research from leading universities, which has uncovered encouraging results in prostate and cardiovascular health. So drink a glass a day and cheat death. Live life.
>
> **POM Wonderful 100% Pomegranate Juice. The Antioxidant Superpower.**

(CX0188_0001, attached hereto as Ex. 6).

Response to Appendix Finding No. 85:
Complaint Counsel agrees that this ad ran sometime between April and June 2008.

(CX0188_0001 (grid at bottom lists "date out" as 4/1/ 2008 and "Project" as "PJ

Advocate Print Ad Cheat Death June 2008")).

86. Complaint Counsel failed to present any other definitive information regarding this ad's dissemination.

Response to Appendix Finding No. 86:
The proposed finding is incorrect. *See* Response to Appendix Finding 85.

87. 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.

Response to Appendix Finding No. 87:
The proposed finding is not supported by any reference to the record, in violation of the

Court's Order on Post-Trial Briefs. Complaint Counsel has presented evidence in CCFF

Section VI.E that Respondents have continued to run advertising claims that they had

been told were deceptive or misleading.

88. Mrs. Resnick testified that she does not recall bringing back the "Cheat death" headline for use in 2008. (L. Resnick, Tr. 191-92).

Response to Appendix Finding No. 88:
The proposed finding mischaracterizes the evidence. Although Mrs. Resnick testified as stated at trial, her testimony is contradicted by her own earlier testimony in the *Welch Foods* lawsuit and by the record as a whole. (*See* CCFF ¶ 353 (Mr. Perdigao testified that "Cheat Death" and similar advertisements were revived in 2008; Mrs. Resnick testified she assumed it was her decision); *see also* CCFF ¶¶ 354-55 (POM received complaints from consumers in 2008, 2009, and 2010 about the "Cheat Death" headline and imagery being advertised at the time)).

89. Complaint Counsel presented no evidence to contradict Mrs. Resnick's testimony regarding the use of this ad in 2008.

Response to Appendix Finding No. 89:
This finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Moreover, the proposed finding is incorrect. *See* Response to Appendix Finding 88.

90. Complaint Counsel's assertion that the ad conveys 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 is not conspicuous, self-evident, or reasonably clear from the face of the ad. (CX0188_0001).

Response to Appendix Finding No. 90:
Complaint Counsel does not contend this ad makes treatment or "clinically proven" claims. (*See* CCFF ¶ 354 and Appendix A). With respect to the other claims in the proposed finding, Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 349-52, 354).

91. 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.

Response to Appendix Finding No. 91:

This finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 349-52, 354).

92. 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. (CX0188_0001). Even the language of the ad itself uses such qualifiers as "helps guard," "emerging science suggests," "contribute," and "encouraging results." (CX0188_0001).

Response to Appendix Finding No. 92:
Complaint Counsel does not contend this ad makes treatment or "clinically proven" claims. (*See* CCFF ¶ 354 and Appendix A). With respect to the other claims in the proposed finding, Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 349-52, 354).

93. 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 "reduces the risk," like a healthy diet of fruits and vegetables and exercise "reduces the risk" of disease. (CX0188_0001).

Response to Appendix Finding No. 93:
Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 349-52, 354).

94. 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).

Response to Appendix Finding No. 94:
Complaint Counsel does not contend this ad makes treatment claims. (CCFF ¶ 354 and Appendix A). Therefore, the proposed finding is irrelevant.

95. 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 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)).

Response to Appendix Finding No. 95:
Complaint Counsel does not contend this ad makes "clinically proven" claims. (CCFF ¶ 354 and Appendix A). Therefore, the proposed finding is irrelevant.

96. 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).

Response to Appendix Finding No. 96:
Complaint Counsel does not disagree that Mrs. Resnick testified as stated, but her testimony is contradicted by the record as a whole, as other POM employees have stated that the ad's message was about preventing disease. (*See* CCFF ¶¶ 350, 354-55).

97. 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).

Response to Appendix Finding No. 97:
The proposed finding is incomplete, because Mrs. Resnick also testified in the cited transcript pages that POM wanted the consumer to read the rest of the body copy, including the statements about medical research and cardiovascular health. (L. Resnick, Tr. 197).

98. 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).

Response to Appendix Finding No. 98:

Complaint Counsel does not disagree that Dr. Butters's report made broad conclusions about the net impression of POM ads in general, but disagrees with his conclusions, including specifically as to this ad.

99. 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).

Response to Appendix Finding No. 99:
Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 349-52, 354). *See also* Response to Appendix Finding 97.

100. 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)).

Response to Appendix Finding No. 100:
The proposed finding mischaracterizes the testimony of Dr. Stewart who stated in the cited testimony only that he was not asked to do a net impression analysis of the challenged ads and that he did not know whether the Commission had evidence of how consumers perceive the ads at the level of a net impression. Moreover, Complaint Counsel presented evidence as to the meaning of this and other POM advertisements. (*See* CCFF ¶¶ 349-52, 354 and Sections V.C – V.G).

101. 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.

Response to Appendix Finding No. 101:
Complaint Counsel does not contend this ad makes "clinically proven" claims. (*See* CCFF ¶ 354 and Appendix A). Therefore, the proposed finding is irrelevant.

102. 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).

Response to Appendix Finding No. 102:

The proposed finding is irrelevant. *See* Response to Finding 38 in Respondents' Findings of Fact.

Drink to prostate health - (CX0260; CX1426_0028, Exh. B)

103. Complaint Counsel claim that, on December 1, 2008, POM ran an advertisement with the headline "Drink to prostate health."

> Sometimes, good medicine can taste great. Case in point: POM 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 POM Wonderful 100% Pomegranate Juice daily for at least two years, these men experienced significantly longer PSA doubling times. Want to learn more about the results of this study? Visit pomwonderful.com/prostate. **Trust in POM.**

(CX260_0001; CX1426_0028, Exh. B, attached hereto as Ex. 7).

Response to Appendix Finding No. 103:
Complaint Counsel agrees.

104. Complaint Counsel failed to present any definitive information regarding this ad's dissemination.

Response to Appendix Finding No. 104:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Moreover, the proposed finding is incorrect; Complaint Counsel has provided evidence that it was disseminated in at least two magazines in December 2008, and Respondents admit it was disseminated. (CX0260_0002; CX0474; CX0371; PX0364_0002).

105. 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.

Response to Appendix Finding No. 105:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel has presented evidence in CCFF Section VI.E that Respondents have continued to run advertising claims that they had been told were deceptive or misleading.

106. 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).

Response to Appendix Finding No. 106:
Complaint Counsel does not contend this ad makes prevent or reduce the risk of prostate cancer claims. (*See* CCFF ¶ 371 and Appendix A). As to the other claims in the proposed finding, Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (*See* CCFF ¶¶ 368-71).

107. Mrs. Resnick testified that she does not recall this specific advertisement, is not familiar with it, and does not know when it ran. (L. Resnick, Tr. 243-44).

Response to Appendix Finding No. 107:
Complaint Counsel has no specific response.

108. Mrs. Resnick testified that she does not know if this specific advertisement actually ran. (CX1359 (L. Resnick, Dep. at 125)).

Response to Appendix Finding No. 108:
Complaint Counsel objects to the deposition testimony cited in the proposed finding as non-designated testimony. Respondents have admitted they disseminated this and other advertisements attached to the Complaint. (PX0364_0002).

109. 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).

Response to Appendix Finding No. 109:
Complaint Counsel does not contend this ad makes prevent or reduce the risk of prostate cancer claims. (*See* CCFF ¶ 371 and Appendix A). As to the other claims in the proposed finding, Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 368-71).

110. 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.

Response to Appendix Finding No. 110:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 368-71).

111. 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). Even the language of the ad itself uses the qualifier "preliminary medical study." (CX260_0001; CX1426_0028, Exh. B).

Response to Appendix Finding No. 111:
Complaint Counsel does not contend this ad makes prevent or reduce the risk of prostate cancer claims. (*See* CCFF ¶ 371 and Appendix A). As to the other claims in the proposed finding, Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 368-71).

112. 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 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. (CX260_0001; CX1426_0028, Exh. B).

Response to Appendix Finding No. 112:
Complaint Counsel does not contend this ad makes reduce the risk of prostate cancer claims. (*See* CCFF ¶ 371 and Appendix A). Therefore, the proposed finding is irrelevant.

113. 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).

Response to Appendix Finding No. 113:
The proposed finding is unsupported by the cited testimony. Dr. Butters did not define "treat" as a substitute for conventional medical treatment. He defined "treat" as medical treatment and then asserted that he didn't see any ad stating or implying that POM

Products "treated any disease." Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 368-71).

114. 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 prostate cancer 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)).

Response to Appendix Finding No. 114:
Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 368-71). However, Complaint Counsel agrees that "proven" does not mean that "everyone in the study" benefitted.

115. 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)).

Response to Appendix Finding No. 115:
The proposed finding mischaracterizes the evidence, as Dr. Butters changed his testimony regarding this advertisement at trial. During his deposition, Dr. Butters testified that the ad could *not* communicate to any reasonable consumer that drinking POM Juice daily is beneficial with respect to prostate cancer. (PX0350 (Butters, Dep. at 122)). At trial, however, he testified, "My conclusion is that -- that the -- the ad will convey the -- the inference will be drawn that POM Wonderful Pomegranate Juice may be beneficial for people who have -- who have had prostate cancer." (Butters, Tr. 2943-44).

116. 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).

Response to Appendix Finding No. 116:
Complaint Counsel does not disagree that Dr. Butters's report made broad conclusions about the net impression of POM ads in general, but disagrees with his conclusions, including specifically as to this ad.

117. 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)).

Response to Appendix Finding No. 117:
Complaint Counsel has no specific response.

118. 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)).

Response to Appendix Finding No. 118:
The proposed finding is unsupported by the cited testimony; neither witness testified about the overall net impression of this ad.

119. 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)).

Response to Appendix Finding No. 119:
The proposed finding mischaracterizes the testimony of Dr. Stewart, who in the cited testimony simply said that he was not asked to do a net impression analysis of the challenged ads and that he did not know whether the Commission had evidence of how consumers perceive the ads at the level of a net impression. Moreover, Complaint

Counsel presented evidence as to the meaning of POM advertisements. (*See* CCFF Sections V.C – V.G).

120. 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.

Response to Appendix Finding No. 120:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Moreover, Complaint Counsel presented evidence on the meaning of this and other POM advertisements. (*See* CCFF Sections V.C – V.G).

121. 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).

Response to Appendix Finding No. 121:
The proposed finding is irrelevant. *See* Response to Finding 38 in Respondents' Findings of Fact.

Drink to Prostate Health - (CX0314_0003; CX0314_0007)

122. Complaint Counsel claim that, on September 9, 2008, POM ran an advertisement with the headline "Drink to prostate health." without body copy. (CX0314_0003; CX0314_0007, attached hereto as Ex. 8).

Response to Appendix Finding No. 122:
The proposed finding mischaracterizes the exhibits at issue as individual ads, when in fact they should be considered together with other pages as multi-page "magazine wrap" or "cover wrap" ads. Specifically, CX0314_0003-06 together constitute one magazine wrap ad, indicated by the cover email (CX0314_0001) and the same job number at the bottom of each page (PJ9745)). CX0314_0007-10 constitutes another magazine wrap ad (indicated by a similar job number footer PJ0225_TIME-Wrap_Dec08"). Documents that Respondents produced as dissemination schedules show that POM used unique project numbers starting with "PJ" to indicate individual ads. (CX0436; CX0437). *See* Responses to Findings 2252, 2419 in Respondents' Findings of Fact. Complaint Counsel agrees that these pages were disseminated as part of CX0314_0003-06 and CX0314_0007-10.

123. Complaint Counsel failed to present any other definitive information regarding this ad's dissemination.

Response to Appendix Finding No. 123:
The proposed finding is incorrect. *See* Response to Appendix Finding 122.

124. 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.

Response to Appendix Finding No. 124:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel has presented evidence in CCFF Section VI.E that Respondents have continued to run advertising claims that they had been told were deceptive or misleading.

125. 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. (CX0314_0003; CX0314_0007).

Response to Appendix Finding No. 125:
The proposed finding is incomplete, as these were not single page ads, but part of multi-page magazine wraps. *See* Response to Appendix Finding 122. Complaint Counsel disagrees with the proposed finding regarding the net impression of the entirety of these advertisements (described in Response to Appendix Finding 122). (CCFF ¶¶ 377-81, 384).

126. 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.

Response to Appendix Finding No. 126:
The proposed finding is incomplete, as these were not single page ads, but part of multi-page magazine wraps. *See* Response to Appendix Finding 122. Complaint Counsel disagrees with the proposed finding regarding the net impression of the entirety of these advertisements (described in Response to Appendix Finding 122). (CCFF ¶¶ 377-81, 384).

127. 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. (CX0314_0003; CX0314_0007).

Response to Appendix Finding No. 127:
The proposed finding is incomplete, as these were not single page ads, but part of multi-page magazine wraps. *See* Response to Appendix Finding 122. Complaint Counsel disagrees with the proposed finding regarding the net impression of the entirety of these

advertisements (described in Response to Appendix Finding 122). (CCFF ¶¶ 377-81, 384).

128. 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 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. (CX0314_0003; CX0314_0007).

Response to Appendix Finding No. 128:
The proposed finding is incomplete, as these were not single page ads, but part of multi-page magazine wraps. *See* Response to Appendix Finding 122. Complaint Counsel disagrees with the proposed finding regarding the net impression of the entirety of these advertisements (described in Response to Appendix Finding 122). (CCFF ¶¶ 377-81, 384).

129. 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).

Response to Appendix Finding No. 129:
The proposed finding is unsupported by the cited testimony. Dr. Butters did not define "treat" as a substitute for conventional medical treatment. He defined "treat" as medical treatment and then asserted that he didn't see any ad stating or implying that POM Products "treated any disease." Moreover, the proposed finding is incomplete, as these were not single page ads, but part of multi-page magazine wraps. *See* Response to Appendix Finding 122. Complaint Counsel disagrees with the proposed finding regarding the net impression of the advertisements. (*See* CCFF ¶¶ 377-81, 384).

130. 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 prostate cancer 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)).

Response to Appendix Finding No. 130:
The proposed finding is incomplete, as these were not single page ads, but part of multi-page magazine wraps. *See* Response to Appendix Finding 122. Complaint Counsel disagrees with the proposed finding regarding the net impression of the entirety of these advertisements (described in Response to Appendix Finding 122). (CCFF ¶¶ 377-81, 384). However, Complaint Counsel agrees that "proven" does not mean that "everyone in the study" benefitted.

131. 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).

Response to Appendix Finding No. 131:
Complaint Counsel does not disagree that Dr. Butters's report made broad conclusions about the net impression of POM ads in general, but disagrees with his conclusions, including specifically as to this ad.

132. 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)).

Response to Appendix Finding No. 132:
The proposed finding is unsupported by the cited testimony; neither witness testified about the overall net impression of these magazine wraps.

133. 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)).

Response to Appendix Finding No. 133:
The proposed finding mischaracterizes the testimony of Dr. Stewart, who in the cited testimony simply said that he was not asked to do a net impression analysis of the challenged ads and that he did not know whether the Commission had evidence of how consumers perceive the ads at the level of a net impression. Moreover, Complaint Counsel presented evidence as to the meaning of POM advertisements. (*See* CCFF Sections V.C – V.G).

134. 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.

Response to Appendix Finding No. 134:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Moreover, Complaint Counsel presented evidence on the meaning of these magazine wraps and other POM advertisements. (*See* CCFF ¶¶ 377-81, 384 and Sections V.C – V.G).

135. 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).

Response to Appendix Finding No. 135:
The proposed finding is irrelevant. *See* Response to Finding 38 in Respondents' Findings of Fact.

Have no health fear . . . POM IS HERE! - (CX0380_0004)

136. Complaint Counsel claim that, on September 10, 2009, POM ran an advertisement with the headline "Have no health fear … POM IS HERE!" and the body copy:

> It's a champion of superior health…It's a medical marvel…It's the Antioxidant Superpower, POM Wonderful® 100% pure pomegranate juice. Unpolluted by cheap filler juices, added sugars or colorants. Backed by published medical research.* Devoted to keeping you alive and well for a good, long time!
>
> *Visit pomwonderful.com/health/research to review published studies.

(CX0380_0004, attached hereto as Ex. 9).

Response to Appendix Finding No. 136:
The proposed finding mischaracterizes the exhibit at issue as an individual ad, when in fact it should be considered together with other pages as a multi-page "magazine wrap" or "cover wrap" ad. CX0380_0001-04 is one ad (indicated by the same job number PJ2006 across all pages). Documents that Respondents produced as dissemination schedules show that POM used unique project numbers starting with "PJ" to indicate individual ads. (CX0436; CX0437). Complaint Counsel agrees, and Respondents concede, that CX0380_0001-04 was disseminated in September 2009. *See also* Response to Finding 2252 in Respondents' Findings of Fact.

137. Complaint Counsel failed to present any other definitive information regarding this ad's dissemination.

Response to Appendix Finding No. 137:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Moreover, the proposed finding is incorrect. *See* Response to Appendix Finding 136.

138. 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.

Response to Appendix Finding No. 138:

The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel has presented evidence in CCFF Section VI.E that Respondents have continued to run advertising claims that they had been told were deceptive or misleading.

139. 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.

Response to Appendix Finding No. 139:

The proposed finding mischaracterizes the record and is incorrect. Complaint Counsel challenges the claims in this magazine wrap as deceptive and is not foreclosed from doing so by Dr. Mazis's testimony. Dr. Mazis testified as to his understanding of the *approximate* date deceptive POM Juice ads were disseminated for the purpose of showing that Dr. Reibstein's survey, conducted in October 2010, was done well after that. This magazine wrap was disseminated only two months after the approximate date given, and thus for the purposes of the reliability of Dr. Reibstein's survey conducted in October 2010 (which was the core issue of Dr. Mazis's testimony on this point), this short time difference is irrelevant. *See* Responses to Findings 2238, 2245 in Respondents' Findings of Fact (Complaint Counsel is challenging POM Juice print ads disseminated prior to *approximately* June 2009 and POM Juice websites as they appeared prior to approximately February 2010).

140. Complaint Counsel's assertion that the ad conveys the message that (a) POM Juice "prevents," "treats," or "reduces the risk" of certain diseases; or (b) POM Juice is "clinically proven" to "prevent," "treat," or "reduce the risk" of certain diseases is not conspicuous, self-evident, or reasonably clear from the face of the ad. (CX0380_0004).

Response to Appendix Finding No. 140:

The proposed finding is incomplete, as this was not a single ad, but part of a multi-page magazine wrap. *See* Response to Appendix Finding 136. Complaint Counsel disagrees with the proposed finding regarding the net impression of this entire ad (described in Response to Appendix Finding 136). (CCFF ¶¶ 377-81, 384).

141. 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.

Response to Appendix Finding No. 141:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. The proposed finding is incomplete, as this was not a single ad, but part of a multi-page magazine wrap. *See* Response to Appendix Finding 136. Complaint Counsel disagrees with the proposed finding regarding the net impression of this entire ad (described in Response to Appendix Finding 136). (CCFF ¶¶ 377-81, 384).

142. 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; or (b) drinking eight ounces of POM Juice is "clinically proven" to prevent, treat or reduce the risk of certain diseases. (CX0380_0004).

Response to Appendix Finding No. 142:
The proposed finding is incomplete, as this was not a single ad, but part of a multi-page magazine wrap. *See* Response to Appendix Finding 136. Complaint Counsel disagrees with the proposed finding regarding the net impression of this entire ad (described in Response to Appendix Finding 136). (CCFF ¶¶ 377-81, 384).

143. 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, 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. (CX0380_0004).

Response to Appendix Finding No. 143:

The proposed finding is incomplete, as this was not a single ad, but part of a multi-page magazine wrap. *See* Response to Appendix Finding 136. Complaint Counsel disagrees with the proposed finding regarding the net impression of this entire ad (described in Response to Appendix Finding 136). (CCFF ¶¶ 377-81, 384).

144. 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).

Response to Appendix Finding No. 144:

The proposed finding is unsupported by the cited testimony. Dr. Butters did not define "treat" as a substitute for conventional medical treatment. He defined "treat" as medical treatment and then asserted that he didn't see any ad stating or implying that POM Products "treated any disease." The proposed finding is incomplete, as this was not a single ad, but part of a multi-page magazine wrap. *See* Response to Appendix Finding 136. Complaint Counsel disagrees with the proposed finding regarding the net impression of this entire ad (described in Response to Appendix Finding 136). (CCFF ¶¶ 377-81, 384).

145. 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 certain diseases 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)).

Response to Appendix Finding No. 145:

The proposed finding is incomplete, as this was not a single ad, but part of a multi-page magazine wrap. *See* Response to Appendix Finding 136. Complaint Counsel disagrees with the proposed finding regarding the net impression of this entire ad (described in

Response to Appendix Finding 136). (CCFF ¶¶ 377-81, 384). However, Complaint Counsel agrees that "proven" does not mean that "everyone in the study" benefitted.

146. 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).

Response to Appendix Finding No. 146:
Complaint Counsel does not disagree that Dr. Butters's report made broad conclusions about the net impression of POM ads in general, but disagrees with his conclusions, including specifically as to this ad.

147. Ms. Kuyoomjian testified that this ad's headline is a "broad claim," meaning that it is not addressing any specific health benefit but just conveying that the product is generally healthy. (CX1357 (Kuyoomijian, Dep. at 195-96)).

Response to Appendix Finding No. 147:
The proposed finding mischaracterizes the evidence, since Ms. Kuyoomjian was not testifying about the magazine wraps advertisements at issue in context.

148. Viewing the "Have no health fear … POM IS HERE!"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 a superhero, that POM Juice is a healthy product. ((PX0158-0033); (PX0329 (Kuyoomijian, Dep. at 195-96)).

Response to Appendix Finding No. 148:
The proposed finding is unsupported by the cited evidence; neither witness testified as to the net impression of the entire magazine wraps at issue.

149. 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)).

Response to Appendix Finding No. 149:

The proposed finding mischaracterizes the testimony of Dr. Stewart, who in the cited testimony simply said that he was not asked to do a net impression analysis of the challenged ads and that he did not know whether the Commission had evidence of how consumers perceive the ads at the level of a net impression. Moreover, Complaint Counsel presented evidence as to the meaning of POM advertisements. (*See* CCFF Sections V.C – V.G).

150. 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.

Response to Appendix Finding 150:

The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. The proposed finding is incomplete, as this was not a single page ad, but part of a multi-page magazine wrap. *See* Response to Appendix Finding 136. Moreover, Complaint Counsel presented evidence on the meaning of this and other POM advertisements. (*See* CCFF ¶¶ 377-81, 384 and Sections V.C – V.G).

151. 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).

Response to Appendix Finding No. 151:

The proposed finding is irrelevant. *See* Response to Finding 38 in Respondents' Findings of Fact.

Healthy, ~~Wealthy~~ & Wise - (CX0331, CX1426_0043, Exh. J)

152. Complaint Counsel claim that, on September 27, 2009, POM ran an advertisement with the headline "Healthy, ~~Wealthy~~ & Wise" with the body copy that appears on CX0331_0001 and CX1426_0043, Exh. J, attached hereto as Ex. 10.

Response to Appendix Finding No. 152:
Complaint Counsel agrees that the ad was disseminated on September 27, 2009, but has provided evidence that it was disseminated in numerous publications and at additional times as well, as late as October 28, 2009. (CX0331_0002-06; CX0474; CX0371).

153. Complaint Counsel failed to present any other definitive information regarding this ad's dissemination.

Response to Appendix Finding No. 153:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Moreover, this finding is incorrect. *See* Response to Appendix Finding 152 for evidence on dissemination.

154. 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.

Response to Finding No. 154:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel has presented evidence in CCFF Section VI.E that Respondents have continued to run advertising claims that they had been told were deceptive or misleading.

155. 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.

Response to Finding No. 155:
The proposed finding mischaracterizes the record and is incorrect. *See* Responses to Findings 2238, 2245 in Respondents' Findings of Fact (Complaint Counsel is challenging POM Juice print ads disseminated prior to approximately June 2009 and POM Juice

websites as they appeared prior to approximately February 2010). Moreover, the proposed finding is irrelevant because the ad at issue is for POMx.

156. 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. (CX0331_0001; CX1426_0043, Exh. J).

Response to Finding No. 156:
Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (*See* CCFF ¶¶ 415, 417-18).

157. Complaint Counsel's assertion that the ad 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. (CX0331_0001; CX1426_0043, Exh. J).

Response to Appendix Finding No. 157:
Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (*See* CCFF ¶¶ 415, 417-18).

158. 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.

Response to Finding No. 158:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (*See* CCFF ¶¶ 415, 417-18).

159. 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. (CX0331_0001; CX1426_0043, Exh. J). Even the language of the ad itself uses such qualifiers as "emerging science suggests," "help protect," "promising results," "initial UCLA study," "hopeful results" and "preliminary studies." (CX0331_0001; CX1426_0043, Exh. J).

Response to Finding No. 159:

Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (*See* CCFF ¶¶ 415, 417-18).

160. 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 "reduces the risk," like a healthy diet of fruits and vegetables and exercise "reduces the risk" of disease. (CX0331_0001; CX1426_0043, Exh. J).

Response to Finding No. 160:
Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (*See* CCFF ¶¶ 415, 417-18).

161. 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).

Response to Finding No. 161:
The proposed finding is unsupported by the cited testimony. Dr. Butters did not define "treat" as a substitute for conventional medical treatment. He defined "treat" as medical treatment and then asserted that he didn't see any ad stating or implying that POM Products "treated any disease." Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (*See* CCFF ¶¶ 415, 417-18).

162. 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 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)).

Response to Appendix Finding No. 162:
Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (*See* CCFF ¶¶ 415, 417-18). However, Complaint Counsel agrees that "proven" does not mean that "everyone in the study" benefitted.

163. 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).

Response to Appendix Finding No. 163:
Complaint Counsel does not disagree that Dr. Butters's report made broad conclusions about the net impression of POM ads in general, but disagrees with his conclusions, including specifically as to this ad.

164. 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)).

Response to Finding No. 164:
Complaint Counsel does not disagree as to the nature of Dr. Butters's testimony but disagrees with his unsupported conclusion.

165. 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))).

Response to Finding No. 165:
The proposed finding is unsupported by the cited Butters deposition testimony.

Complaint Counsel does not disagree that Dr. Butters's report made broad conclusions about the net impression of POM ads in general, but disagrees with the conclusion as to this ad. (*See* CCFF ¶¶ 415, 417-18).

166. 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)).

Response to Appendix Finding No. 166:

The proposed finding mischaracterizes the testimony of Dr. Stewart, who in the cited testimony simply said that he was not asked to do a net impression analysis of the challenged ads and that he did not know whether the Commission had evidence of how consumers perceive the ads at the level of a net impression. Moreover, Complaint Counsel presented evidence as to the meaning of POM advertisements. (*See* CCFF Sections V.C – V.G).

167. 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.

Response to Appendix Finding No. 167:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Moreover, Complaint Counsel presented evidence on the meaning of this and other POM advertisements. (*See* CCFF ¶¶ 415, 417-418 and Sections V.C – V.G).

168. 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).

Response to Appendix Finding No. 168:
The proposed finding is irrelevant. *See* Response to Finding 38 in Respondents' Findings of Fact.

Heart Therapy - (CX0109)

169. Complaint Counsel claim that, on April 1, 2007, POM ran an advertisement with the headline "Heart Therapy" with this body copy:

> Seek professional help for your heart. Drink POM 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. POM 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.

(CX0109_0001, attached hereto as Ex. 11).

Response to Appendix Finding No. 169:
Complaint Counsel agrees that the ad was disseminated on April 1, 2007, but notes that it has also provided evidence that it was disseminated in at least two publications.

(CX0109_0002; CX0474; CX0371).

170. Complaint Counsel failed to present any other definitive information regarding this ad's dissemination.

Response to Appendix Finding No. 170:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Moreover, this finding is incorrect. *See* Response to Appendix Finding 169 for dissemination information..

171. 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.

Response to Appendix Finding No. 171:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel has presented evidence in CCFF Section VI.E that Respondents have continued to run advertising claims that they had been told were deceptive or misleading.

172. 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.

Response to Appendix Finding No. 172:
The proposed finding is a legal conclusion and is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel has presented evidence in CCFF Section VI.E that Respondents have continued to run advertising claims that they had been told were deceptive or misleading.

173. Complaint Counsel's assertion that that the ad conveys 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 is not conspicuous, self-evident, or reasonably clear from the face of the ad. (CX0109_0001).

Response to Appendix Finding No. 173:
Complaint Counsel does not contend that this ad makes treatment or prostate cancer claims. (S*ee* CCFF ¶ 367 and Appendix A). As to the other claims in the proposed finding, Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (S*ee* CCFF ¶¶ 363, 366-67).

174. 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.

Response to Appendix Finding No. 174:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (S*ee* CCFF ¶¶ 363, 366-67).

175. 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. (CX0109_0001). Even the language of the ad itself uses such qualifiers as "helps guard," "emerging science suggests," "initial scientific research" and "encouraging results." (CX0109_0001).

Response to Appendix Finding No. 175:
Complaint Counsel does not contend that this ad makes treatment claims. (*See* CCFF ¶ 367 and Appendix A). As to the other claims in the proposed finding, Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (S*ee* CCFF ¶¶ 363, 366-67).

176. 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. (CX0109_0001).

Response to Appendix Finding No. 176:
Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (S*ee* CCFF ¶¶ 363, 366-67).

177. 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).

Response to Appendix Finding No. 177:
Complaint Counsel does not contend that this ad makes treatment claims. (*See* CCFF ¶ 367 and Appendix A). Therefore, the proposed finding is irrelevant.

178. 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 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)).

Response to Appendix Finding No. 178:
Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (S*ee* CCFF ¶¶ 363, 366-67). However, Complaint Counsel agrees that "proven" does not mean that "everyone in the study" benefitted.

179. 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).

Response to Appendix Finding No. 179:
Complaint Counsel does not disagree that Dr. Butters's report made broad conclusions about the net impression of POM ads in general, but disagrees with his conclusions, including specifically as to this ad.

180. 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)).

Response to Appendix Finding No. 180:
The proposed finding mischaracterizes the testimony of Dr. Stewart, who in the cited testimony simply said that he was not asked to do a net impression analysis of the challenged ads and that he did not know whether the Commission had evidence of how consumers perceive the ads at the level of a net impression. Moreover, Complaint Counsel presented evidence as to the meaning of POM advertisements. (*See* CCFF Sections V.C – V.G).

181. 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.

Response to Appendix Finding No. 181:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel does not contend that this ad makes treatment claims. (*See* CCFF ¶ 367 and Appendix A). As to the other claims in the proposed finding, Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (S*ee* CCFF ¶¶ 363, 366-67).

182. 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).

Response to Appendix Finding No. 182:
The proposed finding is irrelevant. *See* Response to Finding 38 in Respondents' Findings of Fact.

HOLY HEALTH! $25 million in medical research - (CX1426_0030, Exh. D)

183. Complaint Counsel claim that POM ran an advertisement with the headline "Holy Health! $25 Million In Medical Research" with this body copy:

> In a time of major health problems, one 16-ounce hero will unleash its incredible healing powers: POM Wonderful® 100% pure pomegranate juice. Backed by an unheard-of $25 million in medical research, The Antioxidant Superwpower® sweeps into action to help fight for heart and prostate health. Ka-POM!

(CX1426_0030, Exh. D, attached hereto as Ex. 12).

Response to Appendix Finding No. 183:
Complaint Counsel is not challenging the claims from this ad as an example of

Respondents' conduct violating the FTC Act; therefore the proposed finding is irrelevant.

(*See* CCFF Section V and Appendix A).

184. Complaint Counsel failed to present any definitive information regarding this ad's dissemination.

Response to Appendix Finding No. 184:
Complaint Counsel is not challenging the claims from this ad as an example of

Respondents' conduct violating the FTC Act; therefore the proposed finding is irrelevant.

(*See* CCFF Section V and Appendix A).

185. 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.

Response to Appendix Finding No. 185:
Complaint Counsel is not challenging the claims from this ad as an example of

Respondents' conduct violating the FTC Act; therefore the proposed finding is irrelevant.

(*See* CCFF Section V and Appendix A).

186. Complaint Counsel's assertion that the ad conveys 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 is not conspicuous, self-evident, or reasonably clear from the face of the ad. (CX1426_0030, Exh. D).

Response to Appendix Finding No. 186:

Complaint Counsel is not challenging the claims from this ad as an example of

Respondents' conduct violating the FTC Act; therefore the proposed finding is irrelevant.

(*See* CCFF Section V and Appendix A).

187. 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.

Response to Appendix Finding No. 187:
Complaint Counsel is not challenging the claims from this ad as an example of

Respondents' conduct violating the FTC Act; therefore the proposed finding is irrelevant.

(*See* CCFF Section V and Appendix A).

188. 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. (CX1426_0030, Exh. D). Even the language of the ad itself uses such qualifiers as "help" and "fight for." (CX1426_0030, Exh. D).

Response to Appendix Finding No. 188:
Complaint Counsel is not challenging the claims from this ad as an example of

Respondents' conduct violating the FTC Act; therefore the proposed finding is irrelevant.

(*See* CCFF Section V and Appendix A).

189. 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 "reduces the risk," like a healthy diet of fruits and vegetables and exercise "reduces the risk" of disease. (CX1426_0030, Exh. D).

Response to Appendix Finding No. 189:
Complaint Counsel is not challenging the claims from this ad as an example of

Respondents' conduct violating the FTC Act; therefore the proposed finding is irrelevant.

(*See* CCFF Section V and Appendix A).

190. 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).

Response to Appendix Finding No. 190:
Complaint Counsel is not challenging the claims from this ad as an example of

Respondents' conduct violating the FTC Act; therefore the proposed finding is irrelevant.

(*See* CCFF Section V and Appendix A).

191. 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 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)).

Response to Appendix Finding No. 191:
Complaint Counsel is not challenging the claims from this ad as an example of

Respondents' conduct violating the FTC Act; therefore the proposed finding is irrelevant.

(*See* CCFF Section V and Appendix A).

192. Mrs. Resnick testified that she does not recall approving the print headline, "HOLY HEALTH!" for print use. (L. Resnick, Tr. 120).

Response to Appendix Finding No. 192:
Complaint Counsel is not challenging the claims from this ad as an example of

Respondents' conduct violating the FTC Act; therefore the proposed finding is irrelevant.

(*See* CCFF Section V and Appendix A).

193. 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).

Response to Appendix Finding No. 193:

Complaint Counsel is not challenging the claims from this ad as an example of

Respondents' conduct violating the FTC Act; therefore the proposed finding is irrelevant.

(*See* CCFF Section V and Appendix A).

194. 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)).

Response to Appendix Finding No. 194:
Complaint Counsel is not challenging the claims from this ad as an example of

Respondents' conduct violating the FTC Act; therefore the proposed finding is irrelevant.

(*See* CCFF Section V and Appendix A).

195. 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.

Response to Appendix Finding No. 195:
Complaint Counsel is not challenging the claims from this ad as an example of

Respondents' conduct violating the FTC Act; therefore the proposed finding is irrelevant.

(*See* CCFF Section V and Appendix A).

196. 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).

Response to Appendix Finding No. 196:
Complaint Counsel is not challenging the claims from this ad as an example of

Respondents' conduct violating the FTC Act; therefore the proposed finding is irrelevant.

(*See* CCFF Section V and Appendix A).

HOLY HEALTH! $32 Million In Medical Research - (CX0379_0002; CX0372_0002; CX00380_0002)

197. Complaint Counsel claim that, on August 20, 2009 and September 10, 2009, POM ran an advertisement with the headline "Holy Health! $32 million in medical research" with the body copy that appears on CX0379_0002, CX0372_0002 and CX00380_0002, attached hereto as Ex. 13.

Response to Appendix Finding No. 197:
The proposed finding mischaracterizes the exhibits at issue as individual ads, when in fact they should be considered together as multi-page "magazine wrap" or "cover wrap" ads. CX0379_0001-04 is one ad (indicated by the same job number PJ2005 across all pages), as is CX0372_0001-04 (PJ2007) and CX0380_0001-04 (PJ2006). Documents that Respondents produced as dissemination schedules show that POM used unique project numbers starting with "PJ" to indicate individual ads. (CX0436; CX0437). *See* Response to Finding 2252 in Respondents' Findings of Fact. Complaint Counsel agrees that these pages were disseminated as part of CX0379_0001-04, CX0372_0001-04, and CX0380_0001-04.

198. Complaint Counsel failed to present any other definitive information regarding this ad's dissemination

Response to Appendix Finding No. 198:
The proposed finding is incorrect. *See* Response to Finding 2252 in Respondents' Findings of Fact (CX0372_0001-04 dated 9/10/2009; CX0379_0001-04 dated 8/20/2009; CX0380_0001-04 dated 9/10/2009).

199. 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.

Response to Appendix Finding No. 199:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel has presented evidence in CCFF

Section VI.E that Respondents have continued to run advertising claims that they had been told were deceptive or misleading

200. 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.

Response to Appendix Finding No. 200:
The proposed finding mischaracterizes the record and is incorrect. Complaint Counsel challenges the claims in these magazine wraps as deceptive and is not foreclosed from doing so by Dr. Mazis's testimony. Dr. Mazis testified as to his understanding of the *approximate* date deceptive POM Juice ads were disseminated for the purpose of showing that Dr. Reibstein's survey, conducted in October 2010, was done well after that. These magazine wraps were disseminated only two to three months after the approximate date given, and thus for the purposes of the reliability of Dr. Reibstein's survey conducted in October 2010 (which was the core issue of Dr. Mazis's testimony on this point), this short time difference is irrelevant. *See* Responses to Findings 2238, 2245 in Respondents' Findings of Fact (Complaint Counsel is challenging POM Juice print ads disseminated prior to *approximately* June 2009 and POM Juice websites as they appeared prior to approximately February 2010).

201. Mrs. Resnick testified that she did not approve this headline for use. (L. Resnick, Tr. 120).

Response to Appendix Finding No. 201:
The proposed finding mischaracterizes the evidence. In the cited trial testimony, Mrs. Resnick was not testifying about these specific cover wraps, and moreover, she testified she did not recall whether she approved a similar headline.

202. Complaint Counsel presented no evidence to contradict Mrs. Resnick's testimony that she never approved the headline of this ad for use.

Response to Appendix Finding No. 202:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Moreover, the proposed finding mischaracterizes the evidence. *See* Response to Appendix Finding 201.

203. 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. (CX0379_0002; CX0372_0002; CX00380_0002.)

Response to Appendix Finding No. 203:
The proposed finding is incomplete, as these were not single page ads, but part of multi-page magazine wraps. *See* Response to Appendix Finding 197. Complaint Counsel disagrees with the proposed finding regarding the net impression of the entirety of these advertisements (described in Response to Appendix Finding 197). (CCFF ¶¶ 381, 384).

204. Complaint Counsel's assertion that the ad conveys 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 prostate cancer is not conspicuous, self-evident, or reasonably clear from the face of the ad. (CX0379_0002; CX0372_0002; CX00380_0002).

Response to Appendix Finding No. 204:
The proposed finding is incomplete, as these were not single page ads, but part of multi-page magazine wraps. *See* Response to Appendix Finding 197. Complaint Counsel disagrees with the proposed finding regarding the net impression of the entirety of these advertisements (described in Response to Appendix Finding 197). (CCFF ¶¶ 381, 384).

205. 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.

Response to Appendix Finding No. 205:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. The proposed finding is incomplete, as these were not single page ads, but part of multi-page magazine wraps. *See* Response to Appendix

Finding 197. Complaint Counsel disagrees with the proposed finding regarding the net impression of the entirety of these advertisements (described in Response to Appendix Finding 197). (CCFF ¶¶ 381, 384).

206. 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 heart disease or prostate cancer. (CX0379_0002; CX0372_0002; CX00380_0002). Even the language of the ad itself uses such qualifiers as "pilot study," "may indicate," "emerging science suggests," "may be able," "promising," and "further investigate." (CX0379_0002; CX0372_0002; CX00380_0002).

Response to Appendix Finding No. 206:
Complaint Counsel does not contend these ads make heart disease claims. (S*ee* CCFF ¶ 384 and Appendix A). The proposed finding is incomplete, as these were not single page ads, but part of multi-page magazine wraps. *See* Response to Appendix Finding 197. Complaint Counsel disagrees with the proposed finding regarding the net impression of the entirety of these advertisements (described in Response to Appendix Finding 197). (CCFF ¶¶ 381, 384).

207. 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 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. (CX0379_0002; CX0372_0002; CX00380_0002).

Response to Appendix Finding No. 207:
The proposed finding is incomplete, as these were not single page ads, but part of multi-page magazine wraps. *See* Response to Appendix Finding 197. Complaint Counsel disagrees with the proposed finding regarding the net impression of the entirety of these advertisements (described in Response to Appendix Finding 197). (S*ee* CCFF ¶¶ 381, 384).

208. 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).

Response to Appendix Finding No. 208:
The proposed finding is unsupported by the cited testimony. Dr. Butters did not define "treat" as a substitute for conventional medical treatment. He defined "treat" as medical treatment and then asserted that he didn't see any ad stating or implying that POM Products "treated any disease." The proposed finding is incomplete, as these were not single page ads, but part of multi-page magazine wraps. *See* Response to Appendix Finding 197. Complaint Counsel disagrees with the proposed finding regarding the net impression of the entirety of these advertisements (described in Response to Appendix Finding 197). (S*ee* CCFF ¶¶ 381, 384).

209. 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 prostate cancer 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)).

Response to Appendix Finding No. 209:
The proposed finding is incomplete, as these were not single page ads, but part of multi-page magazine wraps. *See* Response to Appendix Finding 197. Complaint Counsel disagrees with the proposed finding regarding the net impression of the entirety of these advertisements (described in Response to Appendix Finding 197). (S*ee* CCFF ¶¶ 381, 384). However, Complaint Counsel agrees that "proven" does not mean that "everyone in the study" benefitted.

210. 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).

Response to Appendix Finding No. 210:
Complaint Counsel does not disagree that Dr. Butters's report made broad conclusions about the net impression of POM ads in general, but disagrees with his conclusions, including specifically as to this ad.

211. 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)).

Response to Appendix Finding No. 211:
The proposed finding mischaracterizes the testimony of Dr. Stewart, who in the cited testimony simply said that he was not asked to do a net impression analysis of the challenged ads and that he did not know whether the Commission had evidence of how consumers perceive the ads at the level of a net impression. Moreover, Complaint Counsel presented evidence as to the meaning of POM advertisements. (*See* CCFF Sections V.C – V.G).

212. 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.

Response to Appendix Finding No. 212:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel does not contend these ads make heart disease claims. (S*ee* CCFF ¶ 384 and Appendix A). The proposed finding is incomplete, as these were not single page ads, but part of multi-page magazine wraps. *See* Response to Appendix Finding 197. Complaint Counsel disagrees with the proposed

finding regarding the net impression of the entirety of these advertisements (described in Response to Appendix Finding 197). (CCFF ¶¶ 381, 384).

213. 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).

Response to Appendix Finding No. 213:
The proposed finding is irrelevant. *See* Response to Finding 38 in Respondents' Findings of Fact.

I'm off to save PROSTATES! - (CX0274_0001; CX1426_0029, Exh. C)

214. Complaint Counsel claim that, on February 1, 2009, POM ran an advertisement with the headline "I'm off to save PROSTATES!" with this 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
>
> *Prostate study details at http://www.pomwonderful.com/health_benefits.html

(CX0274_0001; CX1426_0029, Exh. C, attached hereto as Ex. 14).

Response to Appendix Finding No. 214:
Complaint Counsel agrees that the ad was disseminated on February 1, 2009, but has provided evidence that it was disseminated additional times as well, including as late as March 1, 2009. (CX0274_0002; CX0474; CX0371).

215. Complaint Counsel failed to present any other definitive information regarding this ad's dissemination.

Response to Appendix Finding No. 215:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Moreover, the proposed finding is incorrect. *See* Response to Appendix Finding 214 for evidence on dissemination.

216. 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.

Response to Appendix Finding No. 216:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel has presented evidence in CCFF Section VI.E that Respondents have continued to run advertising claims that they had been told were deceptive or misleading.

217. Mrs. Resnick testified that she does not recall this advertisement, is not familiar with it, and does not know when it ran. (L. Resnick, Tr. 243-44).

Response to Appendix Finding No. 217:
The proposed finding mischaracterizes the evidence. In the cited trial testimony Mrs. Resnick testified that "I don't dispute it, but I don't remember it." (L. Resnick, Tr. 244). Moreover, her testimony is contradicted by Respondents' own admission in their Answer and her earlier testimony that this ad was disseminated. (PX0364_0002; L. Resnick, Tr. 217).

218. Mrs. Resnick testified that she does not know if the advertisement actually ran. (CX1359 (L. Resnick, Dep. at 125)).

Response to Appendix Finding No. 218:
The proposed finding mischaracterizes the evidence. In the cited deposition testimony, Mrs. Resnick actually states, "I don't remember seeing it, but I'm sure I did. . . . I would have seen it." Moreover Respondents admitted in their Answer and Mrs. Resnick testified at trial that this ad was disseminated. (PX0364_0002; L. Resnick, Tr. 217).

219. 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.

Response to Appendix Finding No. 219:
The proposed finding mischaracterizes the record and is incorrect. *See* Responses to Findings 2238, 2245 in Respondents' Findings of Fact (Complaint Counsel is challenging POM Juice print ads disseminated prior to approximately June 2009 and POM Juice websites as they appeared prior to approximately February 2010).

220. Complaint Counsel's assertion that the ad conveys 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 prostate cancer is not conspicuous, self-evident, or reasonably clear from the face of the ad. (CX0274_0001; CX1426_0029, Exh. C).

Response to Appendix Finding No. 220:

Complaint Counsel does not contend this ad makes treatment claims or heart disease claims. (*See* CCFF ¶ 376 and Appendix A). As to the remainder of the claims in the proposed finding, Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 372-76).

221. 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.

Response to Appendix Finding No. 221:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 372-76).

222. 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. (CX0274_0001; CX1426_0029, Exh. C). Even the language of the ad itself uses such qualifiers as "committed to defending," and "improve." (CX0274_0001; CX1426_0029, Exh. C).

Response to Appendix Finding No. 222:
Complaint Counsel does not contend this ad makes treatment claims. (*See* CCFF ¶ 376 and Appendix A). As to the remainder of the claims in the proposed finding, Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 372-76).

223. 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 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. (CX0274_0001; CX1426_0029, Exh. C).

Response to Appendix Finding No. 223:
Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 372-76).

224. 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).

Response to Appendix Finding No. 224:
Complaint Counsel does not contend this ad makes treatment claims. (CCFF ¶ 376 and Appendix A). Therefore, the proposed finding is irrelevant.

225. 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 prostate cancer 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)).

Response to Appendix Finding No. 225:
Complaint Counsel does not contend this ad makes treatment claims. (*See* CCFF ¶ 376 and Appendix A). As to the remainder of the claims in the proposed finding, Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 372-76). However, Complaint Counsel agrees that "proven" does not mean that "everyone in the study" benefitted.

226. 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).

Response to Appendix Finding No. 226:
Complaint Counsel has no specific response.

227. 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).

Response to Appendix Finding No. 227:

The proposed finding is incomplete. At his deposition Dr. Butters actually testified, "I do believe 'I'm off to save prostates' could mean I'm somehow going to protect them or rescue them from disease." He changed his answer by submitting an errata sheet. (Butters, Tr. 2895-98). Then he testified at trial that it is "possible that this 'off to save prostates' ad communicates to viewers that POM Wonderful Juice is protecting or defending prostates from disease." (Butters, Tr. 2901).

228. 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).

Response to Appendix Finding No. 228:
Complaint Counsel does not disagree as to the nature of Dr. Butters's testimony but disagrees with his unsupported conclusion.

229. 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).

Response to Appendix Finding No. 229:
Complaint Counsel does not disagree as to the nature of Dr. Butters's testimony but disagrees with his unsupported conclusion.

230. 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).

Response to Appendix Finding No. 230:
Complaint Counsel does not disagree as to the nature of Dr. Butters's testimony but disagrees with his unsupported conclusion.

231. Viewing the "I'm off to save PROSTATES!" 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 a superhero, that POM Juice is healthy and that POM Juice is good for prostate health, not that it would treat or prevent prostate cancer. ((Butters, Tr. 2905-06); (L. Resnick, Tr. 217-19)).

Response to Appendix Finding No. 231:
The proposed finding is unsupported by the cited testimony from Mrs. Resnick, as she was not testifying about the net impression of the ad but her purported intent. Complaint Counsel does not contend this ad makes treatment claims. (*See* CCFF ¶ 376 and Appendix A). As to the remainder of the claims in the proposed finding, Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 372-76).

232. 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.

Response to Appendix Finding No. 232:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel does not contend this ad makes treatment claims. (*See* CCFF ¶ 376 and Appendix A). As to the remainder of the claims in the proposed finding, Complaint Counsel presented evidence on the meaning of this and other POM advertisements. (*See* CCFF ¶¶ 372-76 and Sections V.C – V.G).

233. 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).

Response to Appendix Finding No. 233:

The proposed finding is irrelevant. *See* Response to Finding 38 in Respondents' Findings of Fact.

I'm off to save PROSTATES! - (CX1426_0037, Exh. H)

234. Complaint Counsel claim that POM ran an advertisement with the headline "I'm off to save PROSTATES!" with this body copy:

> The Antioxidant Superpower. Learn More. (CX1426_0037, Exh. H, attached hereto as Ex. 15).

Response to Appendix Finding No. 234:
Complaint Counsel agrees and notes the dynamic version of the banner ad was provided to the Court at CX0466.

235. Complaint Counsel failed to present any definitive information regarding this ad's dissemination.

Response to Appendix Finding No. 235:
The proposed finding is incorrect. (S*ee* CX0364_0005 (VMS record indicating an internet ad "Off to save prostates" was captured on 2/17/2009; *see also* CX0474, CX0371). Moreover, Respondents in their Answer admitted disseminating this ad. (PX0364_0002).

236. 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.

Response to Appendix Finding No. 236:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel has presented evidence in CCFF Section VI.E that Respondents have continued to run advertising claims that they had been told were deceptive or misleading.

237. Mr. Resnick testified that this ad is another execution of the "I'm off to save prostates" theme that likely appeared on the website since it says "Learn more." Mr. Resnick testified that the statement "I'm off to save prostates" is a "tongue-in-cheek" approach to communicate that POM Juice is healthy for prostates. (CX1376 (S. Resnick, Dep. at 150-51)).

Response to Appendix Finding No. 237:
The proposed finding is incomplete, as Mr. Resnick also testified that by "healthy for prostates," he meant that "we believe that it reduces the risk or postpones the onset of

prostate cancer, okay, and we be- -- we have research that we're comfortable shows that[.]"

238. 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. (CX1426_0037, Exh. H).

Response to Appendix Finding No. 238:
Complaint Counsel does not contend that this ad makes treatment claims or "clinically proven" claims. (S*ee* CCFF ¶ 540 and Appendix A). As to the other claims in the proposed finding, Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 539-40).

239. 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.

Response to Appendix Finding No. 239:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 539-40).

240. 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. (CX1426_0037, Exh. H).

Response to Appendix Finding No. 240:
Complaint Counsel does not contend that this ad makes treatment claims or "clinically proven" claims. (S*ee* CCFF ¶ 540 and Appendix A). As to the other claims in the proposed finding, Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 539-40).

241. 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 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. (CX1426_0037, Exh. H).

Response to Appendix Finding No. 241:
Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 539-40).

242. 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).

Response to Appendix Finding No. 242:
Complaint Counsel does not contend that this ad makes treatment claims or "clinically proven" claims. (S*ee* CCFF ¶ 540 and Appendix A). Therefore, the proposed finding is irrelevant.

243. 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 prostate cancer 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)).

Response to Appendix Finding No. 243:
Complaint Counsel does not contend that this ad makes "clinically proven" claims. (*See* CCFF ¶ 540 and Appendix A). Therefore, the proposed finding is irrelevant.

244. 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).

Response to Appendix Finding No. 244:

Complaint Counsel does not disagree that Dr. Butters's report made broad conclusions about the net impression of POM ads in general, but disagrees with his conclusions, including specifically as to this ad.

245. Viewing the "I'm off to save PROSTATES!" 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 a superhero, that POM Juice is healthy, that POM Juice is good for prostate health. (CX1376 (S. Resnick, Dep. at 150-51); (PX0158-0033)).

Response to Appendix Finding No. 245:
The proposed finding is unsupported by the cited evidence. *See* Responses to Appendix Findings 227, 237. Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (*See* CCFF ¶¶ 539-40).

246. 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)).

Response to Appendix Finding No. 246:
The proposed finding mischaracterizes the testimony of Dr. Stewart, who in the cited testimony simply said that he was not asked to do a net impression analysis of the challenged ads and that he did not know whether the Commission had evidence of how consumers perceive the ads at the level of a net impression. Moreover, Complaint Counsel presented evidence as to the meaning of POM advertisements. (*See* CCFF Sections V.C – V.G).

247. 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.

Response to Appendix Finding No. 247:
Complaint Counsel does not contend that this ad makes "clinically proven" claims. (*See* CCFF ¶ 540 and Appendix A). Therefore, the proposed finding is irrelevant.

248. 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).

Response to Appendix Finding No. 248

The proposed finding is irrelevant. *See* Response to Finding 38 in Respondents' Findings of Fact.

KA-POM! - (CX0379_0003; CX0372_0003; CX0380_0003)

249. Complaint Counsel claim that, on August 20, 2009 and September 10, 2009, POM ran an advertisement with the headline "KA POM!" with the body copy that appears on CX0379_0003, CX0372_0003 and CX380_0003, attached hereto as Ex. 16.

Response to Appendix Finding No. 249:
The proposed finding mischaracterizes the exhibits at issue as individual ads, when in fact they should be considered with other pages as multi-page "magazine wrap" or "cover wrap" ads. CX0379_0001-04 is one ad (indicated by the same job number PJ2005 across all pages), as is CX0372_0001-04 (PJ2007) and CX0380_0001-04 (PJ2006). Documents that Respondents produced as dissemination schedules show that POM used unique project numbers starting with "PJ" to indicate individual ads. (CX0436; CX0437). *See* Response to Finding 2252 in Respondents' Findings of Fact. Complaint Counsel agrees that these pages were disseminated as part of CX0379_0001-04, CX0372_0001-04, and CX0380_0001-04.

250. Complaint Counsel failed to present any other definitive information regarding this ad's dissemination.

Response to Appendix Finding No. 250:
The proposed finding is incorrect. *See* Response to Finding 2252 in Respondents' Findings of Fact (CX0372_0001-04 dated 9/10/2009; CX0379_0001-04 dated 8/20/2009; CX0380_0001-04 dated 9/10/2009).

251. 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.

Response to Appendix Finding No. 251:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel has presented evidence in CCFF Section VI.E that Respondents have continued to run advertising claims that they had been told were deceptive or misleading.

252. 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.

Response to Appendix Finding No. 252:

The proposed finding mischaracterizes the record and is incorrect. Complaint Counsel challenges the claims in these magazine wraps as deceptive and is not foreclosed from doing so by Dr. Mazis's testimony. Dr. Mazis testified as to his understanding of the *approximate* date deceptive POM Juice ads were disseminated for the purpose of showing that Dr. Reibstein's survey, conducted in October 2010, was done well after that. These magazine wraps were disseminated only two to three months after the approximate date given, and thus for the purposes of the reliability of Dr. Reibstein's survey conducted in October 2010 (which was the core issue of Dr. Mazis's testimony on this point), this short time difference is irrelevant. *See* Responses to Findings 2238, 2245 in Respondents' Findings of Fact (Complaint Counsel is challenging POM Juice print ads disseminated prior to *approximately* June 2009 and POM Juice websites as they appeared prior to approximately February 2010).

253. Complaint Counsel's assertion that the ad conveys 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, prostate cancer or erectile dysfunction is not conspicuous, self-evident, or reasonably clear from the face of the ad. (CX0379_0003; CX0372_0003; CX380_0003).

Response to Appendix Finding No. 253:

The proposed finding is incomplete, as these were not single page ads, but part of multi-page magazine wraps. *See* Response to Appendix Finding 249. Complaint Counsel does not contend that these magazine wraps make heart disease claims. (*See* CCFF ¶ 384). As to the other claims in the proposed finding, Complaint Counsel disagrees with the

proposed finding regarding the net impression of the entirety of these advertisements (described in Response to Appendix Finding 249). (CCFF ¶¶ 381, 384).

254. 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.

Response to Appendix Finding No. 254:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. The proposed finding is incomplete, as these were not single page ads, but part of multi-page magazine wraps. *See* Response to Appendix Finding 249. Complaint Counsel disagrees with the proposed finding regarding the net impression of the entirety of these advertisements (described in Response to Appendix Finding 249). (CCFF ¶¶ 381, 384).

255. 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, prostate cancer or erectile dysfunction; 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, prostate cancer or erectile dysfunction. (CX0379_0003; CX0372_0003; CX380_0003).

Response to Appendix Finding No. 255:
The proposed finding is incomplete, as these were not single page ads, but part of multi-page magazine wraps. *See* Response to Appendix Finding 249. Complaint Counsel does not contend that these magazine wraps make heart disease or erectile dysfunction claims. (*See* CCFF ¶ 384). As to the other claims in the proposed finding, Complaint Counsel disagrees with the proposed finding regarding the net impression of the entirety of these advertisements (described in Response to Appendix Finding 249). (CCFF ¶¶ 381, 384).

256. 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 "reduces the risk," like a healthy diet of fruits and vegetables and exercise "reduces the risk" of disease. (CX0379_0003; CX0372_0003; CX380_0003).

Response to Appendix Finding No. 256:
The proposed finding is incomplete, as these were not single page ads, but part of multi-page magazine wraps. *See* Response to Appendix Finding 249. Complaint Counsel does not contend that these magazine wraps make heart disease or erectile dysfunction claims. (*See* CCFF ¶ 384). As to the other claims in the proposed finding, Complaint Counsel disagrees with the proposed finding regarding the net impression of the entirety of these advertisements (described in Response to Appendix Finding 249). (CCFF ¶¶ 381, 384).

257. 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).

Response to Appendix Finding No. 257:
The proposed finding is incomplete, as these were not single page ads, but part of multi-page magazine wraps. *See* Response to Appendix Finding 249. This finding is also unsupported by the cited testimony. Dr. Butters did not define "treat" as a substitute for conventional medical treatment. He defined "treat" as medical treatment and then asserted that he didn't see any ad stating or implying that POM Products "treated any disease." Complaint Counsel disagrees with the proposed finding regarding the net impression of the entirety of these advertisements (described in Response to Appendix Finding 249). (CCFF ¶¶ 381, 384).

258. 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 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)).

Response to Appendix Finding No. 258:
The proposed finding is incomplete, as these were not single page ads, but part of multi-page magazine wraps. *See* Response to Appendix Finding 249. Complaint Counsel does

not contend that these magazine wraps make heart disease or erectile dysfunction claims. (*See* CCFF ¶ 384). As to the other claims in the proposed finding, Complaint Counsel disagrees with the proposed finding regarding the net impression of the entirety of these advertisements (described in Response to Appendix Finding 249). (CCFF ¶¶ 381, 384).

259. 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)).

Response to Appendix Finding No. 259:
The proposed finding mischaracterizes the testimony of Dr. Stewart, who in the cited testimony simply said that he was not asked to do a net impression analysis of the challenged ads and that he did not know whether the Commission had evidence of how consumers perceive the ads at the level of a net impression. Moreover, Complaint Counsel presented evidence as to the meaning of POM advertisements. (*See* CCFF Sections V.C – V.G).

260. 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.

Response to Appendix Finding No. 260:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel does not contend these magazine wraps make heart disease or erectile dysfunction claims. Moreover, Complaint Counsel presented evidence on the meaning of this and other POM advertisements. (S*ee* CCFF ¶¶ 381, 384 and Sections V.C – V.G).

261. 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).

Response to Appendix Finding No. 261:

The proposed finding is irrelevant. *See* Response to Finding 38 in Respondents' Findings of Fact.

Life Support - (CX0033)

262. Complaint Counsel claim that, on December 30, 2004, POM ran an advertisement with the headline "Life Support" with this body copy:

> POM Wonderful Pomegranate 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. (CX0033_0001, attached hereto as Ex. 17).

Response to Appendix Finding No. 262:
Complaint Counsel agrees that the ad was disseminated on December 30, 2004, but has provided evidence that it was disseminated additional times as well, including as late as February 2005. (CX0033_0002; CX0474; CX0371).

263. Complaint Counsel failed to present any other definitive information regarding this ad's dissemination.

Response to Appendix Finding No. 263:
The proposed finding is incorrect. *See* Response to Appendix Finding 262 for evidence of dissemination.

264. 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.

Response to Appendix Finding No. 264:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel has presented evidence in CCFF Section VI.E that Respondents have continued to run advertising claims that they had been told were deceptive or misleading.

265. This ad cannot provide a basis for injunctive relief because (a) it ran seven years ago; and (b) no evidence exists to show that Respondents are likely to run this ad in the future.

Response to Appendix Finding No. 265:
The proposed finding is a legal conclusion and is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel has

presented evidence in CCFF Section VI.E that Respondents have continued to run advertising claims that they had been told were deceptive or misleading.

266. Complaint Counsel's assertion that the ad conveys 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 is not conspicuous, self-evident, or reasonably clear from the face of the ad. (CX0033_0001).

Response to Appendix Finding No. 266:
Complaint Counsel does not contend that this ad makes treatment or "clinically proven" claims or that it makes prostate cancer claims. (S*ee* CCFF ¶ 343 and Appendix A). As to the other claims in the proposed finding, Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 341-43).

267. 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.

Response to Appendix Finding No. 267:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 341-43).

268. 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).

Response to Appendix Finding No. 268:
Complaint Counsel does not contend that this ad makes treatment or "clinically proven" claims or that it makes prostate cancer claims. (S*ee* CCFF ¶ 343 and Appendix A). As to the other claims in the proposed finding, Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 341-43).

269. 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 "reduces the risk," like a healthy diet of fruits and vegetables and exercise "reduces the risk" of disease. (CX0033_0001).

Response to Appendix Finding No. 269:
Complaint Counsel does not contend that this ad makes prostate cancer claims. (S*ee* CCFF ¶ 343 and Appendix A). As to the other claims in the proposed finding, Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 341-43).

270. 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).

Response to Appendix Finding No. 270:
Complaint Counsel does not contend that this ad makes treatment claims. (S*ee* CCFF ¶ 343 and Appendix A). Therefore, the proposed finding is irrelevant.

271. 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 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)).

Response to Appendix Finding No. 271:
Complaint Counsel does not contend that this ad makes "clinically proven" claims or prostate cancer claims. (S*ee* CCFF ¶ 343 and Appendix A). Therefore, the proposed finding is irrelevant.

272. 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)).

Response to Appendix Finding No. 272:
Complaint Counsel does not disagree.

273. 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).

Response to Appendix Finding No. 273:
Complaint Counsel does not disagree that Dr. Butters's report made broad conclusions about the net impression of POM ads in general, but disagrees with his conclusions, including specifically as to this ad.

274. 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)).

Response to Appendix Finding No. 274:
The proposed finding mischaracterizes the testimony, as Mr. Tupper was testifying as to POM's purported intent for the ad. Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 341-43).

275. 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)).

Response to Appendix Finding No. 275:
The proposed finding mischaracterizes the testimony of Dr. Stewart, who in the cited testimony simply said that he was not asked to do a net impression analysis of the challenged ads and that he did not know whether the Commission had evidence of how consumers perceive the ads at the level of a net impression. Moreover, Complaint Counsel presented evidence as to the meaning of POM advertisements. (*See* CCFF Sections V.C – V.G).

276. 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.

Response to Appendix Finding No. 276:
Complaint Counsel does not contend that this ad makes "clinically proven" claims. (S*ee* CCFF ¶ 343 and Appendix A). Therefore, the proposed finding is irrelevant.

277. 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).

Response to Appendix Finding 277:
The proposed finding is irrelevant. *See* Response to Finding 38 in Respondents' Findings of Fact.

Live Long Enough To Watch Your 401(k) Recover - (CX0280) [2]

278. Complaint Counsel, claim that, on March 12, 2009, POM ran an advertisement with the headline "Live Long Enough To Watch Your 401(k) Recover" with the body copy that appears on CX0280_0001, attached hereto as Ex. 18.

Response to Appendix Finding No. 278:
Complaint Counsel agrees that this ad was disseminated on March 12, 2009, but has provided evidence that it was disseminated in numerous publications and at additional times as well, as late as November 2009 (CX0280_0002-04; CX0474; CX0371).

279. Complaint Counsel failed to present any other definitive information regarding this ad's dissemination.

Response to Appendix Finding No. 279:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Moreover, this finding is incorrect. *See* Response to Appendix Finding 278 for evidence on dissemination.

280. 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.

Response to Appendix Finding No. 280:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel has presented evidence in CCFF Section VI.E that Respondents have continued to run advertising claims that they had been told were deceptive or misleading.

281. 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-

[2] This ad, CX0280, is very similar in images and body copy to the challenged POMx ad CX0331/CX1426 Exh. J ('Healthy, ~~Wealthy,~~ and Wise"). The differences, including subheadlines and that CX0280 stated that POMx was "backed by $25 million in medical research at the world's leading universities," while CX0331 stated POMx was backed by $32 million, are minor and Complaint Counsel alleges the same net impression for each of these ads. (*See* CCFF ¶ ¶ 415-418 and Appendix A). Moreover, Respondents' findings with respect to CX0331 (Appendix Findings 152-168) and this ad (Appendix Findings 278-294). Therefore Complaint Counsel adopts and restates its responses to findings regarding CX0331 here, as appropriate.

54). Accordingly, based on these representations, Complaint Counsel cannot now challenge this ad.

Response to Appendix Finding 281:
The proposed finding mischaracterizes the record and is incorrect. *See* Responses to Findings 2238, 2245 in Respondents' Findings of Fact (Complaint Counsel is challenging POM Juice print ads disseminated prior to approximately June 2009 and POM Juice websites as they appeared prior to approximately February 2010). Moreover, the proposed finding is irrelevant because the ad at issue is for POMx.

282. 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. (CX0280_0001).

Response to Appendix Finding No. 282:
See Response to Appendix Finding 156

283. Complaint Counsel's assertion that the ad 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. (CX0280_0001).

Response to Appendix Finding No. 283:
See Response to Appendix Finding 157.

284. 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.

Response to Appendix Finding No. 284:
See Response to Appendix Finding 158.

285. 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. (CX0280_0001). Even the language of the ad itself uses such qualifiers as "initial UCLA MEDICAL STUDY," "hopeful results," "fight," "preliminary studies," and "promising results." (CX0280_0001).

Response to Appendix Finding No. 285:
See Response to Appendix Finding 159.

286. 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 "reduces the risk," like a healthy diet of fruits and vegetables and exercise "reduces the risk" of disease. (CX0280_0001).

Response to Appendix Finding No. 286:
See Response to Appendix Finding 160.

287. 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).

Response to Appendix Finding No. 287:
See Response to Appendix Finding 161.

288. 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 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)).

Response to Appendix Finding No. 288:
See Response to Appendix Finding 162.

289. 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)).

Response to Appendix Finding No. 289:
Complaint Counsel does not disagree with Dr. Butters's testimony that the ad references

a very serious issue.

290. 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).

Response to Appendix Finding No. 290:
See Response to Appendix Finding 163.

291. 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)).

Response to Appendix Finding No. 291:
See Response to Appendix Finding 165.

292. 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)).

Response to Appendix Finding No. 292:
See Response to Appendix Finding 166.

293. 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.

Response to Appendix Finding No. 293:
See Response to Appendix Finding 167.

294. 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).

Response to Appendix Finding No. 294:
See Response to Appendix Finding 168.

Lucky I have super HEALTH POWERS! - (CX0379_0001; CX0372_0001; CX0380_0001; CX0380_0005; CX0380_0007)

295. Complaint Counsel claim that, on August 20, 2009 and September 10, 2009 POM ran an advertisement with the headline "Lucky I have super HEALTH POWERS!" (CX0379_0001; CX0372_0001; CX0380_0001; CX0380_0005; CX0380_0007, attached hereto as Ex. 19).

Response to Appendix Finding No. 295:
The proposed finding mischaracterizes the exhibits at issue as individual ads, when in fact they should be considered together as multi-page "magazine wrap" or "cover wrap" ads. *See* Response to Finding 2252 in Respondents' Findings of Fact. Complaint Counsel agrees that these pages were disseminated as part of CX0379_0001-04, CX0372_0001-04; CX0380_0001-04, and CX0380_0005-07.

296. Complaint Counsel failed to present any other definitive information regarding this ad's dissemination.

Response to Appendix Finding No. 296:
The proposed finding is incorrect. *See* Response to Finding 2252 in Respondents' Findings of Fact.

297. 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.

Response to Appendix Finding No. 297:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel has presented evidence in CCFF Section VI.E that Respondents have continued to run advertising claims that they had been told were deceptive or misleading.

298. 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.

Response to Appendix Finding No. 298:

The proposed finding mischaracterizes the record and is incorrect. Complaint Counsel challenges the claims in these magazine wraps as deceptive and is not foreclosed from doing so by Dr. Mazis's testimony. Dr. Mazis testified as to his understanding of the *approximate* date deceptive POM Juice ads were disseminated for the purpose of showing that Dr. Reibstein's survey, conducted in October 2010, was done well after that. These magazine wraps were disseminated only two to three months after the approximate date given, and thus for the purposes of the reliability of Dr. Reibstein's survey conducted in October 2010 (which was the core issue of Dr. Mazis's testimony on this point), this short time difference is irrelevant. *See* Responses to Findings 2238, 2245 in Respondents' Findings of Fact (Complaint Counsel is challenging POM Juice print ads disseminated prior to *approximately* June 2009 and POM Juice websites as they appeared prior to approximately February 2010).

299. Mrs. Resnick testified that she did not approve this headline for use. (L. Resnick, Tr. 117).

Response to Appendix Finding No. 299:
The proposed finding mischaracterizes the evidence; in the cited trial testimony. Mrs. Resnick testified that she did not recall.

300. Complaint Counsel presented no evidence to contradict Mrs. Resnick's testimony that she never approved the headline of this ad for use.

Response to Appendix Finding No. 300:
See Response to Appendix Finding 299.

301. Nowhere in this ad do Respondents expressly (*i.e.*, unequivocally and directly) state that (a) POM Juice "prevents," "treats," or "reduces the risk" of certain diseases; or (b) POM Juice is "clinically proven" to "prevent," "treat," or "reduce the risk" of certain diseases. (CX0379_0001; CX0372_0001; CX0380_0001; CX0380_0005; CX0380_0007).

Response to Appendix Finding No. 301:

The proposed finding is incomplete, as these were not single page ads, but part of multi-page magazine wraps. *See* Response to Appendix Finding 295. Complaint Counsel disagrees with the proposed finding regarding the net impression of the entirety of these advertisements (described in Response to Finding 295). (CCFF ¶¶ 381, 384).

302. Complaint Counsel's assertion that the ad conveys the message that (a) POM Juice "prevents," "treats," or "reduces the risk" of certain diseases; or (b) POM Juice is "clinically proven" to "prevent," "treat," or "reduce the risk" of certain diseases is not conspicuous, self-evident, or reasonably clear from the face of the ad. (CX0379_0001; CX0372_0001; CX0380_0001; CX0380_0005; CX0380_0007).

Response to Appendix Finding No. 302:
The proposed finding is incomplete, as these were not single page ads, but part of multi-page magazine wraps. *See* Response to Appendix Finding 295. Complaint Counsel disagrees with the proposed finding regarding the net impression of the entirety of these advertisements (described in Response to Finding 295). (CCFF ¶¶ 381, 384).

303. 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.

Response to Appendix Finding No. 303:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. The proposed finding is incomplete, as these were not single page ads, but part of multi-page magazine wraps. *See* Response to Appendix Finding 295. Complaint Counsel disagrees with the proposed finding regarding the net impression of the entirety of these advertisements (described in Response to Finding 295). (CCFF ¶¶ 381, 384).

304. 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. (CX0379_0001; CX0372_0001; CX0380_0001 CX0380_0005; CX0380_0007).

Response to Appendix Finding No. 304:
The proposed finding is incomplete, as these were not single page ads, but part of multi-page magazine wraps. *See* Response to Appendix Finding 295. Complaint Counsel does not contend that these magazine wraps make heart disease claims. (*See* CCFF ¶ 384 and Appendix A). As to the other claims in the proposed finding, Complaint Counsel disagrees with the proposed finding regarding the net impression of the entirety of these advertisements (described in Response to Finding 295). (CCFF ¶¶ 381, 384).

305. 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 "reduces the risk," like a healthy diet of fruits and vegetables and exercise "reduces the risk" of disease. (CX0379_0001; CX0372_0001; CX0380_0001 CX0380_0005; CX0380_0007).

Response to Appendix Finding No. 305:
The proposed finding is incomplete, as these were not single page ads, but part of multi-page magazine wraps. *See* Response to Appendix Finding 295. Complaint Counsel does not contend that these magazine wraps make heart disease claims. (*See* CCFF ¶ 384 and Appendix A). As to the other claims in the proposed finding, Complaint Counsel disagrees with the proposed finding regarding the net impression of the entirety of these advertisements (described in Response to Finding 295). (CCFF ¶¶ 381, 384).

306. 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).

Response to Appendix Finding No. 306:
The proposed finding is incomplete, as these were not single page ads, but part of multi-page magazine wraps. *See* Response to Appendix Finding 295. This finding is also unsupported by the cited testimony. Dr. Butters did not define "treat" as a substitute for conventional medical treatment. He defined "treat" as medical treatment and then asserted that he didn't see any ad stating or implying that POM Products "treated any

disease." Complaint Counsel disagrees with the proposed finding regarding the net impression of the entirety of these advertisements (described in Response to Finding 295). (CCFF ¶¶ 381, 384).

307. 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 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)).

Response to Appendix Finding No. 307:

The proposed finding is incomplete, as these were not single page ads, but part of multi-page magazine wraps. *See* Response to Appendix Finding 295. Complaint Counsel does not contend that these magazine wraps make heart disease claims. (*See* CCFF ¶ 384 and Appendix A). As to the other claims in the proposed finding, Complaint Counsel disagrees with the proposed finding regarding the net impression of the entirety of these advertisements (described in Response to Finding 295). (CCFF ¶¶ 381, 384). However, Complaint Counsel agrees that "proven" does not mean that "everyone in the study" benefitted.

308. 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).

Response to Appendix Finding No. 308:

Complaint Counsel does not disagree that Dr. Butters's report made broad conclusions about the net impression of POM ads in general, but disagrees with his conclusions, including specifically as to this ad.

309. 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)).

Response to Appendix Finding 309:
The proposed finding mischaracterizes the testimony of Dr. Stewart, who in the cited testimony simply said that he was not asked to do a net impression analysis of the challenged ads and that he did not know whether the Commission had evidence of how consumers perceive the ads at the level of a net impression. Moreover, Complaint Counsel presented evidence as to the meaning of POM advertisements. (*See* CCFF Sections V.C – V.G).

310. 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 certain diseases, such as heart disease or prostate cancer.

Response to Appendix Finding No. 310:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel does not contend that these magazine wraps make heart disease claims. (*See* CCFF ¶ 384 and Appendix A). Moreover, Complaint Counsel presented evidence on the meaning of this and other POM advertisements. (*See* CCFF ¶¶ 381, 384 and Sections V.C – V.G).

311. 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).

Response to Appendix Finding No. 311:
The proposed finding is irrelevant. *See* Response to Finding 38 in Respondents' Findings of Fact.

One small pill for mankind. – (CX0120)

312. Complaint Counsel claim that, on May 28, 2007, POM ran an advertisement with the headline "One small pill for mankind" with this body copy:

> Introducing POMx – a highly concentrated, incredibly powerful blend of all natural polyphenol antioxidants made from the very same pomegranates in **POM Wonderful 100% Pomegranate Juice**. Our method of harnessing astonishing levels of antioxidants is so extraordinary, it's patent-pending. So now you can get all the antioxidant power of an 8oz glass of juice in the convenience of a calorie-free capsule.
>
> Ready to take on free radicals? Put up your POMx and fight them with a mighty 1000mg capsule – that's more concentrated pomegranate polyphenol antioxidants than any other 100% pomegranate supplement. An initial UCLA medical study on POM Wonderful 100% Pomegranate Juice showed hopeful results for men with prostate cancer.[1,3] And preliminary human research suggests that our California-grown pomegranate juice also promotes heart health.[2,3] Take your antioxidants into your own hands. **Call 1-888-POM-PILL now, or visit pompills.com/fort and get your first monthly shipment for just ~~$29.95~~ $24.95 with coupon**.
>
> **[1]pomwonderful.com/cancer.html**
> **[2]pomwonderful.com/heart_health.html** [3] These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

(CX0120_0001, attached hereto as Ex. 20) (emphasis in original).

Response to Appendix Finding No. 312:
Complaint Counsel agrees.

313. Complaint Counsel failed to present any other definitive information regarding this ad's dissemination.

Response to Appendix Finding No. 313:
The proposed finding is incorrect. (*See* CX0120_0002; CX0474; CX0371 for additional evidence on dissemination).

314. 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.

Response to Appendix Finding No. 314:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel has presented evidence in CCFF Section VI.E that Respondents have continued to run advertising claims that they had been told were deceptive or misleading.

315. Complaint Counsel's assertion that the ad 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. (CX0120_0001).

Response to Appendix Finding No. 315:
Complaint Counsel does not contend that this ad makes heart disease claims. As to the other claims in the proposed finding, Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 397-401, 405).

316. 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.

Response to Appendix Finding No. 316:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 397-401, 405).

317. 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. (CX0120_0001). Even the language of the ad itself uses such qualifiers as "suggest," "may one day prove an effective weapon," "initial UCLA medical study," "hopeful results," "fight" and "preliminary human research suggests." (CX0120_0001).

Response to Appendix Finding No. 317:

Complaint Counsel does not contend that this ad makes heart disease claims. As to the other claims in the proposed finding, Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 397-401, 405).

318. 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 "reduces the risk," like a healthy diet of fruits and vegetables and exercise "reduces the risk" of disease. (CX0120_0001).

Response to Appendix Finding No. 318:
Complaint Counsel does not contend that this ad makes heart disease claims. As to the other claims in the proposed finding, Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 397-401, 405).

319. 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).

Response to Appendix Finding No. 319:
The proposed finding is unsupported by the cited testimony. Dr. Butters did not define "treat" as a substitute for conventional medical treatment. He defined "treat" as medical treatment and then asserted that he didn't see any ad stating or implying that POM Products "treated any disease." Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 397-401, 405).

320. 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 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)).

Response to Appendix Finding No. 320:
Complaint Counsel does not contend that this ad makes heart disease claims. As to the other claims in the proposed finding, Complaint Counsel disagrees with the proposed

finding regarding the net impression of this advertisement. (CCFF ¶¶ 397-401, 405).

However, Complaint Counsel agrees that "proven" does not mean that "everyone in the study" benefitted.

321. 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)).

Response to Appendix Finding No. 321:
Complaint Counsel has no specific response.

322. Mr. Tupper testified that this ad indicated that there were "hopeful results for men with prostate cancer." (Tupper, Tr. 1004).

Response to Appendix Finding No. 322:
Complaint Counsel has no specific response.

323. 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)).

Response to Appendix Finding No. 323:
The proposed finding is unsupported by the cited evidence; neither Dr. Butters nor Mr. Tupper testified as to the net impression of the ad at issue in the cited transcripts.

324. 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)).

Response to Appendix Finding No. 324:
The proposed finding mischaracterizes the testimony of Dr. Stewart, who in the cited testimony simply said that he was not asked to do a net impression analysis of the challenged ads and that he did not know whether the Commission had evidence of how consumers perceive the ads at the level of a net impression. Moreover, Complaint Counsel presented evidence as to the meaning of POM advertisements. (*See* CCFF Sections V.C – V.G).

325. 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.

Response to Appendix Finding No. 325:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel does not contend that this ad makes heart disease or erectile dysfunction claims. (*See* CCFF ¶ 405 and Appendix A). Moreover, Complaint Counsel presented evidence on the meaning of this and other POM advertisements. (*See* CCFF ¶¶ 397-401, 405 and Sections V.C – V.G).

326. 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).

Response to Appendix Finding No. 326:
The proposed finding is irrelevant. *See* Response to Finding 38 in Respondents' Findings of Fact.

POM Wonderful and Prostate Health - (CX0314_0004; CX0314_0008)

327. Complaint Counsel claim that, on September 9, 2008 and October 23, 2008, POM ran an advertisement with the headline "POM Wonderful and Prostate Health." with the body copy that appears on CX0314_0004 and CX0314_0008, attached hereto as Ex. 21.

Response to Appendix Finding No. 327:
The proposed finding mischaracterizes the exhibits at issue as individual ads, when in fact they should be considered together as multi-page "magazine wrap" or "cover wrap" ads. Specifically, CX0314_0003-06 together constitute one magazine wrap ad, indicated by the same job number at the bottom of each page (PJ9745); *see also* CX1356 (Leow, Dep. at 131 (identifying a four-page ad (Tropicana-000019, produced to the Court as CX0236, which is identical to CX0314_0003-06) as a Time cover wrap)). CX0314_0007-10 constitutes another magazine wrap ad (indicated by a similar job number footer PJ0225_TIME-Wrap_Dec08"). Documents that Respondents produced as dissemination schedules show that POM used unique project numbers starting with "PJ" to indicate individual ads. (CX0436; CX0437). Complaint Counsel agrees that the pages were disseminated as part of CX0314_0003-06 and CX0314_0008.

328. Complaint Counsel failed to present any other definitive information regarding this ad's dissemination.

Response to Appendix Finding No. 328:
The proposed finding is incorrect. *See* Response to Finding 2419 in Respondents' Findings of Fact.

329. 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.

Response to Appendix Finding No. 329:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel has presented evidence in CCFF

Section VI.E that Respondents have continued to run advertising claims that they had been told were deceptive or misleading.

330. 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. (CX0314_0004; CX0314_0008).

Response to Appendix Finding No. 330:
The proposed finding is incomplete, as these were not single page ads, but part of multi-page magazine wraps. *See* Response to Appendix Finding 327. Complaint Counsel disagrees with the proposed finding regarding the net impression of the entirety of these advertisements (described in Response to Appendix Finding 327). (CCFF ¶¶ 377-80, 383-384).

331. 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. (CX0314_004; CX0314_0008).

Response to Appendix Finding No. 331:
The proposed finding is incomplete, as these were not single page ads, but part of multi-page magazine wraps. *See* Response to Appendix Finding 327. Complaint Counsel disagrees with the proposed finding regarding the net impression of the entirety of these advertisements (described in Response to Appendix Finding 327). (CCFF ¶¶ 377-80, 383-84).

332. 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.

Response to Appendix Finding No. 332:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. The proposed finding is incomplete, as these were

not single page ads, but part of multi-page magazine wraps. *See* Response to Appendix Finding 327. Complaint Counsel disagrees with the proposed finding regarding the net impression of the entirety of these advertisements (described in Response to Appendix Finding 327). (CCFF ¶¶ 377-80, 383-84).

333. 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. (CX0314_0004; CX0314_0008). Even the language of the ad itself uses such qualifiers as "emerging science suggests," and "may be able." (CX0314_0004; CX0314_0008).

Response to Appendix Finding No. 333:
The proposed finding is incomplete, as these were not single page ads, but part of multi-page magazine wraps. *See* Response to Appendix Finding 327. Complaint Counsel disagrees with the proposed finding regarding the net impression of the entirety of these advertisements (described in Response to Appendix Finding 327). (CCFF ¶¶ 377-80, 383-84).

334. 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 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. (CX0314_0004; CX0314_0008).

Response to Appendix Finding No. 334:
The proposed finding is incomplete, as these were not single page ads, but part of multi-page magazine wraps. *See* Response to Appendix Finding 327. Complaint Counsel disagrees with the proposed finding regarding the net impression of the entirety of these advertisements (described in Response to Appendix Finding 327). (CCFF ¶¶ 377-80, 383-84).

335. 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).

Response to Appendix Finding No. 335:
The proposed finding is incomplete, as these were not single page ads, but part of multi-page magazine wraps. *See* Response to Appendix Finding 327. This finding is also unsupported by the cited testimony. Dr. Butters did not define "treat" as a substitute for conventional medical treatment. He defined "treat" as medical treatment and then asserted that he didn't see any ad stating or implying that POM Products "treated any disease." Complaint Counsel disagrees with the proposed finding regarding the net impression of the entirety of these advertisements (described in Response to Appendix Finding 327). (CCFF ¶¶ 377-80, 383-84).

336. 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 prostate cancer 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)).

Response to Appendix Finding No. 336:
The proposed finding is incomplete, as these were not single page ads, but part of multi-page magazine wraps. *See* Response to Appendix Finding 327. Complaint Counsel disagrees with the proposed finding regarding the net impression of the entirety of these advertisements (described in Response to Appendix Finding 327). (CCFF ¶¶ 377-80, 383-84). However, Complaint Counsel agrees that "proven" does not mean that "everyone in the study" benefitted.

337. 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)).

Response to Appendix Finding No. 337:
The proposed finding mischaracterizes the testimony of Dr. Stewart, who in the cited testimony simply said that he was not asked to do a net impression analysis of the

challenged ads and that he did not know whether the Commission had evidence of how consumers perceive the ads at the level of a net impression. Moreover, Complaint Counsel presented evidence as to the meaning of POM advertisements. (*See* CCFF Sections V.C – V.G).

338. 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.

Response to Appendix Finding No. 338:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel does not contend this ad makes heart disease or erectile dysfunction claims. (*See* CCFF ¶ 384 and Appendix A). Moreover, Complaint Counsel presented evidence on the meaning of this and other POM advertisements. (*See* CCFF ¶¶ 377-80, 383-84 and Sections V.C – V.G).

339. 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).

Response to Appendix Finding No. 339:
The proposed finding is irrelevant. *See* Response to Finding 38 in Respondents' Findings of Fact.

Risk your health in this economy? NEVER! - (CX0379_0004)

340. Complaint Counsel claim that, on August 20, 2009, POM ran an advertisement with the headline "Risk your health in this economy? NEVER!" with this body copy:

> In a time of financial distress, one 16-ounce hero has devoted itself to maintaining the world's health: POM Wonderful®. One of the POM products backed by $32 million in medical research,* the Antioxidant Superpower will defend you with the full force of its 100% pure pomegranate juice. And you will survive.
>
> (CX0379_0004, attached hereto as Ex. 22).

Response to Appendix Finding No. 340:
The proposed finding mischaracterizes the exhibit page at issue as an individual ad, when in fact it should be considered together with other pages as a multi-page "magazine wrap" or "cover wrap." CX0379_0001-04 is one ad (indicated by the same job number PJ2005 across all pages). Documents that Respondents produced as dissemination schedules show that POM used unique project numbers starting with "PJ" to indicate individual ads. (CX0436; CX0437). *See* Response to Finding 2252 in Respondent's Findings of Fact. Complaint Counsel agrees that this page was disseminated as part of CX0379_0001-04.

341. Complaint Counsel failed to present any other definitive information regarding this ad's dissemination.

Response to Appendix Finding No. 341:
The proposed finding is incorrect. *See* Response to Finding 2252 in Respondent's Findings of Fact (CX0379_0001-04 dated 8/20/2009).

342. 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.

Response to Appendix Finding No. 342:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel has presented evidence in CCFF Section VI.E that Respondents have continued to run advertising claims that they had been told were deceptive or misleading.

343. 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.

Response to Appendix Finding No. 343:
The proposed finding mischaracterizes the record and is incorrect. Complaint Counsel challenges the claims in this magazine wrap as deceptive and is not foreclosed from doing so by Dr. Mazis's testimony. Dr. Mazis testified as to his understanding of the *approximate* date deceptive POM Juice ads were disseminated for the purpose of showing that Dr. Reibstein's survey, conducted in October 2010, was done well after that. This magazine wrap was disseminated only two months after the approximate date given, and thus for the purposes of the reliability of Dr. Reibstein's survey conducted in October 2010 (which was the core issue of Dr. Mazis's testimony on this point), this short time difference is irrelevant. *See* Responses to Findings 2238, 2245 in Respondents' Findings of Fact (Complaint Counsel is challenging POM Juice print ads disseminated prior to *approximately* June 2009 and POM Juice websites as they appeared prior to approximately February 2010).

344. Complaint Counsel's assertion that the ad conveys the message that (a) POM Juice "prevents," "treats," or "reduces the risk" of certain diseases; or (b) POM Juice 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. (CX0379_0004).

Response to Appendix Finding No. 344:
The proposed finding is incomplete, as this was not a single page ad, but part of a multi-page magazine wrap. *See* Response to Appendix Finding 340. Complaint Counsel does not contend that this ad makes heart disease claims. As to the other claims in the proposed finding, Complaint Counsel disagrees with the proposed finding regarding the

net impression of the entirety of this magazine wrap (described in Response to Appendix Finding 340). (CCFF ¶¶ 381, 384).

345. 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.

Response to Appendix Finding No. 345:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. The proposed finding is incomplete, as this was not a single page ad, but part of a multi-page magazine wrap. *See* Response to Appendix Finding 340. Complaint Counsel disagrees with the proposed finding regarding the net impression of the entirety of this magazine wrap (described in Response to Appendix Finding 340). (CCFF ¶¶ 381, 384).

346. 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; or (b) drinking eight ounces of POM Juice is "clinically proven" to prevent, treat or reduce the risk of certain diseases. (CX0379_0004). Even the language of the ad itself uses the qualifier "defend." (CX0379_0004).

Response to Appendix Finding No. 346:
The proposed finding is incomplete, as this was not a single page ad, but part of a multi-page magazine wrap. *See* Response to Appendix Finding 340. Complaint Counsel does not contend that this ad makes heart disease claims. As to the other claims in the proposed finding, Complaint Counsel disagrees with the proposed finding regarding the net impression of the entirety of this magazine wrap (described in Response to Appendix Finding 340). (CCFF ¶¶ 381, 384).

347. 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, 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. (CX0379_0004).

Response to Appendix Finding No. 347:

The proposed finding is incomplete, as this was not a single page ad, but part of a multi-page magazine wrap. *See* Response to Appendix Finding 340. Complaint Counsel does not contend that this ad makes heart disease claims. As to the other claims in the proposed finding, Complaint Counsel disagrees with the proposed finding regarding the net impression of the entirety of this magazine wrap (described in Response to Appendix Finding 340). (CCFF ¶¶ 381, 384).

348. 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).

Response to Appendix Finding No. 348:

The proposed finding is incomplete, as this was not a single page ad, but part of a multi-page magazine wrap. *See* Response to Appendix Finding 340. The proposed finding is also unsupported by the cited testimony. Dr. Butters did not define "treat" as a substitute for conventional medical treatment. He defined "treat" as medical treatment and then asserted that he didn't see any ad stating or implying that POM Products "treated any disease." Complaint Counsel does not contend that this ad makes heart disease claims. As to the other claims in the proposed finding, Complaint Counsel disagrees with the proposed finding regarding the net impression of the entirety of this magazine wrap (described in Response to Appendix Finding 340). (CCFF ¶¶ 381, 384).

349. 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 certain diseases 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)).

Response to Appendix Finding No. 349:

Complaint Counsel does not contend that this ad makes heart disease claims. As to the other claims in the proposed finding, Complaint Counsel disagrees with the proposed finding regarding the net impression of the entirety of this magazine wrap (described in Response to Appendix Finding 340). (CCFF ¶¶ 381, 384). However, Complaint Counsel agrees that "proven" does not mean that "everyone in the study" benefitted.

350. 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).

Response to Appendix Finding No. 350:
Complaint Counsel does not disagree that Dr. Butters's report made broad conclusions about the net impression of POM ads in general, but disagrees with his conclusions, including specifically as to this ad.

351. 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)).

Response to Appendix Finding No. 351:
The proposed finding mischaracterizes the testimony of Dr. Stewart, who in the cited testimony simply said that he was not asked to do a net impression analysis of the challenged ads and that he did not know whether the Commission had evidence of how consumers perceive the ads at the level of a net impression. Moreover, Complaint Counsel presented evidence as to the meaning of POM advertisements. (*See* CCFF Sections V.C – V.G).

352. 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.

Response to Appendix Finding No. 352:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Moreover, Complaint Counsel presented evidence on the meaning of this and other POM advertisements. (*See* CCFF ¶¶381, 384 and Sections V.C – V.G).

353. 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).

Response to Appendix Finding No. 353:
The proposed finding is irrelevant. *See* Response to Finding 38 in Respondents' Findings of Fact.

Science, not fiction - (CX0122) [3]

354. Complaint Counsel claim that, on June 1, 2007, POM ran an advertisement with the headline "Science, not fiction" with this body copy:

> Introducing POMx – a highly concentrated, incredibly powerful blend of all natural polyphenol antioxidants made from the very same pomegranates in **POM Wonderful 100% Pomegranate Juice**. Our method of harnessing astonishing levels of antioxidants is so extraordinary, it's patent-pending. So now you can get all the antioxidant power of an 8oz glass of juice in the convenience of a calorie-free capsule.
>
> Ready to take on free radicals? Put up your POMx and fight them with a mighty 1000mg capsule – that's more concentrated pomegranate polyphenol antioxidants than any other 100% pomegranate supplement. An initial UCLA medical study on POM Wonderful 100% Pomegranate Juice showed hopeful results for men with prostate cancer.[1,3] And preliminary human research suggests that our California-grown pomegranate juice also promotes heart health.[2,3] Take your antioxidants into your own hands. **Call 1-888-POM-PILL now, or visit pompills.com/dvr and get your first monthly shipment for just ~~$29.95~~ $24.95 with coupon**.
>
> **[1]pomwonderful.com/cancer.html**
> **[2]pomwonderful.com/heart_health.html** [3] These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

(CX0122_0001, attached hereto as Ex. 23) (emphasis in original).

Response to Appendix Finding No. 354:
Complaint Counsel agrees that the ad was disseminated on June 1, 2007, but notes that it has also provided evidence that it was disseminated in at least two publications.

(CX0122_0002); CX0474; CX0371).

[3] This ad, CX0122, is very similar, in terms of images and body copy, to the challenged POMx ad CX0120 ("One small pill for mankind"). The differences, including subheadlines, are minor and Complaint Counsel alleges the same net impression for each of these ads. (*See* CCFF ¶ 405 and Appendix A). Moreover, Respondents' proposed findings with respect to CX120 (Appendix Findings 312 -326) are nearly identical. Therefore, Complaint Counsel adopts and restates its responses to findings regarding CX0120 here, as appropriate.

355. Complaint Counsel failed to present any other definitive information regarding this ad's dissemination.

Response to Appendix Finding No. 355:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Moreover, the proposed finding is incorrect. *See* Response to Appendix Finding 354 for the evidence on dissemination.

356. 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.

Response to Appendix Finding No. 356:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel has presented evidence in CCFF Section VI.E that Respondents have continued to run advertising claims that they had been told were deceptive or misleading.

357. Complaint Counsel's assertion that the ad 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. (CX0122_0001).

Response to Appendix Finding No. 357:
See Response to Appendix Finding 315.

358. 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.

Response to Appendix Finding No. 358:
See Response to Appendix Finding 316.

359. 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. (CX0122_0001). Even the language of the ad itself uses such qualifiers as "initial UCLA medical study," "hopeful results," "fight," "preliminary studies" and "promising results." (CX0122_0001).

Response to Appendix Finding No. 359:

See Response to Appendix Finding 317.

360. 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 "reduces the risk," like a healthy diet of fruits and vegetables and exercise "reduces the risk" of disease. (CX0122_0001).

Response to Appendix Finding No. 360:
See Response to Appendix Finding 318.

361. 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).

Response to Appendix Finding No. 361:
See Response to Appendix Finding 319.

362. 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 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)).

Response to Appendix Finding No. 362:
See Response to Appendix Finding 320.

363. Professor Butters testified that this ad is a parody or pun on "science fiction" that constitutes a humorous introduction to the ad. (PX0350 (Butters, Dep. at 140)).

Response to Appendix Finding No. 363:
Complaint Counsel has no specific response.

364. 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)).

Response to Appendix Finding No. 364:
The proposed finding is unsupported by the cited evidence. Complaint Counsel does not disagree that Dr. Butters's report made broad conclusions about the net impression of

POM ads in general, but Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 397-401, 405).

365. 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)).

Response to Appendix Finding No. 365:
See Response to Appendix Finding 324.

366. 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.

Response to Appendix Finding No. 366:
See Response to Appendix Finding 325.

367. 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).

Response to Appendix Finding No. 367:
See Response to Appendix Finding 326.

Science, not fiction - (CX0279)

368. Complaint Counsel claim that, on March 1, 2009, POM ran an advertisement with the headline "Science, not fiction." with the body copy that appears on CX0279_0001, attached hereto as Ex. 24.

Response to Appendix Finding No. 368:
Complaint Counsel agrees.

369. Complaint Counsel failed to present any other definitive information regarding this ad's dissemination.

Response to Appendix Finding No. 369:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Moreover, the proposed finding is incorrect. (*See* CX0279_0002, CX0474, and CX0371 for additional evidence on dissemination).

370. 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.

Response to Appendix Finding No. 370:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel has presented evidence in CCFF Section VI.E that Respondents have continued to run advertising claims that they had been told were deceptive or misleading.

371. 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.

Response to Appendix Finding No. 371:
The proposed finding mischaracterizes the record and is incorrect. *See* Responses to Findings 2238, 2245 in Respondents' Findings of Fact (Complaint Counsel is challenging POM Juice print ads disseminated prior to approximately June 2009 and POM Juice websites as they appeared prior to approximately February 2010). Moreover, the proposed finding is irrelevant because the ad at issue is about POMx.

372. 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. (CX0279_0001).

Response to Appendix Finding No. 372:
Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 406-14).

373. Complaint Counsel's assertion that the ad 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. (CX0279_0001).

Response to Appendix Finding No. 373:
Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 406-14).

374. 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.

Response to Appendix Finding No. 374:
Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 406-14).

375. 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. (CX0279_0001). Even the language of the ad itself uses such qualifiers as "initial UCLA MEDICAL STUDY," "hopeful results," "fight," "preliminary studies," and "promising results." (CX0279_0001).

Response to Appendix Finding No. 375:
Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 406-14).

376. 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 "reduces the risk," like a healthy diet of fruits and vegetables and exercise "reduces the risk" of disease. (CX0279_0001).

Response to Appendix Finding No. 376:
Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 406-14).

377. 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).

Response to Appendix Finding No. 377:
The proposed finding is unsupported by the cited testimony. Dr. Butters did not define "treat" as a substitute for conventional medical treatment. He defined "treat" as medical treatment and then asserted that he didn't see any ad stating or implying that POM Products "treated any disease." Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 406-14).

378. 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 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)).

Response to Appendix Finding No. 378:
Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 406-14). However, Complaint Counsel agrees that "proven" does not mean that "everyone in the study" benefitted.

379. 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)).

Response to Appendix Finding No. 379:

The proposed finding mischaracterizes the testimony of Dr. Stewart, who in the cited testimony simply said that he was not asked to do a net impression analysis of the challenged ads and that he did not know whether the Commission had evidence of how consumers perceive the ads at the level of a net impression. Moreover, Complaint Counsel presented evidence as to the meaning of this and other POM advertisements. (*See* CCFF ¶¶ 406-14 and Sections V.C – V.G).

380. 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.

Response to Appendix Finding No. 380:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel does not contend this ad makes erectile dysfunction claims. Moreover, Complaint Counsel presented evidence as to the meaning of this and other POM advertisements. (*See* CCFF ¶¶ 406-14 and Sections V.C – V.G).

381. 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).

Response to Appendix Finding No. 381:
The proposed finding is irrelevant. *See* Response to Finding 38 in Respondents' Findings of Fact.

Studies Show: 10 out of 10 don't want to die - (CX0029)

382. Complaint Counsel claim that, on November 1, 2004, POM ran an advertisement with the headline "Studies Show That 10 Out Of 10 People Don't Want To Die" with this body copy:

POMEGRANATE JUICE

STUDIES SHOW THAT 10 OUT OF 10
PEOPLE DON'T WANT TO DIE

IT'S NOT EASY BEING ALIVE IN TODAY'S POLLUTED, STRESSED OUT WORLD. Here's a tip: with more naturally occurring antioxidant power than any other drink, a glass of POM Wonderful Pomegranate Juice a day might be just what the doctor ordered.

Fighting Free Radicals

Let's start with the problem: free radicals…unstable little molecules that can accelerate aging, lead to heart disease and stroke, and have even been implicated in cancer. Where do they come from? Everywhere. Free radicals are formed by exposure to air pollution alcohol, pesticides, sunlight, tobacco smoke, drugs, even fried foods. Of course, when you're very young, your body's self-repair mechanism can neutralize the activity of many free radicals. But by the time you're in your twenties, those mechanisms just don't work as well. That's where antioxidants come in. They neutralize free radicals, helping to prevent the cell and tissue damage that leads to disease. Which brings us back to POM Wonderful Pomegranate Juice.

Not All Antioxidants are Equal

Since our bodies don't produce enough antioxidants to do the job on their own, we need a little outside help. POM Wonderful Pomegranate Juice, with a higher level of antioxidants than any other drink, is a real Antioxidant Superpower.

Our Research: Heartening

We've been working with a number of top scientists, including a Nobel Laureate, for 6 years now and our seven published, peer-reviewed papers reveal heartening results. Here's the story: Free radicals are the culprits that turn LDL – or "bad" cholesterol – into that sticky stuff that becomes the plaque that clogs your arteries. Our scientific research shows that pomegranate juice is 8 times

better than green tea at preventing formation of oxidized (sticky) LDL.[1] And 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%.[2]

The Heart Stopping Truth

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.

Just a Glass a Day

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 to be alive.

[1]Aviram M., Drugs Under Experimental and Clinical Research, 2002. Indexed values based on relative amount of oxidized LDL created. [2]Aviram M., Clinical Nutrition 2004.

(CX0029_0001-02, attached hereto as Ex. 25).

Response to Appendix Finding No. 382:
Complaint Counsel agrees that this ad was disseminated on November 1, 2004, but has provided evidence that it was disseminated in at least two publications and at additional times as well, as late as May 2005. (CX0029_0003; CX0474; CX0371).

383. Complaint Counsel failed to present any other definitive information regarding this ad's dissemination.

Response to Appendix Finding No. 383:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Moreover, the proposed finding is incorrect. *See* Response to Appendix Finding 382 for the evidence on dissemination.

384. 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.

Response to Appendix Finding No. 384:

The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel has presented evidence in CCFF Section VI.E that Respondents have continued to run advertising claims that they had been told were deceptive or misleading.

385. 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.

Response to Appendix Finding No. 385:
The proposed finding is a legal conclusion and is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel has presented evidence in CCFF Section VI.E that Respondents have continued to run advertising claims that they had been told were deceptive or misleading.

386. 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).

Response to Appendix Finding No. 386:
Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 329-32, 334-35).

387. 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_0001-02).

Response to Appendix Finding No. 387:
Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 329-32, 334-35).

388. 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.

Response to Appendix Finding No. 388:

Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 329-32, 334-35).

389. 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_0001-02). Even the language of the ad itself uses such qualifiers as "might be," "heartening results," and "pilot study." (CX0029_0001-02).

Response to Appendix Finding No. 389:
Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 329-32, 334-35).

390. 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_0001-02).

Response to Appendix Finding No. 390:
Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 329-32, 334-35).

391. 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).

Response to Appendix Finding No. 391:
The proposed finding is unsupported by the cited testimony. Dr. Butters did not define "treat" as a substitute for conventional medical treatment. He defined "treat" as medical treatment and then asserted that he didn't see any ad stating or implying that POM Products "treated any disease." Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 329-32, 334-35).

392. 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)).

Response to Appendix Finding No. 392:
Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 329-32, 334-35). However, Complaint Counsel agrees that "proven" does not mean that "everyone in the study" benefitted.

393. 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)).

Response to Appendix Finding No. 393:
The proposed finding mischaracterizes the testimony of Dr. Stewart, who in the cited testimony simply said that he was not asked to do a net impression analysis of the challenged ads and that he did not know whether the Commission had evidence of how consumers perceive the ads at the level of a net impression. Moreover, Complaint Counsel presented evidence as to the meaning of POM advertisements. (*See* CCFF Sections V.C – V.G).

394. 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.

Response to Appendix Finding No. 394:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Moreover, Complaint Counsel presented evidence on the meaning of this and other POM advertisements. (*See* CCFF ¶¶ 329-32, 334-35 and Sections V.C – V.G).

395. 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).

Response to Appendix Finding No. 395:
The proposed finding is irrelevant. *See* Response to Finding 38 in Respondents' Findings of Fact.

Super HEALTH Powers! - (CX1426_0027, Exh. A)

396. Complaint Counsel claim that POM ran an advertisement with the headline "Super HEALTH Powers!" with this body copy:

> **100% PURE POMEGRANATE JUICE.** It's 100% pure! It's heroically healthy! It's The Antioxidant Superpower, POM 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!

(CX1426_0027, Exh. A, attached hereto as Ex. 26).

Response to Appendix Finding No. 396:
Complaint Counsel agrees.

397. Complaint Counsel failed to present any definitive information regarding this ad's dissemination.

Response to Appendix Finding No. 397:
The proposed finding mischaracterizes the record; Respondents admitted disseminating the exhibits to the Complaint, including Exhibit A. (PX0364_0002).

398. 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.

Response to Appendix Finding No. 398:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel has presented evidence in CCFF Section VI.E that Respondents have continued to run advertising claims that they had been told were deceptive or misleading.

399. Complaint Counsel's assertion that the ad conveys 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 is not conspicuous, self-evident, or reasonably clear from the face of the ad. (CX1426_0027, Exh. A).

Response to Appendix Finding No. 399:
Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 385-88).

400. 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.

Response to Appendix Finding No. 400:
Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 385-88).

401. 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, prostate cancer or erectile dysfunction; 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, prostate cancer or erectile dysfunction. (CX1426_0027, Exh. A). Even the language of the ad itself uses such qualifiers as "fight for" and "committed." (CX1426_0027, Exh. A).

Response to Appendix Finding No. 401:
Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 385-88).

402. 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 "reduces the risk," like a healthy diet of fruits and vegetables and exercise "reduces the risk" of disease. (CX1426_0027, Exh. A).

Response to Appendix Finding No. 402:
Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 385-88).

403. 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).

Response to Appendix Finding No. 403:
The proposed finding is unsupported by the cited testimony. Dr. Butters did not define "treat" as a substitute for conventional medical treatment. He defined "treat" as medical treatment and then asserted that he didn't see any ad stating or implying that POM Products "treated any disease." Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 385-88).

404. 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 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)).

Response to Appendix Finding No. 404:
Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 385-88). However, Complaint Counsel agrees that "proven" does not mean that "everyone in the study" benefitted.

405. Professor Butters concluded 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).

Response to Appendix Finding No. 405:
The proposed finding is incomplete. Dr. Butters further testified, "I certainly did not do any research on how many people read the hangtags before they bought bottles of POM Wonderful or anything else." He also admitted he has no professional knowledge about the use of point-of-sale marketing and its effectiveness in engaging the attention of potential purchasers, and that he had no scientific evidence to support his assertion about the importance of hangtags relative to print advertisements. (Butters, Tr. 2868-70).

406. 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).

Response to Appendix Finding No. 406:
The proposed finding is incomplete. *See* Response to Appendix Finding 405.

407. 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 Wonderful juice is extremely healthy. (Butters, Tr. 2870-73).

Response to Appendix Finding No. 407:

Complaint Counsel has no specific response.

408. 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).

Response to Appendix Finding No. 408:
The proposed finding is incomplete. Dr. Butters further testified that the phrase, "Proven to fight for cardiovascular, prostate, erectile health," could communicate that it could improve one's odds. (Butters, Tr. 2886).

409. 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).

Response to Appendix Finding No. 409:
Complaint Counsel does not disagree with the nature of Dr. Butters's testimony, but disagrees with his unsupported conclusion.

410. 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)).

Response to Appendix Finding No. 410:
Complaint Counsel has no specific response.

411. 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).

Response to Appendix Finding No. 411:
The proposed finding is incomplete. Dr. Butters further testified that "It may . . . suggest that your health – your cardiovascular, prostate, and erectile health, you may have a lower risk of having bad cardiovascular health or it may . . . have you have a better

cardiovascular, prostate, and erectile health. It may help you. It doesn't say that it will." (Butters, Tr. 2984). Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 385-88).

412. 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)).

Response to Appendix Finding No. 412:
The proposed finding mischaracterizes the testimony of Dr. Stewart, who in the cited testimony simply said that he was not asked to do a net impression analysis of the challenged ads and that he did not know whether the Commission had evidence of how consumers perceive the ads at the level of a net impression. Moreover, Complaint Counsel presented evidence as to the meaning of POM advertisements. (*See* CCFF Sections V.C – V.G).

413. 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.

Response to Appendix Finding No. 413:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Moreover, Complaint Counsel presented evidence on the meaning of this and other POM advertisements. (*See* CCFF ¶¶ 385-88 and Sections V.C – V.G).

414. 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).

Response to Appendix Finding No. 414:
The proposed finding is irrelevant. *See* Response to Finding 38 in Respondents' Findings of Fact.

Take Out A Life Insurance Supplement - (CX0342) [4]

415. Complaint Counsel claim that on February 22, 2010, POM ran an advertisement with the headline "Take Out A Life Insurance Supplement" with the body copy that appears on CX0342_0001, attached hereto as Ex. 27.

Response to Appendix Finding No. 415:
Complaint Counsel agrees that this ad was disseminated on February 22, 2010, but has provided evidence that it was disseminated in additional publications and at additional times, as late as March 14, 2010. (CX0342_0002; CX0474; CX0371).

416. Complaint Counsel failed to present any other definitive information regarding this ad's dissemination.

Response to Appendix Finding No. 416:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Moreover, the proposed finding is incorrect. *See* Response to Appendix Finding 415 for the evidence on dissemination.

417. 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.

Response to Appendix Finding No. 417:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel has presented evidence in CCFF Section VI.E that Respondents have continued to run advertising claims that they had been told were deceptive or misleading.

418. 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.

Response to Appendix Finding No. 418:

[4] The body copy of this ad, CX0342, is substantively identical to CX0348 and CX0350, with the differences being minor (subheadlines and amount of medical research backing). Because Complaint Counsel alleges that these ads have the same net impression, Complaint Counsel adopts and restates the same position with respect to the prior findings on CX0348 and CX0350.

The proposed finding mischaracterizes the record and is incorrect. *See* Responses to Findings 2238, 2245 in Respondents' Findings of Fact (Complaint Counsel is challenging POM Juice print ads disseminated prior to approximately June 2009 and POM Juice websites as they appeared prior to approximately February 2010). Moreover, the proposed finding is irrelevant because the ad at issue is about POMx.

419. 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. (CX0342_0001).

Response to Appendix Finding No. 419:
See Response to Appendix Finding 7.

420. Complaint Counsel's assertion that the ad 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. (CX0342_0001).

Response to Appendix Finding No. 420:
See Response to Appendix Finding 8.

421. 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.

Response to Appendix Finding No. 421:
See Response to Appendix Finding 9.

422. 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. (CX0342_0001). Even the language of the ad itself uses such qualifiers as "emerging science suggests," "help protect," "promising results," "initial UCLA study," "hopeful results" and "preliminary studies." (CX0342_0001).

Response to Appendix Finding No. 422:
See Response to Appendix Finding 10.

423. 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 "reduces the risk," like a healthy diet of fruits and vegetables and exercise "reduces the risk" of disease. (CX0342_0001).

Response to Appendix Finding No. 423:
See Response to Appendix Finding 11.

424. 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).

Response to Appendix Finding No. 424:
See Response to Appendix Finding 12.

425. 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 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)).

Response to Appendix Finding No. 425:
See Response to Appendix Finding 13.

426. Professor Butters testified that this ad employs humor as it is a "joking reference to death." (PX0350 (Butters, Dep. at 141)).

Response to Appendix Finding No. 426:
Complaint Counsel has no specific response.

427. 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).

Response to Appendix Finding No. 427:

Complaint Counsel does not disagree that Dr. Butters's report made broad conclusions about the net impression of POM ads in general, but disagrees with his conclusions, including specifically as to this ad.

428. Viewing the "Take Out A Life Insurance Supplement" 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)).

Response to Appendix Finding No. 428:
The proposed finding is unsupported by the cited evidence. Complaint Counsel does not disagree that Dr. Butters's report made broad conclusions about the net impression of POM ads in general, but disagrees with the conclusion as to this ad.

429. 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)).

Response to Appendix Finding No. 429:
See Response to Appendix Finding 20.

430. 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.

Response to Appendix Finding No. 430:
See Response to Appendix Finding 21.

431. 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).

Response to Appendix Finding No. 431:
See Response to Appendix Finding 22.

Take Out A Life Insurance Supplement - (CX0353)[5]

432. Complaint Counsel claim that on June 14, 2010, POM ran an advertisement with the headline "Take Out A Life Insurance Supplement" with the body copy that appears on CX0353_0001, attached hereto as Ex. 28.

Response to Appendix Finding No. 432:
Complaint Counsel agrees that the ad was disseminated on June 14, 2010, but has provided evidence that it was disseminated in several publications and additional times, as late as September 2010. (CX0353_0002; CX0474; CX0371).

433. Complaint Counsel failed to present any other definitive information regarding this ad's dissemination.

Response to Appendix Finding No. 433:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Moreover, the proposed finding is incorrect. *See* Response to Appendix Finding 432 for the evidence on dissemination.

434. 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.

Response to Appendix Finding No. 434:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel has presented evidence in CCFF Section VI.E that Respondents have continued to run advertising claims that they had been told were deceptive or misleading.

435. 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.

Response to Appendix Finding No. 435:

[5] The body copy of this ad, CX0353, is substantively identical to CX0348, CX0350 and CX0342 and Complaint Counsel alleges that these ads have the same net impression. (*See* CCFF ¶¶ 419, 422, 424). Therefore, Complaint Counsel adopts and restates the same position with respect to the prior findings on CX0348, CX0350, and CX0342 as appropriate.

The proposed finding mischaracterizes the record and is incorrect. *See* Responses to Findings 2238, 2245 in Respondents' Findings of Fact (Complaint Counsel is challenging POM Juice print ads disseminated prior to approximately June 2009 and POM Juice websites as they appeared prior to approximately February 2010). Moreover, the proposed finding is irrelevant because the ad at issue is about POMx.

436. 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. (CX0353_0001).

Response to Appendix Finding No. 436:
See Response to Appendix Finding 7.

437. Complaint Counsel's assertion that the ad 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. (CX0353_0001).

Response to Appendix Finding No. 437:
See Response to Appendix Finding 8.

438. 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.

Response to Appendix Finding No. 438:
See Response to Appendix Finding 9.

439. 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. (CX0353_0001). Even the language of the ad itself uses such qualifiers as "emerging science suggests," "help protect," "promising results," "initial UCLA study," "hopeful results" and "preliminary studies." (CX0353_0001).

Response to Appendix Finding No. 439:
See Response to Appendix Finding 10.

440. 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 "reduces the risk," like a healthy diet of fruits and vegetables and exercise "reduces the risk" of disease. (CX0353_0001).

Response to Appendix Finding No. 440:
See Response to Appendix Finding 11.

441. 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).

Response to Appendix Finding No. 441:
See Response to Appendix Finding 12.

442. 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 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)).

Response to Appendix Finding No. 442:
See Response to Appendix Finding 13.

443. Professor Butters testified that this ad employs humor as it is a "joking reference to death." (PX0350 (Butters, Dep. at 141)).

Response to Appendix Finding No. 443:
Complaint Counsel has no specific response.

444. 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).

Response to Appendix Finding No. 444:

Complaint Counsel does not disagree that Dr. Butters's report made broad conclusions about the net impression of POM ads in general, but disagrees with his conclusions, including specifically as to this ad.

445. Viewing the "Take Out A Life Insurance Supplement" 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)).

Response to Appendix Finding No. 445:
The proposed finding is unsupported by the cited evidence. Complaint Counsel does not disagree that Dr. Butters's report made broad conclusions about the net impression of POM ads in general, but disagrees with the conclusion as to this ad.

446. 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)).

Response to Appendix Finding No. 446:
See Response to Appendix Finding 20.

447. 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.

Response to Appendix Finding No. 447:
See Response to Appendix Finding 21.

448. 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).

Response to Appendix Finding No. 448:
See Response to Appendix Finding 22.

The antioxidant superpill - (CX0180; CX1426_044, Exh. K)[6]

449. Complaint Counsel claim that, on February 3, 2008, POM ran an advertisement with the headline "The antioxidant superpill" with the body copy that appears on CX0180_0001 and CX1426_044, Exh. K, attached hereto as Ex. 29.

Response to Appendix Finding No. 449:
Complaint Counsel agrees.

450. Complaint Counsel failed to present any other definitive information regarding this ad's dissemination.

Response to Appendix Finding No. 450:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Moreover, the proposed finding is incorrect. (*See* CX0180_0002, CX0474, and CX0371 for additional evidence on dissemination). Respondents also admit the exhibits to the Complaint were disseminated. (PX0364_0002).

451. 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.

Response to Appendix Finding No. 451:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel has presented evidence in CCFF Section VI.E that Respondents have continued to run advertising claims that they had been told were deceptive or misleading.

452. 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 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. (CX0180_0001; CX1426_044, Exh. K).

Response to Appendix Finding No. 452:

[6] This ad contains virtually identical body copy, and similar images, to CX0279 ("Science, not fiction"), and has the same net impression. (*See* CCFF ¶¶ 408-409, 411-414). Therefore, Complaint Counsel adopts and restates its responses to prior findings about CX0279, as appropriate.

See Response to Appendix Finding 372.

453. Complaint Counsel's assertion that the ad 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. (CX0180_0001; CX1426_044, Exh. K).

Response to Appendix Finding No. 453:
See Response to Appendix Finding 373.

454. 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.

Response to Appendix Finding No. 454:
See Response to Appendix Finding 374.

455. The overall net impression of this ad is not that not that taking one POMx Pill per day prevents or treats 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. (CX0180_0001; CX1426, Exh. K). Even the language of the ad itself uses such qualifiers as "fights," "initial UCLA MEDICAL STUDY," "hopeful results," "promising results" and "preliminary studies." (CX018_0001; CX1426_044, Exh. K).

Response to Appendix Finding No. 455:
See Response to Appendix Finding 375.

456. 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 "reduces the risk," like a healthy diet of fruits and vegetables and exercise "reduces the risk" of disease. (CX018_0001; CX1426_044, Exh. K).

Response to Appendix Finding No. 456:
See Response to Appendix Finding 376.

457. 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).

Response to Appendix Finding No. 457:
See Response to Appendix Finding 377.

458. 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 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)).

Response to Appendix Finding No. 458:
See Response to Appendix Finding 378.

459. 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)).

Response to Appendix Finding No. 459:
See Response to Appendix Finding 379.

460. 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.

Response to Appendix Finding No. 460:
See Response to Appendix Finding 380.

461. 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).

Response to Appendix Finding No. 461:
See Response to Appendix Finding 381.

The Antioxidant Superpower. - (CX0314_0006)[7]

462. Complaint Counsel claim that, on September 9, 2008, POM ran an advertisement with the headline "The Antioxidant Superpower." with this body copy:

> What's it like to have a personal superhero? Find out by drinking delicious and refreshing POM Wonderful 100% Pomegranate Juice. It has more naturally occurring antioxidants than other drinks. Antioxidants fight free radicals, villainous little molecules that may cause premature aging, heart disease, stroke, Alzheimer's, even cancer. All you need is eight ounces to save the day. Every day.
>
> **The Antioxidant Superpower 100% Pure Pomegranate Juice.**

(CX0314_0006, attached hereto as Ex. 30).

Response to Appendix Finding No. 462:
The proposed finding mischaracterizes the exhibit at issue as an individual ad, when in fact it should be considered together with other pages as a multi-page "magazine wrap" or "cover wrap" ads. *See* Response to Appendix Finding 122. Complaint Counsel agrees that this page were disseminated as part of CX0314_0003-06.

463. Complaint Counsel failed to present any other definitive information regarding this ad's dissemination.

Response to Appendix Finding No. 463:
The proposed finding is incorrect. *See* Response to Appendix Finding 123.

464. 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.

Response to Appendix Finding No. 464:
See Response to Appendix Finding 124.

465. Complaint Counsel's assertion that the ad conveys 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 is not conspicuous, self-evident, or reasonably clear from the face of the ad. (CX0314_0006).

[7] Because this page is part of a magazine wrap, CX0314_0003-0006, and because Complaint Counsel has already responded to similar or identical Findings in this Appendix relating to the same magazine wrap, Complaint Counsel adopts and restates its responses to previous findings regarding CX0314_0003-0006 here, where appropriate.

Response to Appendix Finding No. 465:
Complaint Counsel does not contend this magazine wrap makes heart disease claims.

(*See* CCFF ¶ 384 and Appendix A). As for the other claims in the proposed finding, *see*

Response to Appendix Finding 125.

466. 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.

Response to Appendix Finding No. 466:
See Response to Appendix Finding 126.

467. 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. (CX0314_0006). Even the language of the ad itself uses the qualifier "may cause." (CX0314_0006).

Response to Appendix Finding No. 467:
Complaint Counsel does not contend this magazine wrap makes heart disease claims.

(*See* CCFF ¶ 384 and Appendix A). As for the other claims in the proposed finding, *see*

Response to Appendix Finding 127.

468. 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 "reduces the risk," like a healthy diet of fruits and vegetables and exercise "reduces the risk" of disease. (CX0314_0006).

Response to Appendix Finding No. 468:
Complaint Counsel does not contend this magazine wrap makes heart disease claims.

(*See* CCFF ¶ 384 and Appendix A). As for the other claims in the proposed finding, *see*

Response to Appendix Finding 128.

469. 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).

Response to Appendix Finding No. 469:
See Response to Appendix Finding 129.

470. 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 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)).

Response to Appendix Finding No. 470:
Complaint Counsel does not contend this magazine wrap makes heart disease claims.

(*See* CCFF ¶ 384 and Appendix A). As for the other claims in the proposed finding, *see*

Response to Appendix Finding 130.

471. Mrs. Resnick testified that the term "Antioxidant Superpower," means that POM Juice is full of polyphenol antioxidants and that when tested against orange, blueberry and cranberry juice and green tea and many other juices, POM Juice is the most impressive in polyphenol antioxidants. (CX1375 (L. Resnick, Dep. at 85-86)).

Response to Appendix Finding No. 471:
Complaint Counsel has no specific response.

472. 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).

Response to Appendix Finding No. 472:
See Response to Appendix Finding 131.

473. Viewing the "The Antioxidant Superpower" ad as a whole, including the interaction of the words and visual imagery, the overall net impression of the ad is the ad is humorous and that POM Juice has antioxidants. ((PX0158-0033); (CX1375 (L. Resnick, Dep. at 85-86))).

Response to Appendix Finding No. 473:
The proposed finding is unsupported by the cited evidence; neither witness refers to the

overall net impression of this magazine wrap.

474. 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)).

Response to Appendix Finding No. 474:
See Response to Appendix Finding 133.

475. 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.

Response to Appendix Finding No. 475:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel does not contend this magazine wrap makes heart disease claims. (*See* CCFF ¶ 384 and Appendix A). As for the other claims in the proposed finding, *see* Response to Appendix Finding 134.

476. 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).

Response to Appendix Finding No. 476:
See Response to Appendix Finding 135.

The First Bottle You Should Open In 2010 - (CX0337)[8]

477. Complaint Counsel claim that on January 3, 2010, POM ran an advertisement with the headline "The First Bottle You Should Open In 2010" with the body copy that appears on CX0337_0001, attached hereto as Ex. 31.

Response to Appendix Finding No. 477:
Complaint Counsel agrees.

478. Complaint Counsel failed to present any other definitive information regarding this ad's dissemination.

Response to Appendix Finding No. 478:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Moreover, the proposed finding is incorrect. (*See* CX0337_0002, CX0474, and CX0371 for additional evidence on dissemination).

479. 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.

Response to Appendix Finding No. 479:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel has presented evidence in CCFF Section VI.E that Respondents have continued to run advertising claims that they had been told were deceptive or misleading.

480. 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.

Response to Appendix Finding No. 480:
The proposed finding mischaracterizes the record and is incorrect. *See* Responses to Findings 2238, 2245 in Respondents' Findings of Fact (Complaint Counsel is challenging

[8] This ad, CX0337, is very similar in images and body copy to the challenged POMx ads CX0331 ('Healthy, Wealthy, and Wise") and CX0280 ("Live Long Enough"), and Complaint Counsel alleges the same net impression for each of these ads. (*See* CCFF ¶ 415-418 and Appendix A). Therefore Complaint Counsel adopts and restates its prior responses to findings regarding CX0331 here, as appropriate.

POM Juice print ads disseminated prior to approximately June 2009 and POM Juice websites as they appeared prior to approximately February 2010). Moreover, the proposed finding is irrelevant because the ad at issue is about POMx.

481. 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. (CX0337_0001).

Response to Appendix Finding No. 481:
See Response to Appendix Finding 156.

482. Complaint Counsel's assertion that the ad 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. (CX0337_0001).

Response to Appendix Finding No. 482:
See Response to Appendix Finding 157.

483. 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.

Response to Appendix Finding No. 483:
See Response to Appendix Finding 158.

484. 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. (CX0337_0001). Even the language of the ad itself uses such qualifiers as "emerging science suggests," "help protect," "promising results," "initial UCLA study," "hopeful results" and "preliminary studies." (CX0337_0001).

Response to Appendix Finding No. 484:
See Response to Appendix Finding 159.

485. 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 "reduces the risk," like a healthy diet of fruits and vegetables and exercise "reduces the risk" of disease. (CX0337_0001).

Response to Appendix Finding No. 485:
See Response to Appendix Finding 160.

486. 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).

Response to Appendix Finding No. 486:
See Response to Appendix Finding 161.

487. 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 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)).

Response to Appendix Finding No. 487:
See Response to Appendix Finding 162.

488. 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)).

Response to Appendix Finding No. 488:
Complaint Counsel has no specific response.

489. 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).

Response to Appendix Finding No. 489:
Complaint Counsel does not disagree that Dr. Butters's report made broad conclusions about the net impression of POM ads in general, but disagrees with his conclusions, including specifically as to this ad.

490. 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)).

Response to Appendix Finding No. 490:
The proposed finding is unsupported by the cited evidence. Complaint Counsel does not

disagree that Dr. Butters's report made broad conclusions about the net impression of

POM ads in general, but disagrees with the conclusion as to this ad

491. 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)).

Response to Appendix Finding No. 491:
See Response to Appendix Finding 166.

492. 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.

Response to Appendix Finding No. 492:
See Response to Appendix Finding 167.

493. 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).

Response to Appendix Finding No. 493:
See Response to Appendix Finding 168.

The Only Antioxidant Supplement Rated X - (CX0351)

494. Complaint Counsel claim that on June 1, 2010, POM ran an advertisement with the headline "The Only Antioxidant Supplement Rated X" with the body copy that appears on CX0351_0001, attached hereto as Ex. 32.

Response to Appendix Finding No. 494:
Complaint Counsel agrees.

495. Complaint Counsel failed to present any other definitive information regarding this ad's dissemination.

Response to Appendix Finding No. 485
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Moreover, the proposed finding is incorrect. (*See* CX0351_0002, CX0474, and CX0371 for additional evidence on dissemination).

496. 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.

Response to Appendix Finding No. 496:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel has presented evidence in CCFF Section VI.E that Respondents have continued to run advertising claims that they had been told were deceptive or misleading.

497. 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.

Response to Appendix Finding No. 497:
The proposed finding mischaracterizes the record and is incorrect. *See* Responses to Findings 2238, 2245 in Respondents' Findings of Fact (Complaint Counsel is challenging POM Juice print ads disseminated prior to approximately June 2009 and POM Juice websites as they appeared prior to approximately February 2010). Moreover, the proposed finding is irrelevant because the ad at issue is about POMx.

498. 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, prostate cancer or erectile dysfunction; or (b) taking one POMx Pill per day is "clinically proven" to "prevent," "treat," or "reduce the risk" of heart disease, prostate cancer or erectile dysfunction. (CX0351_0001).

Response to Appendix Finding No. 498:
Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 425-27, 429).

499. Complaint Counsel's assertion that the ad conveys the message that (a) taking one POMx Pill per day "prevents," "treats," or "reduces the risk" of heart disease, prostate cancer or erectile dysfunction; or (b) taking one POMx Pill per day 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 ad. (CX0351_0001).

Response to Appendix Finding No. 499:
Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 425-27, 429).

500. 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.

Response to Appendix Finding No. 500:
Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 425-27, 429).

501. 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, prostate cancer or erectile dysfunction; 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, prostate cancer or erectile dysfunction. (CX0351_0001). Even the language of the ad itself uses such qualifiers as "emerging science suggests," "help protect," "promising results," "initial UCLA study," "potential," "hopeful results" and "preliminary study." (CX0351_0001).

Response to Appendix Finding No. 501:
Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 425-27, 429).

502. 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, prostate cancer or erectile dysfunction, 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. (CX0351_0001).

Response to Appendix Finding No. 502:
Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 425-27, 429).

503. 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).

Response to Appendix Finding No. 503:
The proposed finding is unsupported by the cited testimony. Dr. Butters did not define "treat" as a substitute for conventional medical treatment. Moreover, the finding is incomplete, because Dr. Butters further testified with respect to this ad, "And the ad -- within the context of the ad, "x" would stand for pomegranate extract and pomegranate extreme. And . . . there was sort of a play on pornography, if you will. So, it could also be kind of X-rated, *because it was supposed to correct erectile dysfunction*." (Butters. Tr. 2946 (emphasis added)). Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 425-27, 429).

504. 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, prostate cancer or erectile dysfunction 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)).

Response to Appendix Finding No. 504:
Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 425-27, 429). However, Complaint Counsel agrees that "proven" does not mean that "everyone in the study" benefitted.

505. Mrs. Resnick testified the purpose of this ad was "just meant to give you a chuckle." (L. Resnick, Tr. 266-67).

Response to Appendix Finding No. 505:
The proposed finding mischaracterizes the cited evidence. In the cited trial transcript,

Mrs. Resnick was testifying specifically about the headline of the ad.

506. 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).

Response to Appendix Finding No. 506:
Complaint Counsel agrees, and further notes that Dr. Butters testified that the meaning of

the ad was that POMx would correct erectile dysfunction. *See* Response to Appendix

Finding 503, above.

507. 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).

Response to Appendix Finding No. 507:
Complaint Counsel does not disagree that Dr. Butters's report made broad conclusions

about the net impression of POM ads in general, but disagrees with his conclusions,

including specifically as to this ad.

508. Viewing the "The Only Antioxidant Supplement Rated X" 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 POMx Pills are healthy and that they may help with erectile dysfunction. ((L. Resnick, Tr. 266-67); (PX0350 (Butters, Dep. at 141); (PX0158-0033)).

Response to Appendix Finding No. 508:
The proposed finding is unsupported by the cited evidence, which does not analyze the

net impression of this ad.

509. 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)).

Response to Appendix Finding No. 509:
The proposed finding mischaracterizes the testimony of Dr. Stewart, who in the cited testimony simply said that he was not asked to do a net impression analysis of the challenged ads and that he did not know whether the Commission had evidence of how consumers perceive the ads at the level of a net impression. Moreover, Complaint Counsel presented evidence as to the meaning of POM advertisements. (*See* CCFF Sections V.C – V.G).

510. 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.

Response to Appendix Finding No. 510:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Moreover, Complaint Counsel presented evidence on the meaning of this and other POM advertisements. (*See* CCFF ¶¶ 425-27, 429 and Sections V.C – V.G).

511. 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).

Response to Appendix Finding No. 511:
The proposed finding is irrelevant. *See* Response to Finding 38 in Respondents' Findings of Fact.

The Only Antioxidant Supplement Rated X - (CX0355)[9]

512. Complaint Counsel claim that on July1, 2010, POM ran an advertisement with the headline "The Only Antioxidant Supplement Rated X" with the body copy that appears on CX0355_0001, attached hereto as Ex. 33.

Response to Appendix Finding No. 512:
Complaint Counsel agrees.

513. Complaint Counsel failed to present any other definitive information regarding this ad's dissemination.

Response to Appendix Finding No. 513:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Moreover, the proposed finding is incorrect. (*See* CX0355_0002, CX0474, and CX0371 for additional evidence on dissemination).

514. 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.

Response to Appendix Finding No. 514:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel has presented evidence in CCFF Section VI.E that Respondents have continued to run advertising claims that they had been told were deceptive or misleading.

515. 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.

Response to Appendix Finding No. 515:
The proposed finding mischaracterizes the record and is incorrect. *See* Responses to Findings 2238, 2245 in Respondents' Findings of Fact (Complaint Counsel is challenging POM Juice print ads disseminated prior to approximately June 2009 and POM Juice

[9] This ad, CX0355, is nearly identical in terms of images and body copy to the challenged POMx ad CX0351, and Complaint Counsel alleges the same net impression for both of these ads. (*See* CCFF ¶ 429 and Appendix A). Therefore Complaint Counsel adopts and restates its responses to findings regarding CX0351 here, as appropriate.

websites as they appeared prior to approximately February 2010). Moreover, the proposed finding is irrelevant because the ad at issue is about POMx.

516. 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, prostate cancer or erectile dysfunction; or (b) taking one POMx Pill per day is "clinically proven" to "prevent," "treat," or "reduce the risk" of heart disease, prostate cancer or erectile dysfunction. (CX0355_0001).

Response to Appendix Finding No. 516:
See Response to Appendix Finding 498.

517. Complaint Counsel's assertion that the ad conveys the message that (a) taking one POMx Pill per day "prevents," "treats," or "reduces the risk" of heart disease, prostate cancer or erectile dysfunction; or (b) taking one POMx Pill per day 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 ad. (CX0355_0001).

Response to Appendix Finding No. 517:
See Response to Appendix Finding 499.

518. 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.

Response to Appendix Finding No. 518:
See Response to Appendix Finding 500.

519. 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, prostate cancer or erectile dysfunction; 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, prostate cancer or erectile dysfunction. (CX0355_0001). Even the language of the ad itself uses such qualifiers as "emerging science suggests," "help protect," "promising results," "initial UCLA study," "potential," "hopeful results" and "preliminary study." (CX0355_0001).

Response to Appendix Finding No. 519:
See Response to Appendix Finding 501.

520. 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, prostate cancer or erectile dysfunction, 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. (CX0355_0001).

Response to Appendix Finding No. 520:
See Response to Appendix Finding 502.

521. 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).

Response to Appendix Finding No. 521:
See Response to Appendix Finding 503.

522. 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, prostate cancer or erectile dysfunction 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)).

Response to Appendix Finding No. 522:
See Response to Appendix Finding 504.

523. Mrs. Resnick testified the purpose of this ad was "just meant to give you a chuckle." (L. Resnick, Tr. 266-67).

Response to Appendix Finding No. 523:
See Response to Appendix Finding 505.

524. 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).

Response to Appendix Finding No. 524:
See Response to Appendix Finding 506.

525. 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).

Response to Appendix Finding No. 525:
See Response to Appendix Finding 507.

526. Viewing the "The Only Antioxidant Supplement Rated X" 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 POMx Pills are healthy and that they may help with erectile dysfunction. ((L. Resnick, Tr. 266-67); (PX0350 (Butters, Dep. at 141); (PX0158-0033)).

Response to Appendix Finding No. 526:
See Response to Appendix Finding 508.

527. 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)).

Response to Appendix Finding No. 527:
See Response to Appendix Finding 509.

528. 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.

Response to Appendix Finding No. 528:
See Response to Appendix Finding 510.

529. 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).

Response to Appendix Finding No. 529:
See Response to Appendix Finding 511.

The power of POM, in one little pill - (CX0169; CX1426_0045 Exh. L)

530. Complaint Counsel claim that, on January 6, 2008, POM ran an advertisement with the headline "The power of POM, in one little pill" with the body copy that appears on CX0169_0001, 34.

Response to Appendix Finding No. 530:
Complaint Counsel agrees.

531. CX1426_0045, Exh. L appears to be identical to CX0169_0001. (CX1426_0045, Exh. L; CX0169_0001, attached hereto as Ex. 34).

Response to Appendix Finding No. 531:
Complaint Counsel agrees.

532. Complaint Counsel failed to present any other definitive information regarding this ad's dissemination.

Response to Appendix Finding No. 532:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Moreover, the proposed finding is incorrect. (*See* CX0169_0002, CX0474, and CX0371 for additional evidence on dissemination).

Respondents also admitted disseminating the exhibits to the Complaint. (PX0364_0003).

533. 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.

Response to Appendix Finding No. 533:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel has presented evidence in CCFF Section VI.E that Respondents have continued to run advertising claims that they had been told were deceptive or misleading.

534. This ad cannot provide a basis for injunctive relief because (a) it ran five years ago; and (b) no evidence exists to show that Respondents are likely to run this ad in the future.

Response to Appendix Finding No. 534:
The proposed finding is a legal conclusion and is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel has

presented evidence in CCFF Section VI.E that Respondents have continued to run advertising claims that they had been told were deceptive or misleading.

535. 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. (CX1426_0045, Exh. L; CX0169_0001).

Response to Appendix Finding No. 535:
Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 407, 410, 412-14).

536. Complaint Counsel's assertion that the ad 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_0045, Exh. L; CX0169_0001).

Response to Appendix Finding No. 536:
Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 407, 410, 412-14).

537. 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.

Response to Appendix Finding No. 537:
Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 407, 410, 412-14).

538. 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_0045, Exh. L; CX0169_0001). Even the language of the ad itself uses such qualifiers as "emerging science suggests," "contributing," "fights," "initial UCLA MEDICAL STUDY," "hopeful results," "preliminary studies" and "pilot research suggests." (CX1426_0045, Exh. L; CX0169_0001).

Response to Appendix Finding No. 538:

Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 407, 410, 412-14).

539. 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 "reduces the risk," like a healthy diet of fruits and vegetables and exercise "reduces the risk" of disease. (CX1426_0045, Exh. L; CX0169_0001).

Response to Appendix Finding No. 539:
Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 407, 410, 412-14).

540. 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).

Response to Appendix Finding No. 540:
The proposed finding is unsupported by the cited testimony. Dr. Butters did not define "treat" as a substitute for conventional medical treatment. He defined "treat" as medical treatment and then asserted that he didn't see any ad stating or implying that POM Products "treated any disease." Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 407, 410, 412-14).

541. 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 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)).

Response to Appendix Finding No. 541:
Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 407, 410, 412-14). However, Complaint Counsel agrees that "proven" does not mean that "everyone in the study" benefitted.

542. 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)).

Response to Appendix Finding No. 542:
The proposed finding mischaracterizes the testimony of Dr. Stewart, who in the cited testimony simply said that he was not asked to do a net impression analysis of the challenged ads and that he did not know whether the Commission had evidence of how consumers perceive the ads at the level of a net impression. Moreover, Complaint Counsel presented evidence as to the meaning of POM advertisements. (*See* CCFF Sections V.C – V.G).

543. 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.

Response to Appendix Finding No. 543:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel does not contend this ad makes erectile dysfunction claims. Moreover, Complaint Counsel presented evidence on the meaning of this and other POM advertisements. (*See* CCFF ¶¶ 407, 410, 412-14 and Sections V.C – V.G).

544. 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).

Response to Appendix Finding No. 544:
The proposed finding is irrelevant. *See* Response to Finding 38 in Respondents' Findings of Fact.

The proof is in the POM - (CX0314_0005)[10]

545. Complaint Counsel claim that, on September 9, 2008, POM ran an advertisement with the headline "The proof is in the POM" with the body copy that appears on CX0314_0005, attached hereto as Ex. 35.

Response to Appendix Finding No. 545:
The proposed finding mischaracterizes the exhibit at issue as an individual ad, when in fact it should be considered together with other pages as a multi-page "magazine wrap" or "cover wrap" ads. *See* Response to Appendix Finding 122. Complaint Counsel agrees that this page were disseminated as part of CX0314_0003-06.

546. Complaint Counsel failed to present any other definitive information regarding this ad's dissemination.

Response to Appendix Finding No. 546:
See Response to Appendix Finding 123.

547. 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.

Response to Appendix Finding No. 547:
See Response to Appendix Finding 124.

548. 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 prostate cancer; or (b) POM Juice is "clinically proven" to "prevent," "treat," or "reduce the risk" of heart disease or prostate cancer. (CX0314_0005).

Response to Appendix Finding No. 548:
Complaint Counsel does not contend that this magazine wrap makes heart disease claims. (CCFF ¶ 384 and Appendix A). As for the other claims in the proposed finding, *see* Response to Appendix Finding 125.

549. Complaint Counsel's assertion that the ad conveys 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

[10] Because this page is part of a magazine wrap, CX0314_0003-0006, and because Complaint Counsel has already responded to similar or identical Findings in this Appendix relating to the same magazine wrap, Complaint Counsel adopts and restates its responses to previous findings regarding CX0314_0003-0006 here, where appropriate.

prostate cancer is not conspicuous, self-evident, or reasonably clear from the face of the ad. (CX0314_0005).

Response to Appendix Finding No. 549:
Complaint Counsel does not contend that this magazine wrap makes heart disease claims.

(CCFF ¶ 384 and Appendix A). As for the other claims in the proposed finding, *see*

Response to Appendix Finding 125.

550. 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.

Response to Appendix Finding No. 550:
See Response to Appendix Finding 126.

551. 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. (CX0314_0005).

Response to Appendix Finding No. 551:
Complaint Counsel does not contend that this magazine wrap makes heart disease claims.

(CCFF ¶ 384 and Appendix A). As for the other claims in the proposed finding, *see*

Response to Appendix Finding 127.

552. 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 "reduces the risk," like a healthy diet of fruits and vegetables and exercise "reduces the risk" of disease. (CX0314_0005).

Response to Appendix Finding No. 552:
Complaint Counsel does not contend that this magazine wrap makes heart disease claims.

(CCFF ¶ 384 and Appendix A). As for the other claims in the proposed finding, *see*

Response to Appendix Finding 128.

553. 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).

Response to Appendix Finding No. 553:
See Response to Appendix Finding 129.

554. 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 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)).

Response to Appendix Finding No. 554:
Complaint Counsel does not contend that this magazine wrap makes heart disease claims. (CCFF ¶ 384 and Appendix A). As for the other claims in the proposed finding, *see* Response to Appendix Finding 130.

555. 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)).

Response to Appendix Finding No. 555:
See Response to Appendix Finding 133.

556. 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.

Response to Appendix Finding No. 556:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel does not contend that this magazine wrap makes heart disease or erectile dysfunction claims. (CCFF ¶ 384 and Appendix A). As for the other claims in the proposed finding, *see* Response to Appendix Finding 134.

557. 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).

Response to Appendix Finding No. 557:
See Response to Appendix Finding 135.

What Gets Your Heart Pumping - (CX0192)

558. Complaint Counsel claim that, on May 1, 2008, POM ran an advertisement with the headline "What gets your heart pumping?" with this body copy:

> Supermodels or beaches? 36-24-36? Or perhaps healthy arteries. Drink POM Wonderful 100% Pomegranate Juice. It helps guard your body against free radicals, unstable molecules that emerging science suggests aggressively destroy healthy cells in your body and contribute to disease. 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. Eight ounces a day is enough to keep your heart pumping, even if you're not dating a supermodel.
>
> **POM Wonderful 100% Pomegranate Juice. The Antioxidant Superpower**

(CX0192_0001, attached hereto as Ex. 36).

Response to Appendix Finding No. 558:
Complaint Counsel agrees.

559. Complaint Counsel failed to present any other definitive information regarding this ad's dissemination.

Response to Appendix Finding No. 559:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Moreover, the proposed finding is incorrect. (*See* CX0192_0002, CX0474, and CX0371 for additional evidence on dissemination).

560. 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.

Response to Appendix Finding No. 560:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel has presented evidence in CCFF Section VI.E that Respondents have continued to run advertising claims that they had been told were deceptive or misleading.

561. Complaint Counsel's assertion that the ad conveys 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 is not conspicuous, self-evident, or reasonably clear from the face of the ad. (CX0192_0001).

Response to Appendix Finding No. 561:
Complaint Counsel does not contend that this ad makes treatment or prostate cancer claims. (*See* CCFF ¶ 367 and Appendix A). As to the other claims in the proposed finding, Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 364-67).

562. 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.

Response to Appendix Finding No. 562:
Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 364-67).

563. 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. (CX0192_0001). Even the language of the ad itself uses such qualifiers as "helps guard," "emerging science," and "initial scientific research" and "encouraging results." (CX0192_0001).

Response to Appendix Finding No. 563:
Complaint Counsel does not contend that this ad makes treatment or prostate cancer claims. (*See* CCFF ¶ 367 and Appendix A). As to the other claims in the proposed finding, Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 364-67).

564. 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 "reduces the risk," like a healthy diet of fruits and vegetables and exercise "reduces the risk" of disease. (CX0192_0001).

Response to Appendix Finding No. 564:
Complaint Counsel does not contend that this ad makes treatment or prostate cancer claims. (*See* CCFF ¶ 367 and Appendix A). As to the other claims in the proposed finding, Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 364-67).

565. 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).

Response to Appendix Finding No. 565:
Complaint Counsel does not contend that this ad makes treatment or prostate cancer claims. (*See* CCFF ¶ 367 and Appendix A). Therefore, the proposed finding is irrelevant.

566. 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 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)).

Response to Appendix Finding No. 566:
Complaint Counsel does not contend that this ad makes treatment or prostate cancer claims. (*See* CCFF ¶ 367 and Appendix A). As to the other claims in the proposed finding, Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 364-67). However, Complaint Counsel agrees that "proven" does not mean that "everyone in the study" benefitted.

567. Mr. Tupper 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)).

Response to Appendix Finding No. 567:
The proposed finding is incomplete; Mr. Tupper further 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 94)).

568. 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).

Response to Appendix Finding No. 568:
Complaint Counsel does not disagree that Dr. Butters's report made broad conclusions about the net impression of POM ads in general, but disagrees with his conclusions, including specifically as to this ad.

569. 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))).

Response to Appendix Finding No. 569:
The proposed finding is unsupported by the cited evidence, which does not analyze the net impression of this ad. Moreover, Mr. Tupper testified that the ad refers to the published medical science around the cardiovascular benefits associated with pomegranate juice. *See* Response to Appendix Finding 567.

570. 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)).

Response to Appendix Finding No. 570:
The proposed finding mischaracterizes the testimony of Dr. Stewart, who in the cited testimony simply said that he was not asked to do a net impression analysis of the challenged ads and that he did not know whether the Commission had evidence of how

consumers perceive the ads at the level of a net impression. Moreover, Complaint Counsel presented evidence as to the meaning of POM advertisements. (*See* CCFF Sections V.C – V.G).

571. 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.

Response to Appendix Finding No. 571:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel does not contend that this ad makes treatment, prostate cancer, or erectile dysfunction claims. As to the other claims in the proposed finding, Complaint Counsel presented evidence on the meaning of this and other POM advertisements. (*See* CCFF ¶¶ 364-67 and Sections V.C – V.G).

572. 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).

Response to Appendix Finding No. 572:
The proposed finding is irrelevant. *See* Response to Finding 38 in Respondents' Findings of Fact.

Your New Health Care Plan - (CX0328)[11]

573. Complaint Counsel claim that on November 8, 2009, POM ran an advertisement with the headline "Your New Health Care Plan" with the body copy that appears on CX0328_0001, attached hereto as Ex. 37.

Response to Appendix Finding No. 573:
Complaint Counsel agrees.

574. Complaint Counsel failed to present any other definitive information regarding this ad's dissemination.

Response to Appendix Finding No. 574:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Moreover, the proposed finding is incorrect. (*See* CX0328_0002, CX0474, and CX0371 for additional evidence on dissemination).

575. 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.

Response to Appendix Finding No. 575:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel has presented evidence in CCFF Section VI.E that Respondents have continued to run advertising claims that they had been told were deceptive or misleading.

576. 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.

Response to Appendix Finding No. 576:
The proposed finding mischaracterizes the record and is incorrect. *See* Responses to Findings 2238, 2245 in Respondents' Findings of Fact (Complaint Counsel is challenging

[11] This ad, CX0337, is very similar in images and body copy to the challenged POMx ads CX0331 ('Healthy, Wealthy, and Wise"), CX0280 ("Live Long Enough"), and CX0337 ("The First Bottle"). Complaint Counsel alleges the same net impression for each of these ads. (*See* CCFF ¶ 415-418 and Appendix A). Therefore Complaint Counsel adopts and restates its prior responses to findings regarding CX0331 here, as appropriate.

POM Juice print ads disseminated prior to approximately June 2009 and POM Juice websites as they appeared prior to approximately February 2010). Moreover, the proposed finding is irrelevant because the ad at issue is about POMx.

577. 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. (CX0328_0001).

Response to Appendix Finding No. 577:
See Response to Appendix Finding 156.

578. Complaint Counsel's assertion that the ad 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. (CX0328_0001).

Response to Appendix Finding No. 578:
See Response to Appendix Finding 157.

579. 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.

Response to Appendix Finding No. 579:
See Response to Appendix Finding 158.

580. 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. (CX0328_0001). Even the language of the ad itself uses such qualifiers as "emerging science suggests," "help protect," "promising results," "initial UCLA study," "hopeful results" and "preliminary studies." (CX0328_0001).

Response to Appendix Finding No. 580:
See Response to Appendix Finding 159.

581. 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 "reduces the risk," like a healthy diet of fruits and vegetables and exercise "reduces the risk" of disease. (CX0328_0001).

Response to Appendix Finding No. 581:
See Response to Appendix Finding 160.

582. 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).

Response to Appendix Finding No. 582:
See Response to Appendix Finding 161.

583. 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 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)).

Response to Appendix Finding No. 583:
See Response to Appendix Finding 162.

584. 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).

Response to Appendix Finding No. 584:
See Response to Appendix Finding 163.

585. 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).

Response to Appendix Finding No. 585:
Complaint Counsel has no specific response.

586. Professor Butters describes this advertisement as a "joking reference to a very serious matter." (PX0350 (Butters, Dep. at 142)).

Response to Appendix Finding No. 586:

The proposed finding mischaracterizes the evidence. In the cited deposition transcript, Dr. Butters was only testifying about the ad's headline. Complaint Counsel does not disagree with Dr. Butters's testimony that the ad references a very serious issue

587. 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))).

Response to Appendix Finding No. 587:
Complaint Counsel does not disagree as to the nature of Dr. Butters's testimony, but disagrees with his unsupported conclusions.

588. 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))).

Response to Appendix Finding No. 588:
See Response to Appendix Finding 166.

589. 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.

Response to Appendix Finding No. 589:
See Response to Appendix Finding 167.

590. 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).

Response to Appendix Finding No. 590:
See Response to Appendix Finding 168.

Your Partner In Promoting Lifelong Health, Volume 1, Issue 1: For Your Heart ("Dreher Heart Newsletter") - (CX1426_0048-0048, Exh. M)

591. Complaint Counsel claim that in the Summer of 2007, Respondents disseminated a newsletter with the title "Your Partner In Promoting Lifelong Health" with the body copy that appears on CX01426_0046-0048, Exh. M, attached hereto as Ex. 38.

Response to Appendix Finding No. 591:
Complaint Counsel agrees.

592. Complaint Counsel failed to present any other definitive information regarding this newsletter's dissemination.

Response to Appendix Finding No. 592:
The proposed finding is incorrect. The newsletter was produced by Respondents from their own files with a notation "POMx Heart Newsletter, Pills and Liquid, Monthly, 2nd Continuity Shipment, Summer '07-present (ongoing)." (CX01426_00046). Moreover, Respondents admit this newsletter was disseminated in their Answer. (PX0364-0003).

593. 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.

Response to Appendix Finding No. 593:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel has presented evidence in CCFF Section VI.E that Respondents have continued to run advertising claims that they had been told were deceptive or misleading.

594. 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.

Response to Appendix Finding No. 594:
The proposed finding is a legal conclusion and is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel has presented evidence in CCFF Section VI.E that Respondents have continued to run advertising claims that they had been told were deceptive or misleading.

595. 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 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).

Response to Appendix Finding No. 595:
Complaint Counsel disagrees with the proposed finding regarding the net impression of

this advertisement. (CCFF ¶¶ 435-39, 441).

596. Complaint Counsel's assertion that the ad 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).

Response to Appendix Finding No. 596:
Complaint Counsel disagrees with the proposed finding regarding the net impression of

this advertisement. (CCFF ¶¶ 435-39, 441).

597. 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.

Response to Appendix Finding No. 597:
Complaint Counsel disagrees with the proposed finding regarding the net impression of

this advertisement. (CCFF ¶¶ 435-39, 441).

598. 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).

Response to Appendix Finding No. 598:
Complaint Counsel disagrees with the proposed finding regarding the net impression of

this advertisement. (CCFF ¶¶ 435-39, 441).

599. 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 "may reduce the

risk" or "reduces the risk," like a healthy diet of fruits and vegetables and exercise "reduces the risk" of heart disease. (CX1426_0046-0048, Exh. M).

Response to Appendix Finding No. 599:
Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 435-39, 441).

600. To the extent a "treat" claim can be implied from this newsletter (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).

Response to Appendix Finding No. 600:
The proposed finding is unsupported by the cited testimony. Dr. Butters did not define "treat" as a substitute for conventional medical treatment. He defined "treat" as medical treatment and then asserted that he didn't see any ad stating or implying that POM Products "treated any disease." Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 435-39, 441).

601. 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 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)).

Response to Appendix Finding No. 601:
Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 435-39, 441). However, Complaint Counsel agrees that "proven" does not mean that "everyone in the study" benefitted.

602. 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)).

Response to Appendix Finding No. 602:
The proposed finding mischaracterizes the testimony of Dr. Stewart, who in the cited testimony simply said that he was not asked to do a net impression analysis of the

challenged ads and that he did not know whether the Commission had evidence of how consumers perceive the ads at the level of a net impression. Moreover, Complaint Counsel presented evidence as to the meaning of POM advertisements. (*See* CCFF Sections V.C – V.G).

603. 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.

Response to Appendix Finding No. 603:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel does not contend that this ad makes prostate cancer or erectile dysfunction claims. (*See* CCFF ¶ 441 and Appendix A). Moreover, Complaint Counsel presented evidence on the meaning of this and other POM advertisements. (*See* CCFF ¶¶ 435-39, 441 and Sections V.C – V.G).

604. 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).

Response to Appendix Finding No. 604:
The proposed finding is irrelevant. *See* Response to Finding 38 in Respondents' Findings of Fact.

Your Partner In Promoting Lifelong Health, Volume 1, Issue 2: For Your Prostate ("Dreher Prostate Newsletter") - (CX1426_0049-0051, Exh. N)

605. Complaint Counsel claim that, in the Fall of 2007, POM ran a newsletter with the title "Your partner in promoting lifelong health" with the body copy that appears on CX01426_0049-0051, Exh. N, attached hereto as Ex. 39.

Response to Appendix Finding No. 605:
Complaint Counsel agrees.

606. Complaint Counsel failed to present any other definitive information regarding this newsletter's dissemination.

Response to Appendix Finding No. 606:
The proposed finding is incorrect. The newsletter was produced by Respondents from their own files with a notation "POMx Prostate Newsletter, Pills and Liquid, Monthly, 3rd Continuity Shipment, Fall '07-present (ongoing)." (CX01426_00049). Moreover, Respondents admit this newsletter was disseminated in their Answer. (PX0364-0003).

607. 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.

Response to Appendix Finding No. 607:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel has presented evidence in CCFF Section VI.E that Respondents have continued to run advertising claims that they had been told were deceptive or misleading.

608. 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 newsletter in the future.

Response to Appendix Finding No. 608:
The proposed finding is a legal conclusion and is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel has presented evidence in CCFF Section VI.E that Respondents have continued to run advertising claims that they had been told were deceptive or misleading

609. 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_0049-51, Exh. N).

Response to Appendix Finding No. 609:
Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 440-41).

610. Complaint Counsel's assertion that the ad 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_0049-51, Exh. N).

Response to Appendix Finding No. 610:
Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 440-41).

611. 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.

Response to Appendix Finding No. 611:
Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 440-41).

612. 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_0049-51, 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_0049-51, Exh. N).

Response to Appendix Finding No. 612:
Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 440-41).

613. 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 "reduces the risk" or "may reduce the risk," like a healthy diet of fruits and vegetables and exercise "reduces the risk" of disease. (CX1426_0049-51, Exh. N).

Response to Appendix Finding No. 613:
Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 440-41).

614. 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; Appendix of Advertisements).

Response to Appendix Finding No. 614:
The proposed finding is unsupported by the cited testimony. Dr. Butters did not define "treat" as a substitute for conventional medical treatment. He defined "treat" as medical treatment and then asserted that he didn't see any ad stating or implying that POM Products "treated any disease." Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 440-41).

615. 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 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)).

Response to Appendix Finding No. 615:
Complaint Counsel disagrees with the proposed finding regarding the net impression of this advertisement. (CCFF ¶¶ 440-41). However, Complaint Counsel agrees that "proven" does not mean that "everyone in the study" benefitted.

616. 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)).

Response to Appendix Finding No. 616:
The proposed finding mischaracterizes the testimony of Dr. Stewart, who in the cited testimony simply said that he was not asked to do a net impression analysis of the

challenged ads and that he did not know whether the Commission had evidence of how consumers perceive the ads at the level of a net impression. Moreover, Complaint Counsel presented evidence as to the meaning of POM advertisements. (*See* CCFF Sections V.C – V.G).

617. 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.

Response to Appendix Finding No. 617:
The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs. Complaint Counsel does not contend that this ad makes heart disease or erectile dysfunction claims. (*See* CCFF ¶ 441 and Appendix A). Moreover, Complaint Counsel presented evidence on the meaning of this and other POM advertisements. (*See* CCFF ¶¶ 440-41 and Sections V.C – V.G).

618. 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).

Response to Appendix Finding No. 618:
The proposed finding is irrelevant. *See* Response to Finding 38 in Respondents' Findings of Fact.