ORIGINAL

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

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

RESPONDENTS' POST-TRIAL BRIEF

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I. SUMMARY OF THE CASE

While trial of this matter was complex, it confirmed that Complaint Counsels' central argument is straightforward scientific and legal error. Complaint Counsel asserts that Respondent POM Wonderful LLC's ("POM") extraordinary science is insufficient to substantiate its health benefit claims because, in Complaint Counsels' view, such claims may only be substantiated by large clinical randomized placebo controlled trials ("RCTs"). That assertion is false, however, as the evidence and expert testimony at trial established. Nutritional science cannot be reduced, by regulatory fiat, into a pharmaceutical testing regime for any health claim about wholesome foods. If Complaint Counsel succeeds in imposing its rigid new RCT requirement to POM's whole food products, Complaint Counsel would, in effect, prohibit the dissemination of all emerging science on the benefits of any food product, even those benefits relating to obviously safe and healthy whole food products derived from fruits or vegetables. Under the false guise of scientific propriety, POM would be just one victim of this crusade which Complaint Counsel is now asking this Commission to formally bless. However, when the best-possible scientific information on human nutrition is suppressed by unscientific paternalism, the American public also suffers.

The United States Supreme Court has already decided this precise point against Complaint Counsel. In *Matrixx Initiatives, Inc. v. Siracusano*, 131 S.Ct. 1309 (2011), the Supreme Court recognized that RCTs are not required to show a causal relationship between a health benefit and a product. The Supreme Court explained that medical researchers "do not limit the data they consider to the results of randomized clinical trials or to statistically significant evidence." *Id.* at 1320. The Supreme Court further recognized that even the FDA "sometimes acts on the basis of evidence that suggests, but does not prove causation." *Id*. Other courts have likewise recognized that Complaint Counsels' attempt to substitute a "one size fits all" approach is both scientifically and legally indefensible. *See In re Pfizer*, 81 F.T.C. 23 (1972) (requiring six part cost-benefit analysis that includes considering claim and type of product);

Pearson v. Shalala, 164 F.3d 650, 656-58 (D.C. Cir. 1999) (advocating cost-benefit analysis and preferring "disclosure over outright suppression").

If that were not enough -- and it is -- in sometimes dramatic fashion at trial, Complaint Counsels' own science experts repeatedly betrayed the fallacy of Complaint Counsels' extreme and unscientific position on RCTs. As one of the more spectacular examples, Complaint Counsels' star expert witness, Professor Meir Stampfer, had explained in a recently published article that RCTs are not necessarily a superior or even an appropriate method for testing the health benefits of nutrients, as distinguished from drugs. (RX 5007 Appendix). In his paper, Professor Stampfer opined specifically that (1) RCTs may not be appropriate for nutrient recommendations to prevent disease, as distinguished from testing drugs used to treat disease; and (2) 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." (RX 5007 at 479-481). That is the scientific truth, and Complaint Counsels' legalistic arguments against it are incorrect and unavailing.

Complaint Counsels' other experts fared no better, admitting at trial that (1) they had personally made significant public health recommendations based on evidence falling far short of RCTs; (2) they had previously performed hundreds of therapies and surgical procedures on patients without the benefit of RCTs (and based only on animal studies), despite the fact that, unlike drinking pomegranate juice, the risks imposed by those procedures included serious bodily injury, and even death; and (3) RCTs may not be scientifically or economically appropriate for testing fruit products. (RFF 299, 342, 346, 348-353, 751). Professor Stampfer and other experts of Complaint Counsel conceded further the central point of this case--that when the risk of harm is slight, an advertiser should err on giving the public information about the potential benefits of the product – without more firmly establishing causality. (RFF 212, 234).

Complaint Counsel have also argued that a singular scientific RCT standard should apply to all "dietary supplements," focusing on POM's pill and liquid extract products, as was required

in *Daniel Chapter One*. However, Complaint Counsels' assumptions were countered by their own former expert witness in that case, Dr. Dennis Miller. Significantly, Dr. Miller testified that the health benefits of POM's 100% juice product, as well as POM's extract products, can certainly be shown without RCTs.

According to Dr. Miller, the primary issues that determine the level of science required to support a health benefit claim are (a) the type of product at issue and (b) whether it is advertised as a replacement for conventional medical care. (RFF 657). As Dr. Miller testified, because POM's products are obviously safe and are not being advertised as a replacement for conventional medical care, RCTs are not required to substantiate claims of a health benefit. Dr. Miller reasoned further that, at least with respect to the areas of within his clinical expertise, POM's claims regarding its products were supported by competent and reliable scientific evidence. He added that under circumstances such as these, where the product is so obviously safe, even sound basic science could be enough to support a health benefit claim. (PX 0206).

The standard described by Dr. Miller, consistent with *Matrixx* and *Pfizer*, is the governing scientific standard for this action. And under that standard, or indeed any credible scientific standard, Respondents have an unprecedented level of science to support their health benefit claims, science which includes RCTs, but is also much broader.

In stark contrast to the science made available to the Commission in *Daniel Chapter One*, Respondents have more than sufficient reliable and credible scientific evidence to form a "reasonable basis" for their claims, including under the FTC's "competent and reliable" standard. The trial covered an unparalleled range of scientific studies supporting the benefits of pomegranate juice for human health. Moreover, while POM has not conducted colossal pharmaceutical-style RCTs at a cost of hundreds of millions of dollars, it has nonetheless conducted significant studies, including RCTs that show health benefits from consuming the Challenged Products.

Complaint Counsels' case also fails because it is premised on an extremely aggressive and unrealistic view of what POM's advertising actually conveys. Specifically, Complaint

Counsel construe all POM's advertising regarding health benefits as conveying the message that the products are "clinically proven" to "reduce the risk of, prevent or treat disease" or that its consumption is a "silver bullet" against disease. But Complaint Counsels' proffered interpretations are inconsistent with a reasonable facial reading of the advertisements in question. Rational consumers understand puffery. They do not believe, for example, that the slogan "Live Forever" means "you will be immortal if you drink this product."

There are clear and important distinctions between saying that (1) a product is good for you, or may assist in improving your odds against disease (just like the Mediterranean diet and regular exercise reduce the risk of disease) and (2) saying it is a "silver bullet" against disease, or is a powerful drug. The public understands that exercise may improve your odds against certain diseases, but they do not thereby consider exercise to be a "silver bullet" against all manner of illness. They must be credited with significantly more intelligence and reason than Complaint Counsel grants them. Additionally, Complaint Counsel attempts to mimic the FDA's regulatory scheme by refusing to distinguish between the alleged "disease claims" types ('treat" or "reduce the risk"), treating them as identical in order to impose a pharmaceutical paradigm upon nutritional advertising. Yet their own medical experts distinguish between "prevent" and "treat" claims in examining the level of scientific support that each claim may require.

In another example of Complaint Counsels' unwillingness to engage the facts that underlie their allegations, Complaint Counsel ignore that consumers know POM's pomegranate juice is a fruit juice. Reasonable consumers do not interpret POM's advertising as conveying claims that the product can treat their diseases, such that they should disregard conventional medical treatments. Instead, reasonable consumers want to be more educated about their diet and nutrition, without thereby abandoning their doctor or conventional medical therapies. As POM's expert, Professor David Reibstein, testified at trial, only 1.9% of POM's juice consumers in the real world reference any specific disease when asked why they purchase the product. Complaint Counsel ask the Commission to ignore the real evidence of how reasonable consumers view the benefits of POM's products, without presenting any of their own extrinsic

evidence to support their implausible assertions about what POM'S advertising supposedly conveys.

Indeed, Complaint Counsel have exercised a complete turnabout in this case. Complaint Counsel conspicuously failed to ask their marketing expert, Professor Michael Mazis, to provide any expert opinion to support their claims on subjects they have previously relied on him for. Specifically, (1) Professor Mazis did not conduct any facial analysis of POM's ads or offer expert opinion on them, the messages they conveyed, or their materiality to the purchasing decisions of consumers; (2) Professor Mazis failed to conduct any independent surveys of the ads to counter the survey presented by Professor Reibstein; and (3) Professor Mazis did not provide any expert opinion on the number of exposures to the ads received by consumers, despite testifying that repeated exposures were critical to having any effect at all on consumers. (Mazis, Tr. 2752; Stewart, Tr. 3228-3229). He testified, in fact, that there was no evidence that Respondents' advertisements caused anyone to buy the Challenged Products. (Mazis, Tr. 90, 95, 96, 2700). Accordingly, on the required element of materiality, and assuming that the presumption in favor of Complaint Counsel applied, Respondents successfully rebutted the presumption and Complaint Counsel has failed to meet their burden of proof.

Consistent with their preference for legal argument over empirical evidence, Complaint Counsel also did not present other evidence significant to their claims.

1. On the issue of falsity, Complaint Counsel failed to present any expert opinion or extrinsic evidence that POM's health benefits were, in fact, false, i.e., that the Challenged Products did not, in fact, provide the health benefits that Complaint Counsel claims POM promised.

2. Although Complaint Counsel challenged the benefits of antioxidants in their pretrial briefing, they essentially forfeited the argument at trial, and presented little, but half-hearted, expert testimony on the subject. By contrast, POM's expert witness, Dr. David Heber, opined that there is strong support for the benefits of antioxidants. In addition, Dr. Heber provided expert testimony supporting the safety of POM's products, the bioavailability of

POM's products, the equivalency of POM Juice and POMx, the several mechanisms of action at play in the human body from the pomegranate's antioxidant and anti-inflammatory properties, as well as the general benefits of the Challenged Products in several areas of human health, including the heart, prostate, and erectile health.

3. Complaint Counsel presented no expert opinion challenging the Challenged Products' safety, despite its importance to the case under *Pfizer*. That omission reflects the fact that Complaint Counsels' own witness, Professor Stampfer, had previously taken a public position on this issue that contradicts Complaint Counsels' position.

4. Complaint Counsel presented no expert opinion or argument on the constituents or contents of the Challenged Products, never denying that they are wholly derived from the pomegranate fruit.

5. Complaint Counsel do not allege and have not presented any expert opinion suggesting that the advertising for the Challenged Products convey the explicit or implied message that the product can be or should be used as a substitute for conventional medical therapies.

As Respondents' pretrial briefing explained, this action is particularly significant because it involves an attempted sea change in American regulatory jurisdiction. In essence, Complaint Counsel wants to seize ground from the FDA, anointing themselves as the primary regulator of claims that manufacturers make about the health benefits of food products. In doing so, Complaint Counsel implicitly derogates the FDA's authority, and improperly subjects all American advertising and promotion to Complaint Counsels' misinterpretation of the FDA's pharmaceutical regulation regime. That short cut is not permitted by law.

Instead, Complaint Counsel is bound by the flexible standards reflected in *Matrixx* and *Pfizer*, and consistent with Dr. Millers' assessment of the relevant cost-benefit considerations to determine the type of science necessary to support a claim. And under that standard, Complaint Counsel have entirely failed to prove their case against POM's advertising.

In addition, Complaint Counsel's legal argument that only RCTs matter is also not legally sustainable for at least the following reasons:

1. Complainant's argument that "one size fits all" is contrary to the "reasonable basis" test under *Pfizer* that requires the Court to consider, among other things, the type of "product" at issue and to engage in a cost-benefit analysis to determine whether a "reasonable basis" exists for the claim.

2. Complainant's interpretation of the *Pfizer* factors, which ignores the food vs. drug distinction, tacitly permits the FTC to dictate, in effect, a rigid legal standard requiring RCTs, subsuming all the other *Pfizer* factors, merely by retaining testifying experts who work almost exclusively in the pharmaceutical drug arena, and who recognize only RCTs. This interpretation of the *Pfizer* factors would turn the "reasonable basis" test on its head, violate the commercial speech cases of *Pearson v. Shalala* discussed further below, and allow testifying pharmaceutical scientists, to dictate a legal standard retroactively, violating Respondents' due process rights under the Administrative Procedures Act ("APA") (5 U.S.C. § 500, *et seq*.) and the Fifth Amendment.

3. Complainant's argument represents a complete turnabout from its own previously issued policy statements. The FTC previously conceded that the rigid standard now advocated here improperly implicates the First Amendment.

4. Separate and apart from Complainant's position on *Pfizer*, this Court must be guided by the commercial speech doctrine line of cases under, *Pearson v. Shalala*, 130 F. Supp. 2d 105 (D.D.C. 2001) ("*Pearson II*"), *Pearson v. Thompson*, 141 F. Supp. 2d 105 (D.D.C. 2001) ("*Pearson III*"), *Whitaker v. Thompson*, 248 F. Supp.

2d 1 (D.D.C. 2002) ("*Whitaker I*"), *Whitaker v. Thompson,* 239 F. Supp. 2d 43 (D.D.C. 2003) (*"Whitaker II"*), and *Alliance for Natural Health, supra,* 714 F. Supp. 2d 48. These cases, following *Central Hudson Gas & Electric Corp. v. Public Service Commission of New York,* 447 U.S. 557, 100 S.Ct. 2343 (1980), insist that the determination of whether commercial speech is "false or misleading" cannot depend on whether there exists significant scientific agreement in support for the claim; *i.e.* speech cannot be deemed false or misleading merely because experts do not agree, as that standard would require commercial actors to show the statements are in fact true (although POM can show this in any event), and go well beyond what is required to show the speech is not "false or misleading." Instead, it is enough, under these cases, that there exists "credible evidence" for a claim. This Court's construction of *Pfizer's* "reasonable basis" test, as well as the FTC's own competent and reliable test, should be applied, if at all, consistent with the *Pearson v. Shalala* line of cases.

Just as significant, Complaint Counsel seek to implement, for the first time, a radically new mechanism in its proposed order against POM that incorporates the FDA's prior approval system. This would require POM to obtain prior approval by the FDA before making certain health claims in advertisements. This blatant attempt to prevent reoccurrence of the agency's loss in the district court in *Lane Labs* is unsustainable for at least the following reasons:

1. Complainant's requirement that Respondents obtain prior FDA-approval before making certain health claims in advertising bears no rational relationship to the conduct challenged in the complaint. Although Complaint Counsel may seek a remedy deemed adequate to cope with alleged unlawful practices, the remedy

must have a "reasonable relation to the unlawful practices found to exist." *Standard Oil Co. v. FTC*, 577 F.2d 653, 662 (9th Cir. 1978). Here, by requiring prior FDA approval, Complaint Counsel are stifling Respondents' ability (and right) to make any health claims regarding a fruit juice (and its derivatives) given the FDA's stringent requirements for approving a new drug. This restriction is not narrowly tailored and bears no reasonable relation to the conduct alleged in this case.

2. In addition, the requirement to obtain prior approval by the FDA before making health claims constitutes an impermissible shift of the government's burden to justify its restrictions on speech. *See Thomas v. Chcagoi Park Dist.*, 534 US 316, 122 S. Ct 775; 151 L.Ed. 2d 783 (2002); *United States v. Playboy Entm't Group, Inc*. 529 US 803, 120 S.Ct. 1878; 146 L.Ed. 2d 865 (2000). The D.C. Court of Appeals in *Pearson v. Shalala* (and in the progeny of that case) make clear, however, that independent of the Nutrition Labeling and Education Act ("NLEA"), Pub.L. No. 101-535, 104 Stat. 2353 (1990) (21 U.S.C. § 343 *et seq*.), the FDA (and, indeed, every agency of this government that would presume to restrict health claims) may not impose a prior restraint on nutrient-disease claims unless it first carries the burden of establishing that no qualification of the claim is sufficient to eliminate its alleged misleadingness. *See Pearson I*, 164 F.3d at 659; *Pearson II* 130 F.Supp. 2d at 112-13, 118-19; *Pearson III*, 141 F.Supp. 2d at 112; *Alliance for Natural Health*, 714 F.Supp. 2d at 53, 62, 65; *Whitaker I*, 248 F.Supp. 2d at 14.

As reflected at the trial of this matter, Complaint Counsel's aggressive "New World Order" that it is asking the Commission to adopt, should be rejected.

II. THE PARTIES' PRESENTATION OF EVIDENCE AT TRIAL

An exceptional amount of evidence was presented at trial and is part of this record. During nineteen days of trial, twenty-four live witnesses testified, including all fourteen experts, and over fifteen hundred exhibits were admitted into the record. Moreover, the amount of scientific evidence presented in support of Respondents' position is unprecedented for a food company, such as POM. Complaint Counsel, in essence, agreed with this very proposition at the outset of the trial. Indeed, Complaint Counsel conceded during the course of Ms. Hippsley's opening statement that this case is different from previous cases brought before the Commission. (RFF 20). Specifically, more than ninety scientific studies and reports are part of the record in support of Respondents' case. (RFF 22). Thus, as is reflected by Respondents' extensive body of scientific evidence and Complaint Counsels' admission, Respondents are indeed not selling "snake oil." (RFF 20).

A. Respondents' Experts

Respondents offered the testimony of eight expert witnesses during the course of the trial. Respondents' experts testified regarding the extraordinary body of credible scientific evidence demonstrating that the Challenged Products have significant health benefits supporting any reasonable construction of POM's advertisements. With respect to the science, Respondents offered the testimony of Drs. Denis Miller, David Heber, Dean Ornish, Arthur Burnett, Irwin Goldstein and Jean deKernion. Respondents also presented expert testimony of Professor Ronald Butters that none of POM's advertisements stated or implied that the Challenged Products actually prevented or treated any disease. Respondents also presented expert testimony of Professor David Reibstein who rebutted any presumption of materiality.

1. Dr. Denis Miller

Dr. Denis Miller, who is an esteemed pediatric oncologist with over forty years of clinical and research experience, confirmed that the consensus of the scientific community would be that Respondents do not need RCTs to substantiate POM's claims because the Challenged Products are absolutely safe, pure fruit products. (RFF 110-111). He also opined that Respondents have never suggested that the Challenged Products be used as substitutes for conventional medical treatment. Above all else, Dr. Miller recognized that the nature of the product and its safety are the linchpins in determining the level of substantiation required to support one's claim. (RFF 116).

Moreover, Dr. Miller has previously testified as an expert for Complaint Counsel in several other matters, such as the *Daniel Chapter One* case. (RFF 115). Dr. Miller made it clear that the case against Respondents is absolutely different from the case against the respondents in *Daniel Chapter One*. Unlike the facts here, the respondents in *Daniel Chapter One* produced no reliable science, their product was recommended in place of conventional medical treatment and had potentially toxic side effects. (RFF 117-118).

2. Dr. David Heber

Respondents offered Dr. David Heber, a practicing physician, Professor of Medicine and Public Health at UCLA and the Director of the UCLA Center for Human Nutrition which he founded in 1996 within the UCLA School of Medicine. (RFF 120). Dr. Heber conclusively established that the Challenged Products are safe, bioavailable and bioequivalent in providing health benefits to humans. (RFF 129-130).

Dr. Heber also reviewed Respondents' substantive bodies of science in the areas of cardiovascular, prostate and erectile health. He concluded that 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. (RFF 131). Dr. Heber also concluded that it is likely that the Challenged Products lengthen PSA doubling time for men who have prostate cancer and that those men may experience a deferred recurrence of the disease or death from prostate cancer. (RFF 132). Moreover, Dr. Heber opined that the Challenged

Products are likely to reduce the risk of prostate problems for men who have not yet been diagnosed with prostate cancer. (RFF 133).

Furthermore, Dr. Heber opined that animal studies showed that pomegranate juice markedly improved 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. (RFF 134). Additionally, Dr. Heber opined that the *Forest/Padma-Nathan RCT Study* (as defined herein) showed that consumption of POM Juice significantly improved erectile function among men with erectile dysfunction. Dr. Heber opined that that the study had major clinical significance in showing a benefit from POM Juice despite barely missing statistical significance. (RFF 135).

Dr. Heber testified as to the proper substantiation standard applicable to the Challenged Products. Dr. Heber, like Dr. Miller, agreed that POM's health claims with respect to the Challenged Products can be properly substantiated without RCTS, which he opined are both expensive and often unreliable in dealing with foods, as opposed to drugs. (RFF 125). Dr. Heber opined that experts in nutrition evaluate whether competent and reliable science support health claims for safe, pure fruit products such as pomegranate juice based on the totality of evidence, which does not necessarily include RCTs. (RFF 126).

3. Dr. Dean Ornish

Respondents offered Dr. Dean Ornish as an expert in the area of cardiovascular health, a world renowned medical doctor and clinical professor of medicine at the University of California at San Francisco. (RFF 136). Dr. Ornish validated POM's use of basic science to support POM's cardiovascular health claims and affirmed pomegranate juice's beneficial impact on reducing the risk of cardiovascular disease.

Dr. Ornish testified that, in a nutritional context, *in vitro* and animal studies may be more effective in testing the efficacy of a nutrient. (RFF 141). Dr. Ornish opined that the totality of Respondents' scientific evidence must be considered when making cardiovascular health claims, which need not be substantiated by expensive RCTs. (RFF 140). Moreover, Dr. Ornish opined that Complaint Counsels' rigid 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. (RFF 142). 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. (RFF 143).

4. Dr. Arthur Burnett

Respondents offered Dr. Arthur Burnett as an expert in the area erectile health, a Professor of Urology at the Johns Hopkins University School of Medicine/Johns Hopkins Hospital who is world-renowned for his groundbreaking work on nitric oxide. (RFF 144, 2007-2024). Dr. Burnett has treated between 10,000 and 15,000 patients for erectile dysfunction. (RFF 148, 2011). Dr. Burnett validated POM's science that establishes that pomegranate juice is beneficial to erectile health. (RFF 151, 2100-2106).

Dr. Burnett opined that Respondents' basic scientific and clinical evidence supports the conclusion that pomegranate juice's high antioxidant content improves erectile health and function by increasing the level and preservation of nitric oxide. (RFF 153, 2095, 2100-2106). Dr. Burnett also concluded that a safe pure fruit juice, like pomegranate juice, which is not used as a substitute for proper medical treatment, does not require RCTs to substantiate health claims. (RFF 154; 2120-2123).

5. Dr. Irwin Goldstein

Respondents offered Dr. Irwin Goldstein as an expert in sexual medicine and on the impact of pomegranate juice, antioxidants, and nitric oxide on erectile function and dysfunction. (RFF 155-164; 2025-2046). Dr. Goldstein is a board certified urologist and sexual medicine physician who has been involved in sexual medicine clinical practice, clinical research, and basic research since 1980. (RFF 155; 2025-2046). Dr. Goldstein affirmed that competent and reliable scientific evidence fully supports that pomegranate juice produces a benefit to proper and effective erectile function. (RFF 164; 2098-2099).

Dr. Goldstein opined that RCT studies are not required to substantiate claims that pomegranate juice can aid in erectile health and that *in vitro* and animal studies demonstrated a

likelihood that pomegranate juice improves erectile health. (RFF 162; 2120-2122; 2098-2099). Dr. Goldstein also opined that the consumption of pomegranate juice is a logical option for men who are not responsive to conventional drugs or who are unwilling to consider invasive or mechanical therapies for treatment of their erectile dysfunction. (RFF 163; 2112).

6. Dr. Jean deKernion

Respondents offered Dr. Jean deKernion as an expert in the area of prostate health. (RFF 165-174). Dr. deKernion is the Chairman of the Department of Urology and Senior Associate Dean for Clinical Affairs at the UCLA School of Medicine and served as the Dean of Urology at the UCLA School of Medicine for twenty-six years. (RFF 165-166). Dr. deKernion is also a practicing urologist certified by both the American Board of Surgery and the America Board of Urology. (RFF 167). Dr. deKernion confirmed that the Challenged Products are beneficial to prostate health.

Dr. deKernion opined there is a high degree of probability that the Challenged Products inhibit the clinical development of prostate cancer cells even in men that have not diagnosed with prostate cancer. (RFF 173). Dr. deKernion also concluded there was a high degree of probability that the Challenged Products provide a special benefit to men with PSA after radical prostatectomy and that POM products lengthened PSA doubling time and, thus, may defer death from prostate cancer. (RFF 174). Dr. deKernion confirmed the findings of the PSA doubling-time studies of Drs. Pantuck and Carducci which both showed a dramatic lengthening of PSA doubling time. (RFF 172). Dr. deKernion further opined that that PSA doubling-time is a valid and effective endpoint for recurrence and death from prostate cancer after a radical prostatectomy. (RFF 172).

7. Professor Ronald Butters

Moreover, Respondents offered Professor Ronald Butters as an expert in the field of linguistics, and he testified to the meaning of Respondents' advertisements. (RFF 175). Professor Butters viewed all of Respondents' advertisements listed in Complaint Counsels' complaint and all the advertisements admitted into evidence. He considered all of Respondents

advertisements in their totality. (RFF 180). He also took into account the nature of the Challenged Products and based his opinion on the actual language in the advertisements and the implied messages as would be interpreted by a reasonable person. (RFF 181-183).

In summary, Professor Butters concluded that none of Respondents advertisements stated explicitly or implied that the Challenged Products actually prevented or cured any disease. (RFF 183). He also testified that none of Respondents' 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. (RFF 184).

8. Professor David Reibstein

Respondents offered Professor Reibstein as an expert on materiality. (RFF 186-189). Professor Reibstein is a professor of marketing at The Wharton School at The University of Pennsylvania, has designed and executed hundreds of surveys and market research studies, including studies concerning consumer behavior. (RFF 186, 188). Professor Reibstein's survey demonstrated that fewer than 1.5% of buyers (i) bought (ii) would buy again or (iii) would recommend to a friend POM Juice because they believe it cures or prevents a specific disease. (RFF 2565; 2577; 2593; 2600-2607; 2619).

III. COMPLAINT COUNSELS' EXPERTS

Unlike Respondents' experts, all of Complaint Counsels' proffered experts were significantly impeached and failed to offer opinions on many of the critical subjects at issue in this case. First, although they initially espoused a drug standard requiring RCTs to substantiate the health benefits of a natural food product, Complaint Counsels' experts subsequently contradicted themselves and conceded a lesser standard of evidence is in fact appropriate. Second, Complaint Counsels' experts did not provide any testimony denying the bioavailability, absorbency, or safety of the Challenged Products or challenging the equivalency of POM Juice and POMx. In addition, Complaint Counsel failed to provide any expert testimony on what message Respondents' advertisements convey or on materiality, including a factual analysis of the ads or a competing survey.

A. Professor Meir Stampfer

Complaint Counsel offered the expert opinion of Professor Meir Stampfer on the subject of nutrition and its relationship to the prevention and treatment of cardiovascular disease, and prostate cancer. (RFF 206-218). Professor Stampfer, however, is not a practicing physician, cardiologist, or urologist. (RFF 206). At trial, contrary to opinions expressed in his expert report, Professor Stampfer conceded that are RCTs are not required (or even better) for nutritional-based research and admitted that he has made public statements or recommendations that food and beverage products lower the risk of certain diseases, in the absence of RCTs and even when the product is not completely safe. (RFF 208-209).

Moreover, Professor Stampfer provided no opinion on the safety or bioavailability of the Challenged Products , the equivalency of POM Juice and POMx, or the several mechanisms of action at play in the human body from the pomegranate's antioxidant and anti-inflammatory properties. (RFF 214).

B. Dr. Arnold Melman

Dr. Arnold Melman testified as Complaint Counsels' expert in the field of urology and erectile health. (RFF 220). Dr. Melman, like Professor Stampfer, also contradicted himself when he confessed to have marketed a gene transfer therapy for erectile dysfunction (described as "modifying the aging process" and "fountain of youth") based solely on animal research. Dr. Melman admitted he made such recommendations knowing that people have died and become very sick from gene transfer therapy and without the support of elaborate clinical studies he previously required. (RFF 224-225).

C. Dr. James Eastham

Dr. James Eastham testified as Complaint Counsels' expert in the field of urology, specializing in prostate cancer. (RFF 228-231). At trial, Dr. Eastham testified that RCTs are necessarily 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. (RFF 228). Despite his insistence that RCTs are needed to support claims made about a harmless

product, such as fruit juice, Dr. Eastham nonetheless has performed hundreds of prostatectomies, which carry the risk of very serious side effects, even without the support of RCTs. (RFF 229). Dr. Eastham also insisted that no one accepts PSA doubling time as a surrogate for progression or death from prostate cancer. (RFF 230). 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." (RFF 230-231).

D. Dr. Frank Sacks

Dr. Frank Sacks testified as Complaint Counsels' expert in nutrition and cardiovascular disease. (RFF 232-237). 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. (RFF 232). However, he conceded that his requirement of two RCTs is the FDA standard for drugs, and he admitted that in evaluating a natural food, RCTs are simply not necessary in all cases. (RFF 234). For example, 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. (RFF 235)).

E. Professor David Stewart

Complaint Counsel offered Professor David Stewart as a rebuttal witness to Professor Ronald Butters. (RFF 238). Professor Stewart conceded that he was not offering any opinion on how consumers would interpret Respondents' advertisements, but was only criticizing Professor Butters' methodology. (RFF 239). Indeed, he stated that he did not even know if Complaint Counsel had any evidence on the meaning of the advertisements. (RFF 239). Additionally, Professor Stewart conceded that he was not opining on Respondents' intent and did not know the intent of POM's advertising. (RFF 246).

F. Professor Michael Mazis

Complaint Counsel offered Professor Michael Mazis as a rebuttal expert to Professor Reibstein. (RFF 247). Professor Mazis testified that a statement is material only if it affects consumers' purchasing decision. (RFF 249). However, Professor Mazis conceded that, to his knowledge, there was no evidence that Respondents' advertisements caused anyone to buy the Challenged Products because they prevented, cured or treated any disease or even that "POM ads were material to the purchase decision." (RFF 249).

IV. THE MANUFACTURE, SALE AND SAFETY OF THE CHALLENGED PRODUCTS

A. The Challenged Products Are Wholly Derived From The Pomegranate

The Challenged Products are either a safe food product or dietary supplement wholly derived from the pomegranate fruit. (RFF 493-494). The POM Juice is produced by pressing the whole fruit containing both arils (pomegranate berries) and the peel (aka husk) and internal membrane. 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. (RFF 494; CX1363 (S. Resnick, Dep. at 46-47).

B. The Challenged Products Are Not Advertised Or Marketed As Drug Products

POM has never advertised the Challenged Products as drugs. (RFF 495; Tupper Tr. at 3008). Nor has POM ever intended to advertise POM Juice as a drug. (RFF 496; Tupper Tr. at 3008). POM's primary audience are affluent, health conscious customers, who want to take an active approach to health via good nutrition. (CX1375; (L. Resnick, Tropicana Dep. at 131); CX 1357 (Kuymoomjian, Dep. at 102).

Neither of the Challenged Products are labeled to say they are drugs or that they "treat" or "prevent" any condition. For example, the drug aisles of a grocery store may contain products such as "'Tough Actin' Tinactin," that state on the product that it "prevents" or "cures" most athlete's foot, or ads for Bengay that state the product "stops pain" and provides "fast relief from minor arthritis, backache, muscle & joint pain." The Challenged Products, however, are not advertised or marketed in this way. (RFF 500-501).

POM Juice is sold in the refrigerated produce section of the grocery store. (RFF 499, 500). Consumers must go to the fresh produce aisle of a store to purchase any POM Juice product. (RFF 498) (CX0967_0014). Further, the marketing for POMx includes the whole food nutritional story that it is "The Power of Pom, now in a Pill." (RFF 495, 501) (CX 1359 (L.Resnick, Dep. at 194-95)).There is no advertising for POMx that suggests it is something other than fruit derived, or that it treats or prevents anything (unlike "Tough Actin' Tinactin," Ben Gay or any pharmaceuticals). Rather it is marketed to those interested in the fruit, but without the calories or sugar. (RFF 501, 502).

C. The Challenged Products Are Safe for Human Consumption

The pomegranate in its various forms (including POM Juice, POMx Pills and POMx Liquid) is safe for human consumption. The safety of these products has been clearly established by FDA regulations regarding pomegranates, scientific studies conducted by premier scientists and the expert opinion of Dr. David Heber. Complaint Counsel have failed to rebut these facts.

First and foremost, Complaint Counsel presented no evidence that the Challenged Products are not safe for human consumption. (RFF 1033-1039). Indeed, Complaint Counsel presented no affirmative evidence such as expert opinion, scientific studies or literature, lay testimony or any other evidence relevant to whether the Challenged Products are safe for human consumption. (RFF 1033-1039). In fact, it was not within the scope of any of Complaint Counsels' experts' assignments, and none opined in their expert report, on the safety of the Challenged Products. (RFF 1033-1034). Complaint Counsels' expert, Dr. Sacks and Professor Stampfer, admitted that both have no opinion about whether the Challenged Products are safe or not. (RFF 1035-1038).

Moreover, Complaint Counsels' experts, Drs. Sacks and Melman, both conceded that there are no adverse side effects associated with consuming pomegranate juice. (RFF 1038-1039). And Professor Stampfer conceded that there is no safety concern with consuming pomegranate juice apart from it being a sugary beverage, "but that is not specific to pomegranate juice." (RFF 1035, 1039).

Second, the FDA identifies pomegranate as being "generally recognized as safe" ("GRAS") for human consumption. See 32 U.S.C. § 231(s); 21 C.F.R. § 182.20; (RFF 1000-1002). To establish such recognition, it must be shown that there is a consensus of expert opinion regarding the safety of the use of the substance. 21 C.F.R. § 170.30(a).

Third, the body of modern science also confirms that POM Juice and POMx are safe for human consumption. *See, e.g.,* 21 CFR §§ 170.30, 182.20. Researchers at Accelovanc Inc. in San Diego also validated the safety of POMx Pills in a clinical study where no adverse events or changes in blood count, serum chemistry or urinalysis was observed in the human subjects after consuming the extract for four weeks. (RFF 1005-1029). Researchers at Tufts University School of Medicine also confirmed in a clinical study that the consumption of pomegranate juice had no drug interaction in the human volunteers. (RFF 1005-1029). The results of another study examining the toxicity of POMx oil in rats continuously exposed to the product over a 90-day test period also revealed no adverse events that were considered to be of toxicological significance. (RFF 1030-1032).

Finally, Respondents' expert, Dr. Heber, opined that pomegranate juice and its extract have a "high degree" of safety and are safe for human consumption. (RFF 994-995). Dr. Heber testified that humans have consumed pomegranate juice for centuries as a safe and nutritious food and confirmed that unlike some drugs, pomegranate juice has no adverse side effects. (RFF 991- 999). Complaint Counsel presented no contradictory evidence. (RFF 1033-1039). Similarly, Dr. Heber is not personally aware of any reported cases of toxicity where consumers were injured by drinking pomegranate juice. (RFF 1004).

V. THE DEVELOPMENT OF POM'S SCIENCE PROGRAM

A. Initiation Of The Program

Years before selling POM Juice, the Resnicks set out to better understand the health benefits of the pomegranate, both because of Mr. Resnick's own personal battle with cancer and the folklore surrounding the fruit's medicinal properties. RFF . In 1998, the Resnicks collaborated with Dr. Michael Aviram, world-renowned for his groundbreaking work exploring

the antioxidant properties of red wine, to assist them in learning about the antioxidant power and potential health 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). What Dr. Aviram saw in his initial research was remarkable and he told Mr. Resnick that the antioxidant properties in the pomegranate were the most powerful he had ever researched. (CX1358 (Aviram, Dep. at 7); PX0004; CX1363 (S. Resnick, Coke Dep. at 66)).

Dr. Aviram's initial research spawned a massive scientific undertaking by the Resnicks, who invested more than $35 million in scientific research. (S. Resnick, Tr. 1864; CX1363 (S. Resnick, Coke Dep. at 74; Tupper, Tr. 1015). The Resnicks have recruited renowned scientists to conduct research at some of the most prestigious academic and research institutions in the world. (Liker, Tr. 1878-80, 1887-89; CX1350 (Liker, Dep. at 32-33); S. Resnick, Tr. 1857, 1860-61). Indeed, POM has sponsored more than a hundred studies on the pomegranate, including seventeen published human studies, at forty-four respected institutions. (Liker, Tr. 1887-88; PX0014; PX0050; PX0060; PX0061; PX0004; PX0006; 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).

B. Respondents' Methodology In Sponsoring Studies

Respondents established that they engage in a diligent effort to ascertain the truth about the existence of the health benefits from consuming pomegranates. In doing so, they consulted with many of the most esteemed scientists and scientific advisors in the country to help guide them in designing the studies, in interpreting results and in setting the direction of Respondents' future research. (RFF 378-439; Liker, Tr. 1889-91). The goal in substantial part was to conduct well-designed research that would yield credible and reliable results. (RFF 378-439; Liker, Tr. 1878-80, 1887-89; CX1350 (Liker, Dep. at 32-33); S. Resnick, Tr. 1857, 1860-61).

Multiple groups of distinguished scientists and advisors help guide Mr. Resnick in his selection of the science. (RFF 378-390; Liker, Tr. 1889-91). Mr. Resnick has regular meetings with POM's Medical Director, Dr. Harley Liker, and POM's Chief Science Officer. (RFF 385-389, 326-328; Liker, Tr. 1889-91; PX0524 (S. Resnick Dep. at 32); PX0326 (Gillespie Dep. at 32-34, 36-37). Mr. Resnick also attends POM's research summits wherein the scientists conducting the research discuss the ongoing findings of their research. (RFF 329-334, 384; Liker, Tr. 1890-92; Tupper, Tr. 1026-27; S. Resnick, Tr. 1858-59, 1872; CX1360 (S. Resnick, Dep. at 157-58)).

Mr. Resnick is also advised by experts in their respective fields who participate in POM's advisory board meetings. (RFF 378-380, 385; S. Resnick, Tr. 1859; Liker, Tr. 1892-93). Generally speaking, 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. (RFF 336; Liker, Tr. 1889-93). Members of POM's advisory boards discuss the studies that are ongoing as well as those that have been completed and make recommendations about the direction of POM's future research. (RFF 337-338; S. Resnick, Tr. 1859; Liker, Tr. 1892-93). POM's scientific advisory boards are divided by health areas but each is made up of highly regarded individuals in the scientific and regulatory world. (RFF 339; Liker, Tr. 1892-93). Members of POM's scientific advisory boards have included Dr. Phillip Kantoff, who is employed at the Dana-Farber Cancer Institute at Harvard Medical School and runs the genitourinary oncology program. (RFF 339-341; Liker, Tr. 1892; Kantoff, Tr. 3257). Dr. David Kessler, the former head of the FDA, has also participated in POM's research advisory meetings. (RFF 340-342; S. Resnick, Tr. 1859, 1872). Impressively, Dr. P.K. Shah of Cedars-Sinai Medical Center, who is a world-renowned cardiologist, has also been involved with POM's advisory group. (RFF 343-344; Liker, Tr. 1893).

C. The High Cost Of Conducting RCTs

Respondents have chosen to sponsor basic research, clinical studies and some RCTs. Mr. Resnick, however, has not sponsored any large RCTs that would typically be required for drug approval because economics necessarily play a role in defining the parameters of Respondents' research. (RFF 360; Liker, Tr.1886-87; S. Resnick, Tr. 1716). For example, Mr. Resnick has sometimes declined to add more participants to a study when asked. (RFF 323; S. Resnick, Tr. 1716; Liker, Tr. 1886-87; PX0050; PX0344 (Liker, Dep. at 37-38, 188-89)).

Respondents believe that, despite not conducting large and lengthy RCTs, their science is both competent and reliable. Moreover, Respondents deny that they have ever sacrificed the studies' scientific integrity, soundness, or reliability. Instead, Respondents characterize their decisions as normal economic-based decisions necessary to moderate costs. (RFF 364; S. Resnick, Tr.1716-18; CX1360 (S. Resnick, Dep. at 228-29)).

D. Respondents' Reliance Upon The Peer-Review Process

Respondents also relied, in part, on the peer-review process, including the publication in prestigious, peer-reviewed journals as an indication that the sponsored science was both credible and reliable. (RFF 391-394; Liker, Tr. 1899-1900). *See, e.g.*, *Daubert v. Merrell Dow Pharms*, 43 F.3d 1311, 1318 (9th Cir. 1995) ("[A]ccept[ance] for publication in a reputable scientific journal after being subjected to the usual rigors of peer review is a significant indication that [the research] is taken seriously by other scientists, *i.e.*, that it meets at least the minimal criteria of good science.").

In this case, more than seventy of Respondents' studies have been published in prestigious peer-reviewed journals. (RFF 393; Liker, Tr. 1888). At a minimum, the publication of Respondents' research is evidence that the scientists at those prestigious journals had vetted the research Respondents conducted and considered the studies important enough to publish them.

E. Respondents Relied Upon The Statements Of Scientists To Understand The Benefits Shown From The Research

Respondents also reasonably relied, in part, upon statements by well-regarded scientists regarding the results of the studies. (RFF 395-435) (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)).

1. Statements Regarding Respondents' Promising Cardiovascular Research

Many of Respondents' scientists made promising statements regarding the results of Respondents' cardiovascular research conducted on pomegranate products. Respondents reasonably relied on those statements to evaluate the results of the research.

For example, 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. (RFF 396-415; CX1363 (S. Resnick, Coke Dep. at 57, 66)).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))

- Similarly, in an August 2008 email, sent to Stewart and Lynda Resnick and Matt Tupper, Dr. Aviram stated "[t]he 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)

- Dr. Aviram stated in a January 2008 email that pomegranate juice and POMx were "very potent protectors against cardiovascular diseases." (PX0479-0001). 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). Dr. Aviram provided his opinion to Respondents that POMx "indeed promotes cardiovascular health." (PX0500-0003)

- Dr. 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). 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)). 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))

- Dr. Ornish, in an email to Respondent Stewart Resnick and cc'ing Respondent Matt Tupper, announced the acceptance of his myocardial perfusion study and 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). Additionally, in an email cc'ing both Stewart and Lynda Resnick, Dr. Dean Ornish characterized the health benefits of pomegranate juice as "extraordinary." (PX0511).

Additionally, other doctors and cardiovascular researchers who were deposed in this case further corroborated that Respondents research showed a benefit from consuming pomegranate juice. (RFF 404-409; CX1350 (Liker, Dep. at 222); CX1358 (Aviram, Dep. at 6):

- For example, Dr. Aviram stated at his deposition 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). He also testified 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)).

- 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)). Indeed, he testified that "[o]ne glass a day has been shown to drastically reduce heart artery plaque" is an accurate statement. (CX1350 (Liker, Dep. at 221-22)).

Most notable is the fact that the cardiovascular researchers have also made statements to the public and recommendations to their patients regarding the benefits of pomegranates. (RFF 410-415) (PX0423-0001; CX1336 (Davidson, Dep. at 225-26)):

- 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). Indeed, Dr. Davidson testified in deposition that he has recommended pomegranate juice or POMx to some of his patients and the data from his research on pomegranates supports a likely cardiovascular health benefit. (CX1336 (Davidson, Dep. at 225-26)).

2. Statements Regarding Respondents' Promising Prostate Health Research

There were also many statements concerning the promising results of prostate research on pomegranate products that Respondents reasonably relied on to evaluate the reliability and significance of the research. (RFF 416-431). At trial, Mr. Resnick testified that scientists 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):

- For example, with respect to the Pantuck Phase II study, Dr. Harley Liker told Respondents that the study proves that pomegranate juice slows down the progression PSA. (CX1350 (Liker, Dep. at 174-75))

- Similarly, 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).

- 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)).

Additionally, like the cardiovascular researchers, the prostate health researchers also testified that consumption of the Challenged Products results in some benefit to prostate health. (RFF 421-426; CX1341 (Pantuck Dep. at 108, 254-55, 264)):

- For example, Dr. Pantuck, in deposition, stood behind the results of his research and selection of endpoints. (CX1341 (Pantuck Dep. at 108, 254-55). 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 and affirmed 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 108, 254-55)). Dr. Pantuck confirmed at his deposition that from a patient care standpoint PSA doubling time is extremely important. (CX1341 (Pantuck Dep. at 255)).

Dr. Pantuck also made public statements regarding the promising research on the benefits of pomegranates on prostate health. (RFF 427-431) (PX0428-0001); (PX0347 (Pantuck, Dep. at 270-71)). For example, Dr. Pantuck has publicly made positive remarks about the findings in his research done for Respondents. (PX0428-0001):

- 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" and that "[i]n 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; PX0347 (Pantuck, Dep. at 270-71)).

- Dr. Pantuck also discusses the benefits of pomegranate juice with his patients. (PX0347 (Pantuck, Dep. at 270-71)).

3. Statements Regarding Respondents' Promising Erectile Health Research

Respondents similarly reasonably relied upon the statements of Nobel Laureate Dr. Louis Ignarro concerning the promising results of erectile health research (RFF 432-435):

- Dr. Ignarro represented to Mr. Resnick that he strongly believes pomegranate juice is 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)).

- Dr. 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).

F. Respondents' Insistence on Scientific Rigor and Integrity

Notwithstanding the enthusiasm Respondents' received from the scientists themselves, Respondents double-check both positive and negative results and independently verify the results to ensure the information is accurate before it is published or made publicly available. (RFF 436; CX1360 (S. Resnick, Dep. at 200-01, 1693); (Liker, Tr. 1903-04); PX0023).

For example, Respondents delayed the publication of Dr. Aviram's 2004 study that showed an amazing 30% reduction of arterial plaque so the data could be verified. (RFF 438; Liker, Tr. 1903). Similarly, Respondents delayed the publication of Dr. Ornish's Bev I study on myocardial perfusion, which showed a statistically significant benefit, so that an independent third-party could double-check the results. (RFF 439; S. Resnick, Tr. 1693; Liker, Tr. 1904; PX0023).

G. POM's Policy Regarding Publication Of The Research

Mr. Resnick has never improperly interfered with the publication of any report or dictated the contents of any report. (RFF 441) (CX1372 (S. Resnick, Tropicana Dep. at 33)). Nor has he ever asked any scientist not to publish a manuscript or report. (RFF 442; CX1360 (S. Resnick, Dep. at 75); CX1358 (Aviram, Dep. at 76); CX1339 (Ornish, Dep. at 85)).

Complaint counsel, however, have insinuated that the delay in the publication of the Davidson CIMT study was nefarious or motivated by a desire to hide the results. There is absolutely no support for this assertion. In fact, the evidence shows the exact opposite. (RFF 443-447) (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)).

The delay of the publication of Dr. Davidson's CIMT study was solely caused by confusion within POM's internal scientific team, which necessitated that the results of the study

be re-read by a blinded independent group. (RFF 443-447) (Liker, Tr. 1895-96; CX1350 (Liker, Dep. at 146, 149-50, 163-64)). Individuals at POM, including Mr. Tupper and Mr. Resnick, collectively made the decision to go forward with the publication of Dr. Davidson's CIMT study and let the peer-review process decide whether or not the study was worthy of publication. (RFF 445) (CX1350 (Liker, Dep. at 165-66)). Indeed, any suggestion that Respondents attempted to hide the 18-month results of the Davidson CIMT study is belied by the fact that both the 18-month and 12-month results were ultimately published in the American Journal of Cardiology, one of the leading journals in cardiovascular medicine. (RFF 445-447; Liker, Tr. 1902; PX0014).

Accordingly, the breadth of evidence and testimony establishes that Respondents relied upon both the peer-review process and the information conveyed to them by the scientists to inform them regarding credibility and reliability of the research.

H. POM's Continued Investment In Research

The Resnicks' investment in POM's research program has and continues to be motivated by a desire to better understand the health benefits of the Challenged Products. (S. Resnick, Tr.1859; Liker, Tr. 1881-84; CX1336 (Davidson, Dep. at 142)). As set forth in detail below, (1) POM does not artificially "power-up" the research to reach statistical significance; (2) POM continues to invest in basic and animal research; (3) POM is motivated to expand the scope of its research; (4) POM has conducted a review of its science portfolio; and (5) POM is seeking FDA botanical drug approval for POMx pills. (CX1363 (S. Resnick, Coke Dep. at 59); S. Resnick, Tr. 1752-1753, 1859; CX1336 (Davidson Dep. at 142); CX1374 (Tupper, Ocean Spray Dep. at 87); Tupper, Tr. 3001; CX1360 (S. Resnick, Dep. at 145-146); Tupper, Tr. 3006-08; CX1353 (Tupper, Dep. at 47-49); Tupper, Tr. 2979-81); Liker, Tr. 188101884, 1887-88). In sum, the evidence overwhelming shows that the Resnicks were and are motivated to do a social good by investing in POM's research and sharing it with the public rather than, as Complaint Counsel suggests, attempting to exploit the research to make unsupported health claims and gain market share.

1. POM Does Not Artificially Power-Up the Research to Reach Statistical Significance

In developing POM's research program, the Resnicks' approach has been to listen to the advice of their scientific advisors and fund those studies that were more likely to show the real effects, whether positive or negative, from the consumption of pomegranate juice. (S. Resnick, Tr. 1662, 1859; Liker, Tr. 1881; CX1336 (Davidson Dep. at 142; RFF 273-276)). Neither the Resnicks nor POM ever attempted to "game the system" by pre-selecting studies they knew would show a positive result by "powering up" the study so that statistical significance could be reached, even though negligible benefits to study participants occurred. (RFF 272). Instead, the Resnicks have always aspired to better understand how the Challenged Products work and whether a real benefit can be shown. Whether the findings reached statistical significance was not their focus. (S. Resnick, Tr.1859; Liker, Tr. 1881-84; CX1336 (Davidson, Dep. at 142) (RFF 272-276)).

As recently noted by the Supreme Court in *Mattrix*, clinically significant research can come in many different forms; not just RCTs or research that reaches an FDA-approved level of science or statistical significance. That fact that a study is small or just shy of statistical significance does not mean the research is not useful or truthful. 131 S.Ct. at 1320.

2. POM Continues to Invest in Basic and Animal Research Even When Human Studies Have Demonstrated Positive Results

POM's continued investment in basic and *in vitro* research in areas where it has seen positive human studies is further evidence of the Resnicks' commitment to the truth and desire to expand the boundaries of scientific knowledge regarding the benefits of pomegranates. (RFF 294-295); CX1363 (S. Resnick, Coke Dep. at 59); S. Resnick, Tr. 1752-1753; CX1336 (Davidson Dep. at 142); CX1374 (Tupper, Ocean Spray Dep. at 87); Tupper, Tr. 984-85, 3001; CX1360 (S. Resnick, Dep. at 145-146); (PX0009, PX0002, PX0125, PX0017, PX0010).). Indeed, POM currently has ongoing basic research in the areas of cardiovascular health and prostate health despite having previously sponsored human clinical research yielding positive results. (RFF 293-294; Tupper, Tr. 984-985, 994; PX0023; PX0014; PX0060; PX0061).

3. POM Continues to Expand the Scope of Its Research

Additionally, POM continues to invest in many different areas of science to expand the breadth of POM's research to include many different health conditions that are connected to inflammation and oxidation. (RFF 280-281; Tupper, Tr. 2999-3002; deKernion, Tr.3046; Heber Tr.1957, 2112-13, 2185). Because additional beneficial characteristics of the Challenged Products and its derivatives have come to light over time, POM's research efforts have branched out in several directions to examine the role that oxidation and inflammation play in many seemingly unrelated diseases and conditions. (RFF 281; CX1353 (Tupper, Dep. at 47-49); Tupper, Tr. 2979-81; Heber Tr.1957, 2112-13, 2185).

Moreover, the Resnicks continue to invest in research examining regarding a variety of different health conditions because of their belief that all of POM's research builds upon itself and is interrelated, whether or not the results show positive or negative results. (RFF 282-283; Tupper, Tr. 2999). Indeed, POM finds value in all of its studies even if they are not ultimately published. (RFF 281, 283;Tupper, Tr. 3000-02).

4. POM Has Undertaken a Review of Its Entire Science Portfolio to Evaluate the Rigor of Its Research

As part of their internal preparation to potentially submit an application to the FDA for botanical drug approval, Respondents conducted candid reviews of POM's entire science portfolio to examine whether and to what extent their research would meet the FDA requirements, with its current limited recognition of the surrogate markers used in Respondents' research. (RFF 299; Tupper, Tr. 3011). In connection with this review, several summaries of POM's science program were examined, including a summary entitled "Medical Portfolio Review." (RFF 300). The Medical Portfolio Review was prepared by Respondent Matt Tupper 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. (RFF 300; Tupper, Tr. 942, 939, 3008-09; CX1353 (Tupper, Dep. at 248-49)). In this summary, POM ranked its portfolio of cardiovascular research as a three on a scale of ten. (Tupper, Tr. 3010-11; CX1029_0003). This

ranking referred to an assessment given by doctors who were oriented to drug approval. (RFF 301). That score was also due to the fact that POM previously considered using different endpoints than those used by the FDA to approve a drug for heart disease. (Tupper, Tr. 3001; RFF 302).

Nevertheless, putting aside the strict FDA requirements and FDA lens, Mr. Tupper testified that he personally ranks POM's portfolio of erectile, prostate and cardiovascular science each as an eight on a scale of ten. (RFF 303; Tupper, Tr. 3012).

5. POM is Seeking FDA Botanical Drug Approval of POMx

As a corollary to the Resnicks' continued investment and expansion of POM's research program, POM is currently seeking botanical drug approval for POMx from the FDA under two different health indications. (RFF 296;Tupper, Tr. 3006-08). The desire to do so is not motivated by the belief that POM advertised its products as drugs, but instead to distinguish their products from their competitors in the marketplace. (RFF 297; Tupper, Tr. 3006-08).

6. Like POM, Leading Government and Medical Research Centers Focus On The Relationship Between Nutrients, Foods And Disease

POM is not alone in its focus on the relationship between nutrients and diseases. Instead, it stands with the most prestigious government and medical research institutions, which have recognized the importance of such research, including research on pomegranates and POM-sponsored studies and the need to disseminate it to the public. (PX0301-PX0324). Indeed, both the USDA and the National Institutes of Health fund research exploring the connection between foods and improving health and reducing illness. (PX0301-PX0318; PX0392-PX0418; http://www.nih.gov/about/ and http://www.nih.gov/about/mission.htm (last visited, Jan. 8, 2012).

Similarly, prestigious medical institutions regularly publicize the relationship between the pomegranate fruit and its role in alleviating disease on their websites or publications:

- University of Texas MD Anderson Cancer Center (pomegranate juice may decrease PSA levels and is being studied for its ability to delay or prevent recurrent prostate cancer);

- MD Anderson Cancer Center (pomegranate inhibits "aromatase, which plays a key role in breast cancer growth," pomegranates are high in antioxidants "known to reduce the inflammation that plays a part in heart disease, cancer, high blood pressure and other diseases," and pomegranate may be beneficial for erectile dysfunction and high cholesterol);

- Memorial Sloan-Kettering Cancer Center (pomegranate juice shown to "suppress inflammatory cell signaling, inhibit prostate tumor grown, and lower serum PSA levels," and "benefit patients with carotid artery stenosis, in those with hypertension, hyperlipdemia, mild to moderate erectile dysfunction," citing POM sponsored Pantuck, Aviram, and Forest studies);

- Johns Hopkins Hospital ("among men with prostate cancer, daily glasses of pomegranate juice have slowed the increase in PSA levels after treatment," pomegranate juice can reduce the progression of atherosclerosis in the coronary arteries by inhibiting the oxidation of LDL cholesterol, pomegranate juice also "appears to stimulate the production of nitric oxide, a chemical that helps blood vessels relax.");

- Mayo Clinic ("it's thought that pomegranate juice could block or slow the buildup of cholesterol in your arteries", citing to POM-sponsored Davidson study, and "drinking pomegranate juice may slow the progression of prostate cancer".)

VI. POM'S CARE IN ADVERTISING AND CHANGES IN ADVERTISING OVER TIME

Respondents have proceeded conservatively to fully understand the physiological effects of pomegranates before using such research results in their advertising. (Tupper, Tr. 2981). Even when initial research findings are positive, POM will delay sharing the results from the public until the science is sufficiently developed. (Tupper, Tr. 2979). In fact, POM has independent institutions double-check even very positive results to verify their accuracy. (S. Resnick, Tr. 1693; Heber, Tr. 1964; S. Resnick, dep. at 200-201). Moreover, 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 exercised restraint and has chosen not to discuss those results in its advertising. (Tupper, Tr. 2979-81) The purpose of POM's conservative approach is to ensure that what is portrayed in the advertisements is consistent and accurate with the results of the scientific studies themselves. (Tupper, Tr. 2979; S. Resnick, dep. at 200-201).

As a result of two NAD decisions in 2005 and 2006, POM's advertisements changed significantly. (L. Resnick, Tr. 162, 168). Prior to these decisions, from 2003 through 2006, the

language and graphics in POM's advertisements regarding the health benefits of POM Juice appeared to be more aggressive. After the decisions, however, POM qualified its messages and began to describe the scientific studies in its advertisements. (Tupper, Tr. 2985-87; 3029).

Largely as a result of the 2005 and 2006 NAD decisions, POM stopped making generalized statements in advertisements about its science. (Tupper, Tr. 2986-87). Since 2006, when discussing the health benefits of the Challenged 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). In some cases, POM would direct consumers back to its website to read the full scientific study. (Tupper, Tr. 2985). In addition, as a result of the NAD decisions, POM has implemented a more formalized process for vetting advertisements and describing the health benefits of its products. (Tupper, Tr. 2977-78). All of these changes are designed to better ensure that accurate information is presented to the public through POM's advertising. (Tupper, Tr. 2985-86).

VII. HOW TO EVALUATE THE SCIENCE BEHIND THE CHALLENGED PRODUCTS

Complaint Counsel and Respondents seem to agree that 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 at issue, but disagree on what that means, *e.g.* whether only RCTs can be considered in demonstrating effects in humans, whether both positive and so-called "negative" studies should be considered in that analysis and whether any scientific value can be derived from small or "pilot" studies.

A. In Evaluating the Potential Health Benefits Of A Natural and Safe Foods Such As The Challenged Products, The Totality Of The Scientific Evidence Should Be Considered, Including Basic Science, Animal Research And "Pilot" Studies

In evaluating the health benefits of a natural and safe food, the totality and preponderance of the evidence should be examined, 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. 1948-40, 2166, 2182; Miller, Tr. 2194; PX0206-

0007, 15; Ornish, Tr. 2327-31). In examining the totality of the evidence, basic science, animal research and "pilot" studies, not just RCT can be relied upon as competent and reliable evidence to substantiate a health benefit claim. In some cases, basic science alone can be sufficient substantiation. (PX0206-0010-0011, 0013; Miller, Tr. 2194). While there may be limitations to extrapolating results from *in vitro* and animal studies to predict an effect in humans, it is false to suggest, as Complaint Counsel do, that such research has no value in determining the therapeutic efficacy of a food product. (PX0025-0007).

In fact, Complaint Counsels' own cardiovascular 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)). 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)). Therefore, it is no surprise that Dr. Sacks considers all levels of science in issuing national guidelines for the prevention or treatment of cardiovascular disease. (PX0361 (Sacks Dep. at 71)).

In addition, small studies or "pilot" studies are also instructive and 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)). In fact, "sometimes small studies can be more informative than large studies." (Heber, Tr. 1963). Although a study with a small number of participants may make it more difficult to achieve overall statistical significance, any positive finding just means the treatment has to be that much more powerful and consistent. (Ornish, Tr. 2362-2363; CX1338 (Padma-Nathan, Dep. at 108-109); PX0349 (Burnett, Dep. at 138-141); Ornish, Tr. 2352-53; Liker, Tr. 1884-86). For these reasons, Complaint Counsel err by insisting that RCTs can be the only evidence capable of substantiating a health benefit claim.

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 Causal Link

Complaint Counsel and their experts have repeatedly argued that the results of Respondents' scientific research should be disregarded in their entirety if the findings do not achieve statistical significance or if the studies are "underpowered." (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). This is inconsistent with the holding in *Mattrix*, where the Supreme Court held "[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." 131 S.Ct. at 1319. Indeed, "courts frequently permit expert testimony on causation based on evidence other than statistical significance." *Id.* "[M]edical professionals and researchers do not limit the data they consider to the results of randomized clinical trials or to statistically significant evidence." *Id.* at 1320.

In this case, evidentiary support for Respondents' advertising claims should not be so narrowly limited as to include only research whose end result reaches statistical significance. Instead, Respondents have presented significant, contrary testimony and evidence demonstrating that 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)). Indeed, strict reliance on statistical significance in determining whether or not pomegranate juice offers a beneficial health benefit is an arbitrary and unnecessary convention. (Ornish, Tr. at 2340).

C. The Absence Of A Statistically Significant Or Positive Results Do Not Prove The Opposite Conclusion

Complaint Counsel and their experts dispute the health benefits of the Challenged Products because Respondents' scientific research allegedly did not produce statistically significant changes in certain and/or all of their studies and, as a result, Complaint Counsel contend that no benefit can be derived from the Challenged Products. (Melman, Tr. 1130-31; Sacks, Tr. 1488-89, 1507, 1512-13, 1516-19). The mere absence of significant, affirmative

evidence in support of a particular claim, however, does not translate into negative evidence against the claim. *Pearson v. Shalala*, 130 F.Supp.2d 105, 115 (D.D.C 2001) ("Pearson II").

It is well-established in the scientific community that the absence of a statistically significant positive result in a study does not prove the negative, or in the other words, the absence of evidence is not evidence of absence. (Heber, Tr. 1981). In science, it is possible for a "type II" error to occur, which means there could be a statistically significant difference, but the sample size was not sufficiently large to detect a change. (PX0025-0019; CX1339 (Ornish, Dep. at 70-71)). Indeed, even Complaint Counsels' 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 did not cause the intended result. (Sacks, Tr. 1608).

Importantly, Complaint Counsel allege that Respondents deliberately violated the FTCA by continuing to make false and misleading representations after studies by Drs. Davidson, Ornish and others purportedly "showed no significant difference[s]" following the consumption of pomegranate juice. (RFF 615)(CX1426_0017-0018). Complaint Counsel is wrong for several reasons. First, a "negative" result in any given study, assuming *arguendo*, that those studies were negative, do not support the opposite hypothesis of the study. Second, the Davidson study was not inconsistent with the Aviram study and, if anything, supportive of the results found in Dr. Aviram's work. Although the Davidson study did not show a positive, statistically significant difference at 18 months, the analysis performed after the study's completion revealed a positive and statistically significant difference among the higher risk subgroup that was more similar to the profile of participants in Dr. Aviram's study. This result is consistent with the Aviram study whose participants were at much higher risk than Davidson's.

Respondents, however, did not (and cannot have) deliberately violated the FTCA when their scientific research on pomegranate juice and/or its extracts never proved the opposite hypothesis: that pomegranate juice and/or their extracts do not have a positive benefit. (Heber, Tr. 1981; PX0025-0019; Sacks, Tr. 1608-09; CX1352 (Heber, Dep. at 218); PX0361 (Sacks, Dep. at 223-224, 230, 238, 243); Goldstein, Tr. 2598-99)).

D. RCTS ARE NOT REQUIRED TO SUBSTANTIATE THE HEALTH BENEFITS OF NATURAL AND SAFE FOODS SUCH AS THE CHALLENGED PRODUCTS

Complaint Counsel claim, contrary to mainstream nutritional science, that RCTs are required in all cases to demonstrate the efficacy of a natural and safe food product. Complaint Counsel are mistaken legally and scientifically. First, as a matter of law, "[n]othing in the Federal Trade Commission Act…. requires placebo-controlled, double-blind studies. The Act forbids false and misleading statements, and a statement that is plausible but has not been tested in the most reliable way cannot be condemned out of hand." *F.T.C. v. QT, Inc.*, 512 F.3d 858, 861 (7th Cir. 2008); *see also F.T.C. v. Direct Mktg. Concepts, Inc.*, 624 F.3d 1, 9 (1st Cir. 2010) ("a double-blind study is not necessarily required" to satisfy a reasonable basis claim).

1. RCTs Are Sometimes Not Possible or Even Better in Evaluating The Health Benefits Of A Food Or Nutrient

There is widespread scientific agreement that RCTs are not possible or even better for evaluating the health benefits of a food or nutrient. (RFF 618-622; Miller, Tr. 2194; Heber, Tr. 1948-50, 2056, 2166, 2182; Ornish, Tr. 2327-31; RX5007; Stampfer, Tr. 831, 834; PX0362 (Stampfer, Dep. at 73-79)). In fact, in the field of nutritional epidemiology, which analyzes the connections between nutrition and disease, it is well-accepted that RCTs are not the best source of valid and reliable information on nutrition. (RFF 623-629).

There are multiple reasons for this consensus. First, ethical principles do not permit randomizing individuals to diets that may have negative health effects. (RX5007; PX0362 (Stampfer, Dep. at 78)). It is very difficult to ensure that large numbers of participants adhere to an altered diet over long-term periods. (RX5007; PX0362 (Stampfer, Dep. at 75-76)). Second, the cost of such studies creates an almost insurmountable barrier, given that no exclusive intellectual property rights (like a pharmaceutical patent) will result from a nutritional trial. (RX5007; PX0362 (Stampfer, Dep. at 75-76)). Third, in a nutritional context, a hypothesis about disease causation can, rarely, if ever, be directly tested in humans using the RCT design. (Stampfer, Tr. 832-833; PX0362 (Stampfer, Dep. at 73, 98); RX5007). If RCTs were required

before it could be said that scientific evidence supports a particular claim about the health benefits of food, the field of nutrition science would be almost eliminated.

Notably, Complaint Counsels' own expert witness in this area, Professor Stampfer, openly concedes that evidence-based medicine/nutrition is not restricted to RCTs. (Stampfer, Tr. 831, 837; RX5007). Professor Stampfer indicated that scientific evidentiary support for nutritional claims will necessarily be based on observational studies, and RCT trials, due to the various feasibility issues pertaining to RCTs. (Stampfer, Tr. 830, 834; PX0362 (Stampfer, Dep. at 73-79); RX5007). Professor Stampfer even goes so far as to concede that "there are situations where you would determine causality in the absence of a randomized trial," and that an RCT is not required to conclude a causal link regarding a nutrient and disease. (PX0362 (Stampfer, Dep. at 73, 99).

Indeed, in an 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; RX5007). Professor Stampfer further 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." (RX5007).

2. Many Factors Favor Disclosure of Potential Health Benefits to the Public in the Absence of RCTs

Respondents' expert, Dr. Miller, confirms that when a food product is absolutely safe and where there is no suggestion that the product be used as a substitute for conventional medical treatment, then it is appropriate to rely on the totality of the science (and in some cases, only basic science), and 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).

Complaint Counsels' own expert, Professor Stampfer, conceded that he "believe[s] that it may be appropriate to use evidence short of an RCT 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). As such, it is no surprise that Professor Stampfer testified that when there is little risk and little cost involved we should "definitely" make that potential benefit available to the public rather than withhold it. (Stampfer, Tr. 838).

This view is evidenced by the number of public health recommendations and clinical practices followed in the absence of RCTs. Federal agencies and internationally recognized academic institutions have publicized their research on some of the same health benefits at issue in this case using *in vitro,* animal and small-scale human models as the bases for their scientific inquiries. For example, the Agricultural Research Service, which is the U.S. Department of Agriculture'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). Even the FDA has approved pharmaceutical products without requiring the type of rigorous clinical trials Complaint Counsel argues are applicable here. From 1973 through 2006, the FDA approved 31 oncology drugs without an RCT using the Accelerated Approval and Priority Review Program ("Fast Track Program").

Finally, much of what physicians provide patients in their clinical practices have not been proven to be beneficial in RCTs. (PX0025-0007; Sacks, Tr. 1559; PX0361 (Sacks Dep. at 111); CX1341 (Pantuck, Dep. at 276-277)). For example, Complaint Counsels' 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 actually worked. (Eastham Tr. 1331-32; PX0358 (Eastham, Dep. at 154-155)). Also, Dr. Pantuck stated that clinicians remove kidneys without a RCT showing the benefits of nephrectomy. (CX1341 (Pantuck, Dep. at 276-277)). Further, Complaint Counsels' experts, Professor Stampfer and Dr. Sacks, admitted that they have

made public health recommendations that were not supported by RCTs. (Stampfer, Tr. at 810, 813-814; PX0300 (Stampfer, Dep. at 173); PX0361 (Sacks, Dep. at 35-38, 130-131)).

VIII. THE SCIENCE BEHIND THE ANTIOXIDANT AND ANTI-INFLAMMATORY PROPERTIES OF THE CHALLENGED PRODUCTS

A. The Challenged Products Contain Powerful Antioxidants Which Stabilize Free Radicals And Reduce The Cellular Damage Caused By Oxidation

Respondents have shown that the Challenged Products have beneficial nutritional effects on cardiovascular, prostate and erectile health. The human body suffers harmful effects from the biological processes know as oxidative stress and inflammation. Through numerous peer-reviewed scientific studies confirmed (at the *in vitro*, animal and human level) and expert opinions, Respondents have presented competent and reliable evidence supporting the anti-oxidative and anti-inflammatory properties of the Challenged Products. Additionally, Respondents offered into evidence scientific studies and expert opinions showing that the compounds found in the Challenged Products are bioavailable in humans, that POMx is bioequivalent to POM Juice and the Challenged Products are safe for human consumption.

1. Respondents Presented Substantial Evidence on the Potency of the Polyphenol Antioxidants in the Challenged Products

Humans are constantly exposed to oxidative stress. (RFF 751). Normal cellular metabolism produces as its by-products various highly reactive molecules, collectively termed "oxidants." (RFF745). These oxidants, known as "free radicals," include a variety of different chemicals which, like oxygen, are capable of inflicting oxidation damage. 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. (RFF748-749; 753-754) . Although the body has mechanisms to curtail free radical damage, over the long term, the human body cannot eliminate oxidative damage by relying on its own antioxidant defenses. (RFF 752). Net oxidative damage accrues, contributing to cardiovascular disease, cancer and other ailments. (RFF748-750; 758-754).

Antioxidants neutralize free radicals by inhibiting oxidation at a molecular, cellular and organ level or helping to repair the damage caused by oxidation. (RFF 755). These mechanisms of action of antioxidants thereby prevent some of the damaging health effects of oxidation. (RFF 757). Thus, consuming foods with increased antioxidant potency promotes overall health in a number of organ systems by different mechanisms, which is well accepted with the scientific community. (RFF 759-761 . In fact, research agencies of the United States Government recognize the health benefits of antioxidants, including their ability to fight the cellular damage caused by free radicals. (RFF 763-779). (RFF).

Here, Respondents have presented substantial evidence that antioxidants play a critical role in protecting cells against the harmful effects of free radicals. (RFF 785-793; 797-810). Respondents have also shown that the Challenged Products have exceptionally powerful antioxidant effects and contain among the most potent naturally-occurring polyphenol antioxidants found in foods or dietary supplements. (RFF 780-787). The exceptional potency of the Challenged Products have been scientifically demonstrated in numerous *in vitro*, animal and in human clinical studies showing that the consumption of the products can, among other health benefits, reduce the oxidation of LDL and early and late stage plaque development and have positive effects on, among other things, cardiovascular, prostate and erectile health.

2. Complaint Counsel Have Failed To Rebut Respondents' Evidence on the Nutritional Benefits of Antioxidants' in Fighting Free Radicals

Complaint Counsel failed to rebut Respondents' evidence on the exceptional antioxidant effects of the Challenged Products on the maintenance of human health. (RFF 811-816). First, Complaint Counsels' experts, Professor Stampfer and Dr. Eastham, never opined in this case that the Challenged Products actually do not provide the health benefits advertised by Respondents. (RFF 815-816). Rather, they avoid making this bold, unsustainable assertion by merely opining that, based on the limited materials they reviewed, there is no competent or reliable scientific evidence to support Respondents' health benefit claims. (RFF815-816). This qualified opinion is a far cry from affirmatively claiming that the Challenged Products do not provide health

benefits. In this regard, Complaint Counsel did not conduct their own testing of the Challenged Products to prove or disprove any of Respondents' health-benefit claims.

Moreover, Complaint Counsel presented no expert opinion or affirmative evidence rebutting Respondents' evidence concerning either the antioxidant potency of the Challenged Products or that they contain more antioxidants than comparative fruit juices or supplements. (RFF 813-814). Indeed, Complaint Counsels' expert, Professor Stampfer, concedes that he has no opinion about the particular classes of antioxidant compounds within pomegranates or the extent to which the antioxidant effect of pomegranate juice on human health is attributable to anthocyanins as opposed to other antioxidants such as punicalagins. (RFF818-819). Conversely, Respondents presented the expert opinion of Dr. David Heber, a world-renowned expert in nutrition, who has opined that antioxidants are beneficial to one's health, including cardiovascular, erectile and prostate health. (RFF 755-759; 798-799).

Complaint Counsel presented no evidence refuting the fact that antioxidants, including the hydrolysable tannins and ellagic acid found in the Challenged Products, neutralize free radicals or that free radicals play an role in cardiovascular disease and cancer. (RFF 811-812; 829-830). Nor could Complaint Counsel advance such a frivolous argument given the great weight of scientific research and literature clearly establishes the facts as advanced by Respondents.

B. Antioxidants Impact The Level And Preservation Of Nitric Oxide In The Body Which Is Beneficial To Cardiovascular Health And Erectile Function

Respondents have also shown that the antioxidants in the Challenged Products are beneficial to health through the mechanism of impacting nitric oxide ("NO") in the body. NO plays a key role in inflammation, blood flow regulation, cell growth and smooth muscle relaxation, all of which offer protection against atherosclerosis. (RFF 837; 839). For example, NO helps maintain healthy blood vessels, which improves blood flow to almost every organ in the body. (RFF 836). Maintaining healthy blood vessels and the flow of blood to the heart and penis are important to cardiovascular health and erectile function, respectively. (RFF 838).

Antioxidants are well known to increase and prolong cellular concentrations of NO by protecting it from oxidation. (RFF 832, 839).

Here, Respondents presented competent and reliable scientific evidence as well as expert opinion that consumption of the Challenged Products also affects NO in that they increase and prolong cellular concentrations of NO by protecting it from oxidation. (RFF 839). As for erectile health, because NO plays a crucial role in the erectile process (RFF 837-838), the Challenged Products demonstrated an ability to increase the level and prolong the concentration of NO, and support the conclusion that consumption of the products supports erectile health. (RFF 839).

Complaint Counsel provided no credible evidence contradicting Respondents' evidence of the beneficial effects of the Challenged Products on NO. For example, Complaint Counsel provided no expert opinion that NO does not help maintain healthy blood vessels and blood flow or that antioxidants do not protect NO against oxidative destruction. RFF 842 . Nor did Complaint Counsel dispute NO's role in cardiovascular and erectile health. RFF 843. Complaint Counsel also presented no expert opinion sufficient to prove that Respondents' heart, prostate and erectile health claims are not substantiated by competent and reliance evidence.

C. Antioxidants Lessen Inflammation Which Provides Health Benefits In Regard To Cardiovascular Health, Cancer And Erectile Function

Respondents provided competent and reliable scientific evidence and expert opinion that the antioxidants in the Challenged Properties have anti-inflammatory properties, which are beneficial to human health. Complaint Counsel have failed to contradict this evidence.

It is well established in the scientific community that inflammation plays a critical role in mediating atherosclerosis, the narrowing of arteries caused by buildup of cholesterol-based fatty plaques. (RFF 847). Atherosclerosis is the primary cause of heart disease, and because it leads to restricted blood flow, is a causative factor in erectile dysfunction. (RFF 847-848). Inflammation is also a characteristic prostate cancer. (RFF 846). Each of these facts is undisputed. (RFF 846-848).

Although inflammation can be caused by many factors, activation of nuclear factor-kB ("NF-kB"), the oxidative stress responsive transcription factor, has been linked with a variety of inflammatory diseases and ailments, including prostate cancer, cardiovascular disease and erectile dysfunction. (RFF 846-847, 849). However, the pathway that activates NF-kB can be inhibited by phytochemicals, thus limiting the development of these inflammatory diseases and ailments. (RFF 859). Each of these facts is undisputed. (RFF 849, 859). In regard to the role of NF-kB in anti-inflammatory disease, Respondents have presented competent and reliable evidence in the form of scientific studies and expert opinion demonstrating that the antioxidants in the Challenged Products inhibit the pathway that activates NF-kB, thereby reducing inflammation and improving blood flow in the arteries. (RFF 860-861). This fact is not disputed. (RFF 870-873).

Moreover, Respondents also demonstrated that the Challenged Products are impactful on human health by lessening inflammation in another way. High-density lipoprotein ("HDL") contains an antioxidant enzyme called PON1 that protects against oxidation. (RFF 855). Respondents presented scientific studies and expert opinion showing that the antioxidants in the Challenged Products increase PON1 association with HDL, thereby reducing inflammation in coronary arteries which is beneficial to cardiovascular health and other inflammatory diseases. (RFF 862).

In sum, the anti-inflammatory properties of the Challenged Products have been established through competent and reliable scientific studies and expert opinion and offer yet another pathway through which the Challenged Products may contribute to health.

D. The Antioxidants In The Challenged Products Are Bioavailable In Humans

Studies on the human metabolism of the Challenged Products conclusively demonstrate that the polyphenol antioxidants found in the products are bioavailable in humans, meaning the body is able to absorb and use them. No evidence in the record contradicts this fact.

The only evidence on the bioavailabilty of the Challenged Products was presented by Respondents in the form of scientific studies examining the bioavailability of pomegranate-based

products in humans and the expert opinion of Dr. David Heber. (RFF 874; 881-909). When confronted with the overwhelming evidence supporting the bioavailability of the Challenged Products in humans, Complaint Counsel did not present any contradictory evidence. (RFF 910-914). For example, it was not within the scope of Complaint Counsels' experts' assignment, and none opined in their expert report that credible and reliable scientific evidence shows that the Challenged Products are not bioavailable in humans. (RFF 910-914). Despite Complaint Counsels' failure to present any evidence on bioavailability, the record is replete with credible scientific evidence and expert opinion presented by Respondents supporting the bioavailability of the Challenged Products in humans. (RFF 881-909)

As stated by Dr. Heber in his expert report, scientific studies conclusively "demonstrate the bioavailability of the antioxidants found in pomegranate juice." (RFF 874). Complaint Counsel presented no scientific evidence refuting either Dr. Heber's expert opinion or the scientific studies presented by Respondents. (RFF 910-914).

E. POMx Pills And POMx Liquid Are Bioequivalent To POM Juice

Studies consistently and persuasively establish the equivalency of the POMx to POM Juice. These studies show not only that the POMx products contain similar amounts of active pomegranate polyphenol antioxidants as POM Juice, but also that these antioxidants are similarly bioavailable, thereby providing similar health benefits. (RFF 915-951). The scientific equivalence of the active antioxidants in the POMx products and POM Juice is confirmed by the expert opinion of Dr. Heber. (RFF 925). Complaint Counsel presented no evidence to the contrary. (RFF 952-958).

In sum, the evidence in the record fully supports the conclusion that POMx Pills and POMx Liquid have equivalent antioxidant power as POM Juice.

IX. RESPONDENTS' HEART, PROSTATE AND ERECTILE CLAIMS ARE SUBSTANTIATED BY COMPETENT AND RELIABLE SCIENTIFIC EVIDENCE

A. POM's Heart Health Claims Are Substantiated

Complaint Counsel allege that Respondents have falsely represented in their advertisements, either expressly or by implication, that: (1) drinking eight ounces of POM Juice, or taking one POMx Pill or one teaspoon of POMx Liquid, daily, prevents or reduces the risk of, or treats, heart disease by: (a) decreasing arterial plaque; (b) lowering blood pressure; and/or (c) improving blood flow to the heart; and (2) studies prove the same. (Compl, §§ 12, 19).

Although Respondents deny that they make these purported claims, the totality of Respondents' scientific evidence from in vitro studies, animal research, and human clinical trials nevertheless demonstrates that the Challenged Products are likely to be beneficial in maintaining cardiovascular health and help reduce the risk of cardiovascular disease by reducing arterial plaque, lowering blood pressure, and improving blood flow. (RFF 1206-1211).

B. Overview of Cardiovascular Heart Disease

Heart disease, including heart attacks or angina, occurs as the result of decades long damage to blood vessels. (RFF 1046-1047). The process begins with the oxidation of the protein known as low density lipoprotein ("LDL" or bad cholesterol) which circulates in the blood. (RFF 1048). Once LDL becomes oxidized, the chemical nature of the protein changes, causing it to reside and accumulate in the blood vessel. (RFF 1049). Macrophages, white blood cells that respond to inflammation by digesting cellular debris, begin to engulf and devour the oxidized cholesterol. (RFF 1052). These macrophages continue to accumulate until they develop into "foam cells." (RFF 1053). These foam cells become full of cholesterol and actually burst, bringing in more macrophages and more inflammation. (RFF 1053). As this process progresses, plaque begins to form as yellow steaks in the coronary arteries. (RFF 1054-1055).

In addition, blood flow becomes disturbed when blood passes through plaque or atherosclerotic lesions. This disturbance leads to an increase in shear stress that damages endothelial cells, the thin layer of cells that lines the interior of blood vessels, further contributes to oxidative stress, and initiates the development of atherosclerosis. Ultimately, the build-up of plaque or the rupture of an inflamed plaque can interrupt blood flow to the heart either

temporarily (resulting in chest pain or angina) or longer (resulting in scarring or death to the heart muscle, commonly referred to as a heart attack).

Antioxidants play an important role in mitigating heart disease by, among other things, inhibiting oxidative stress, including reducing LDL oxidation (and its uptake) and inflammation. In addition, the presence of nitric oxide in the body also helps offer protection against atherosclerosis by regulating blood flow and contributing to smooth muscle relaxation. (RFF 1059-1063; 1082-1085).

C. Respondents' Basic Science Demonstrates the Beneficial Effects of Pomegranate Juice and Its Derivatives on Cardiovascular Health.

Respondents have sponsored at least 15 published studies evaluating the effects of pomegranate juice and/or its derivatives on cardiovascular health in vitro and animals. (RFF 1064). Around 2000 (and continuing to the present), Dr. Michael Aviram began the earliest studies investigating pomegranate juice's potential benefits to the cardiovascular system. (RFF 1065). Dr. Aviram and his colleagues observed several beneficial effects of pomegranate juice and its extracts at the cellular and animal stage, including but not limited to: (1) reduction in oxidation of LDL cholesterol; (2) lessening the "uptake" of oxidized LDL by macrophage foam cells; (3) decrease in size of atherosclerotic lesions and foam cells; and (4) diminishing of platelet aggregation. (RFF 1077).

Respondents here also funded considerable *in vitro* and animal studies to examine the impact of pomegranate juice on nitric oxide and its effects cardiovascular health. Dr. Louis Ignarro, recipient of the Nobel Prize, Dr. deNegris, and Dr. Napoli conducted a number of studies in which they found that pomegranate juice and/or POMx; among other things: (1) increased and preserved levels of nitric oxide in cell cultures; (2) decreased LDL oxidation, the size of atherosclerotic plaques, and foam cell formation; and (3) reversed effects of shear stress. (RFF 1088).

D. Respondents' Clinical Research Confirms Results Found in Earlier Cellular and Animal Studies and Shows Positive Effects on Arterial Plaque, Blood Pressure and Blood Flow.

In addition to 15 published studies at the cellular and animal level, Respondents have sponsored approximately 10 published studies analyzing the effects of pomegranate juice and/or its extracts on cardiovascular health in human subjects. (RFF 1089). Among these studies, Dr. Dean Ornish, Respondents' own expert in cardiovascular health, examined the effects of POM Juice on a patient's myocardial perfusion (blood flow). (RFF 1127-1138). After three months, patients drinking POM Juice experienced a 35 percent comparative benefit in blood flow. (RFF 1131). In another study by Dr. Michael Davidson, a subgroup of patients at high risk for cardiovascular disease experienced a statistically significant reduction in carotid intima-media thickness ("CIMT") after 18 months. (RFF 1139-1146). Given the subgroup at risk, Dr. Davidson's finding alone could benefit tens of millions of people in the United States. (RFF 1470).

Respondents' body of human research is consistent with, and confirms, the findings made in Respondents' basic science. Together, the totality of Respondents' scientific of evidence at the cellular, animal, and human level constitutes competent and reliable evidence that the Challenged Products are beneficial to cardiovascular health by decreasing arterial plaque, lowering blood pressure, and improving blood flow to the heart. (RFF 1206-1211).

E. Complaint Counsels' Expert on Cardiovascular Disease/Health, Dr. Frank Sacks, Fails to Rebut the Conclusions of Respondents' Experts, Dr. Dean Ornish and Dr. David Heber, that Competent and Reliable Scientific Evidence Exists to Show that the Challenged Products Are Beneficial in Reducing Arterial Plaque, Lowering Blood Pressure, and Improving Blood Flow.

Complaint Counsels' expert on cardiovascular disease, Dr. Frank Sacks, fails to (and cannot) diminish the validity of Respondents' extensive body of research on pomegranate juice and its effects on cardiovascular health. Here, Dr. Sacks attempts to discredit Respondent's heart health studies by adopting an indefensible "drug" standard for evaluating cardiovascular research and by trying to isolate and pick apart Respondents' studies, one by one, rather than considering the entire body of science as a whole. Dr. Sacks' expert opinions should be dismissed on both counts.

1. RCTs Are Not Necessary (or Even a Better Method) to Prove the Health Benefits of a Natural Food or Juice, Such as Pomegranate Juice and Its Various Forms.

Dr. Sacks' rigid requirement that only RCTs should be considered in evaluating the therapeutic value of a food is not only contradicted by the scientific community (including Complaint Counsels' own expert, Dr. Meir Stampfer), but also by Dr. Sacks' own concessions at trial and deposition. Although he claims RCTs (some costing $6, $60, or $600 million) are absolutely needed to substantiate health claims even if a product is completely safe and provides a potential benefit to the public, Dr. Sacks nevertheless concedes that we should weigh the risk that the product will do harm against the potential of keeping information from the public. (RFF 1214; 1235-1240).

Indeed, in his testimony, Dr. Sacks admits that in evaluating a natural food, RCTs are simply not necessary in all cases. For instance, 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. (RFF 1217). In researching and developing the DASH diet, Dr. Sacks concedes that it is not necessary to test the efficacy of all individual fruits that a person may decide to choose to consume by conducting a RCT because the "category of fruit," including pomegranates, has already been studied. (RFF 1222). Moreover, in designing the DASH diet, Dr. Sacks admits that fruits and fruit juices are treated same. (RFF 1221).

In addition, Dr. Sacks also acknowledges that RCTs are not feasible because of logistical, financial, and ethical considerations. For example, in some cases, studies cannot be blinded, i.e., the subjects would know whether they are being subjected to a high or low sodium diet or, in other cases, the studies would be too expensive. (RFF 1241-1248). Finally, Dr. Sacks actually proves the point that RCTs are not necessary to substantiate the health benefit claim of a food or nutrient when he confessed that he has recommended (or would recommend) fish oil (Omega-3) or a reduction in sodium to patients with coronary heart disease even though no RCTs have been conducted on them. (RFF 1227-1234)

In short, as validated by Respondents' experts, Dr. Ornish, Dr. Heber, and Dr. Miller, and even Complaint Counsels' own expert, Dr. Meir Stampfer, the appropriate standard for evaluating whether a food is beneficial in maintaining cardiovascular health and lessening the risk of cardiovascular disease is that the totality of the evidence should be examined given that: (1) pomegranate juice and its extracts are safe; (2) no one suggests that pomegranate juice or its extracts should be offered in lieu of conventional medical treatment or surgery; (3) the expense associated for conducting a FDA drug study for a non-patentable, natural food is exorbitant and prohibitive; and (4) the potential benefit or information to be gained by the public outweighs any plausible harm. (RFF 1184-1205).

2. Dr. Sacks' Individual Criticisms of Respondents' Cardiovascular Science Lack Merit and Should Be Disregarded.

Dr. Sacks also tries to depict Respondents' cardiovascular research on humans to be inconsistent and therefore unreliable. In particular, Dr. Sacks claims that Dr. Aviram's finding of a 30 percent reduction in arterial plaque and 21 percent reduction in systolic blood pressure to be contradicted by subsequent studies, published and unpublished, conducted by Dr. Ornish, Dr. Davidson, and others. Dr. Sacks, however, is wrong. First, Dr. Aviram's finding of a 30 percent reduction in arterial plaque in his 2004 study remains valid following Dr. Ornish's unpublished 2005 IMT study ("Bev II") and Dr. Davidson's published 2009 IMT study because: (1) Dr. Ornish's Bev II study was underpowered, never reached statistical significance, and accordingly, as Dr. Sacks confesses, the absence of a positive result does not prove a negative benefit (i.e. that pomegranate juice did not improve IMT); (2) Dr. Davidson's study examined a healthier patient group, those at moderate risk of coronary heart disease (carotid artery plaque of less than 2.0 mm), while Dr. Aviram's study investigated those with carotid artery stenosis (a narrowing of the carotid artery due to plaque). Furthermore, Dr. Aviram's and Dr. Davidson's studies are entirely consistent 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. Thus, neither Dr. Ornish's

nor Dr. Davidson's studies could (or should) be interpreted to contradict, in any way, Dr. Aviram's published finding on arterial plaque.

F. Respondents' Prostate Health Claims Are Substantiated by Competent and Reliable Scientific Evidence

In its Complaint and during the proceedings, Complaint Counsel accused POM, through its advertisements, of making unsubstantiated claims that drinking POM Juice and/or taking POMx (pill and/or liquid) daily (1) prevents or reduces the risk of prostate cancer and (2) treats prostate cancer. (CX1426, ¶¶14-15, 19). POM denies ever making such claims and a review of the Challenged Advertisements, as demonstrated through the proceedings, show that POM never made such claims. (RFF 2197-2622). POM's "prostate" ads instead used cheeky puffery phrases concerning prostate health like "Drink to prostate health" or "I'm off to save PROSTATES!" combined with qualifying text stating, "improve prostate health" or "*hopeful results for prostate health*" or "hopeful results for men with prostate cancer." *Id.* Not once has POM claimed that the Challenged Products "prevents" or "treats" prostate cancer. Even when the advertisements cited some of POM's underlying research, those statements were qualified with language like, "an initial UCLA medical study" or the study showed "statistically significant prolongation of PSA doubling times." *Id.*

Even assuming that POM did make "prevents" or "treats" prostate cancer claims, a multitude of basic and clinical studies underlying POM's prostate advertising demonstrates there is competent and reliable science to support such claims. Further, the testimony and cross-examination of the parties' experts has only served to highlight and confirm that POM's prostate health claims are substantiated and the peer-reviewed science behind them is well-founded.

1. PSA Doubling Time Is A Valid Surrogate For Recurrence And/Or Death From Prostate Cancer

PSA doubling time ("PSADT"), a measure of the time it takes the levels of prostate specific antigen ("PSA")—a protein made by prostate cells—to double in a man's blood, is currently the best marker for recurrence of prostate cancer following radical prostatectomy or radiation therapy. (deKernion, Tr. 3055). Generally, the shorter the doubling time the greater

the risk of recurrence of cancer. (deKernion, Tr. 3084, 3124). As studied and demonstrated in multiple peer reviewed articles in very reputable journals, PSADT accurately reflects prostate cancer cell behavior and there is now widespread acceptance of PSADT as a valid surrogate and predictor of recurrence of prostate cancer and death. For example, in a study by *Pound, et al.* (JAMA 1999), the investigators found a strong correlation between the length of the PSADT after radical prostatectomy and biochemical recurrence and the expected clinical recurrence (PX0163). Similarly, in a study by *Patel, et al.* (Journal of Urology 1997), the authors found that PSADT was correlated with the risk of clinical recurrence—the longer the doubling time the lower of the risk of clinical recurrence (PX0162).

In yet another study by *Tollefson, et al.* (Mayo. Clin. Proc. 2007) (PX0166), the authors found 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 "the only significant factor that predicts clinical progression." (PX0166-0001, 6 (emphasis added)). And a recent study by *Teeter, et al.* (Urology 2011) (PX0167) similarly correlated length of PSADT with risk of mortality noting 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." (PX0167-0001, 3, 5). The multitude of additional peer-reviewed articles cited by Respondents' prostate expert, Dr. deKernion, only serve to confirm this fact. *See* Dr. deKernion Expert Report and Reference Articles appended to thereto. (PX0161-PX0188).

2. Complaint Counsels' Expert's Challenge of PSADT as a Marker Is Not Well-Taken

Complaint Counsels' prostate expert, Dr. James Eastham, challenged the appropriateness of PSADT as a surrogate marker for prostate cancer clinical recurrence or survival. (PX0298-0010-0011; Eastham, Tr. 1340-44). His logic and conclusion are suspect for a number of reasons.

First, as noted above, it is anathema to literally dozens of published articles over the last 20 years that have found PSADT to be the best marker for prostate cancer clinical recurrence and eventual mortality. (PX0161-PX0188).

Second, even Dr. Eastham himself explicitly admitted in a 2005 article he authored that: "PSA doubling time has emerged as an important factor in the evaluation of men with newly diagnosed prostate cancer or prostate cancer that recurs after treatment. PSA doubling time can be used as a surrogate marker for prostate cancer specific death." (PX0178-0001). He further admits in the article that "PSADT is an important marker in men with biochemical failure after local therapy for prostate cancer, and it predicts the probable response to salvage radiotherapy, progression to metastatic disease and prostate cancer specific death." (PX0178-0009). Dr. Eastham failed to explain his apparent change of heart (during these proceedings) as to the usefulness of PSADT.

Third, most, if not all of treating urologists, including Dr. Eastham and Dr. deKernion, utilize PSADT as a prognostic marker for recurrence of prostate cancer and mortality following radical prostatectomy. (deKernion Tr., 3051; Eastham, Tr. 1343-44; PX0161-0004, 0007). Why it is useful and prognostic in his practice, but not otherwise, was again not explained by Dr. Eastham.

Tellingly, and only after being challenged about the obvious contradiction in his testimony and his article cited above, did Dr. Eastham concede that PSADT following radical prostatectomy was a prognostic marker for clinical progression and death from prostate cancer following radical local treatment. (Eastham Tr. 1342-44). He attempted to qualify this admission by stating that PSADT is only accepted as a prognostic marker for clinical progression and recurrence of prostate cancer and death at baseline, meaning immediately after radical prostate treatment, but stops being predictive after baseline. (Eastham, Tr. 1342-44). He was unable to articulate why PSADT is predictive and useful immediately following treatment but no longer useful after that. He was similarly unable to state when in time following treatment, PSADT stops being predictive. (Eastham Tr., 1340-44).

His apparent explanation only further convolutes his analysis: changes or modulation of PSADT have not been accepted as a surrogate for clinical recurrence of prostate cancer or death even though the marker itself may be useful as such at baseline. (Eastham, Tr. 1342-44; Tr. 1340-41). Again, Dr. Eastham had no explanation for this novel theory. *Id.* If a marker is prognostic of one's chances of recurrence of disease, why would something that is able to modulate the readings from that marker not be indicative of changes to the underlying disease? Dr. Eastham even suggested that no physician or researcher would ever propose that changes in PSADT are prognostic of prostate cancer behavior following radical prostate treatment, and yet Drs. deKernion and Heber both do. (Heber, Tr. 2151; deKernion, Tr. 3055; PX0161-0007, 0011-0012). Complaint Counsels' expert, Dr. Meir Stampfer similarly opined that PSADT was "a predictor of disease of mortality" and that, if the extension of PSADT time is true, it would substantially prolong lives. (Stampfer, Tr. 869, 873). This view is the dominant one and consistent with several peer reviewed articles that specifically studied changes or modulation of PSADT and correlated them with chances of clinical recurrence of prostate cancer. (PX0168-PX0170).

In sum, PSADT is a widely accepted surrogate for prostate cancer clinical recurrence and death following radical prostatectomy and Complaint Counsels' challenge to it fails. (PX0161-PX0188).

3. The Evidence is "Very Convincing" That Pomegranate Juice Affects, Promotes And Supports Prostate Health

In a 2006 study, entitled "(*Phase II Study of Pomegranate Juice for Men with Rising Prostate-Specific Antigen Following Surgery or Radiation for Prostate Cancer)*," published in the prestigious Clinical Cancer Research Journal, *Pantuck, et al.* (UCLA Medical School) (PX0060), studying men that had undergone radical prostatectomy or radiotherapy, found that drinking 8 ounces of POM juice daily materially lengthened PSADT in nearly 50% of men after 18 months - in fact, PSADT almost tripled. The study also found that when POM Juice was tested *in vitro* on prostate cell assays, it was found to both decrease prostate cancer cell

proliferation by 12% (i.e., slow its growth) and stimulate prostate cancer cell apoptosis (cell death) by 17%. Additionally, serum nitric oxide increased by 23% in men that consumed POM. *Id.* As testified to during the proceedings, nitric oxide is a molecule that has been found to inhibit inflammation, which is correlated with higher risk of cancer. (PX0060; CX1407_0228-0231).

In 2008, Dr. Pantuck presented a follow-up report to his 2006 study to the American Society of Clinical Oncology. (PX0061). His follow-up work demonstrated that for those subjects that continued with the pomegranate juice regimen, they maintained the lengthening of their PSADT as compared to those who did not continue the pomegranate juice. (CX1341 (Pantuck, Dep. at 136); Eastham, Tr. 1305). This study was subsequently published in the prestigious Journal of Urology in 2009. (PX0061).

A randomized Phase II trial by *Carducci, et al.* (Johns Hopkins School of Medicine) in 2011 (PX0175) entitled "(*A Phase II Study of Pomegranate Extract for Men with Rising Prostate-Specific Antigen Following Primary Therapy*)," published in the highly respected Journal of Clinical Oncology, confirmed the initial clinical findings demonstrated by the first *Pantuck, et al.* study. In the *Carducci* study, 104 men who had previously been treated for prostate cancer, were randomized into a double-blind clinical trial and were given either 1 or 3 doses of POMx Pills (equivalent to 8 ounces of pomegranate juice) for 18 months. Their PSADT was measured over that time and it was again found that there was a significant effect of POMx Pills on PSADT independent of dose—it lengthened it significantly—nearly doubling it.

4. The Clinical Research On POM Is Consistent With The Pre-Clinical Basic Science Which Shows A Robust Effect Of POM On Prostate Cancer Cells

The *Pantuck* and *Carducci* clinical studies were consistent with earlier (and later) pre-clinical laboratory and animal studies that showed a robust effect of POM Juice on prostate cancer in *in vitro* and in *in vivo* mouse models. (PX0065-PX0071). In this pre-clinical research, which studied human prostate cancer in the lab and inside of mouse models, POM Juice was

found to inhibit cancer cell growth, promote prostate cell death, and inhibit the inflammatory process which is correlated with the growth of cancer. *Id.*

For example, in a study by *Seeram, Heber et al.*, "(*Pomegranate Ellagitannin-Derived Metabolites Inhibit Prostate Cancer Growth and Localize to the Mouse Prostate Gland*)," J. of Agric. Food Chem. 2007 (PX0069), the researchers evaluated the effects of pomegranate extract on prostate cancer growth in severe combined immunedeficient mice injected with human prostate cancer cells and on prostate cancer cells *in vitro* (in a Petri dish). (PX0069-0001). The study showed that the pomegranate extract significantly inhibited the growth of the human prostate cancer in the mouse as compared to the control. (*Id.*) Similarly, it was found that the hydrolyzed derivatives of ellagitannins—the most abundant polyphenol anti-oxidant present in pomegranate juice, significantly inhibited the growth of human prostate cancer cells *in vitro.* (*Id.*) Finally, it was found that the bioactive derivatives of ellagitannins discussed above, was found to localize in the mouse prostate tissue. (*Id.*) All of these findings strongly suggest that POM has a significant anti-tumor effect on prostate cancer.

In another study, by *Rettig MB, Heber et al.*, "(*Pomegranate Extract Inhibits Androgen-Independent Prostate Cancer Growth Through a Nuclear Factor-κB-Dependent Mechanism*)," Molecular Cancer Therapy 2008 (PX0070), the researchers evaluated POMx Pills and POM Juice and found that their consumption in immunedeficient mouse with human prostate cancer grafts led to cancer cell growth reduction and decreased PSA levels. As explained by Dr. deKernion during his testimony, 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. (deKernion, Tr. 3044-47). In this study, POMx was found to inhibit NF-kB and cancer cell viability in a dose response fashion *in vitro* and in the human prostate cancer graft mice model—this was similar to the juice. (PX0070). Based on these results, 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. (*Id.*)

Similarly, in another study by *Sartippour MR et al.,* "*Ellagitannin-rich Pomegranate Extract Inhibits Angiogenesis in Prostate Cancer in vitro and in vivo*," International Journal of Oncology 2008 (PX0071), it was found that POMx significantly inhibited angiogenesis (blood vessel growth) both *in vitro* on human prostate cancer tissue and in immunedeficient mice grafted with human prostate cancer tissue. Angiogenesis is a critical element of cancer growth as sufficient blood flow is necessary to support the fast growing cancer cells. (PX0071-0001). Prostate cancer cell growth in turn is directly linked to PSADT. (PX0161-PX0188). Given this, the researchers concluded, "[t]hese 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).

5. RCTs Are Not Necessary In The Context Of A Food Like Pomegranate Juice

Despite a significant body of published research showing a profound effect of POM Juice on prostate cancer (both basic and clinical), Complaint Counsel still challenged the science supporting the likely beneficial effects of pomegranate juice on prostate heath and prostate cancer. In doing so, Complaint Counsel ignore, as it must, the significant pre-clinical science performed on antioxidants and pomegranate juice, and attempts to apply a scientific standard used only with drugs in order to downplay the clinical research showing a significant benefit.

Complaint Counsels' criticism, through Dr. Eastham, was that the research performed on pomegranate juice with regard to prostate cancer was not done to the standard of the FDA and that of a drug—in other words RCT. Dr. Eastham insisted that RCT studies are <u>always</u> required for health claims no matter the risk (or lack thereof). (Eastham, Tr. 1329-1331). But such a standard is simply misplaced in the context of a food. Particularly in the context of prostate cancer, which can take decades to clinically affect or ultimately kill the patient, Complaint

Counsels' position would almost certainly discourage or eliminate altogether the dissemination to the public of any information regarding food that may potentially positively affect prostate health or prostate cancer progression. Given the limited treatment options available to men for prostate cancer pre and post radical local treatment, and the significant potential side-effects, this makes little sense. (Eastham, Tr. 1331-32) Nevertheless, Dr. Eastham insisted an RCT is always required, despite the fact that such a study would involve between 10,000 to 30,000 participants, cost in the range of $600 million, and likely take decades to complete. (Eastham, Tr. 1322-28).

Tellingly, Dr. Eastham does not practice what he preaches. During cross-examination, he reluctantly admitted that although he allegedly believes no health claims can be made and no treatment untaken without RCTs "proving" the efficacy of the substance or treatment being studied, Dr. Eastham himself performed about 200 radical prostatectomies per year for a number of years, even though no RCT showed that the operation provided any benefit to the patient. (Eastham, Tr. 1323-32). And unlike drinking pomegranate juice, the potential side-effects of Dr. Eastham's many prostatectomies include impotence, bleeding, embolisms, infection plus the risks of general anesthesia. *Id.* Dr. Eastham's admission is fatal to his extreme position and demonstrates that his alleged purity as to required level of substantiation of RCT is simply not true.

6. Competent And Reliable Evidence Supports POM's Prostate Health Claims

The basic science showing a direct effect of The Challenged Products on prostate cancer cell apoptosis, proliferation and serum nitric oxide levels, and the clinical research showing POM Juice materially lengthened PSADT, support the "very convincing" science that POM Juice has a significant inhibitory effect on prostate cancer. (PX0351 (deKernion, Dep. at 53-56); Heber, Tr. 1993-96). Similarly, and based on the above science, Dr. deKernion testified that there is a "high degree of probability" that POM Juice can inhibit the clinical development of prostate cancer in men who have not been diagnosed with that disease and "compelling" evidence that it may prevent or reduce the risk of ever contracting prostate cancer. (PX00161;

deKernion, Tr. 3119-20). And at the very least, POM Juice can delay very invasive and more radical treatments and their concomitant severe side-effects and can be used as a reasonable adjunct (meaning in addition to but not as a substitute) to traditional medical care. (PX00161; deKernion, Tr. 3104). Dr. Heber shares this opinion with others, as he testified, "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).

In sum: (1) basic pre-clinical science supports the clinical findings of a robust effect of the Challenged Products on prostate cancer tumor behavior; (2) PSADT is the best marker for risk of clinical recurrence of prostate cancer and mortality following radical local treatment; (3) consumption of the Challenged Products has been shown to materially lengthen PSADT following radical prostatectomy; (4) the Challenged Products are not drugs and therefore should not be governed by an FDA drug standard; and (5) given the above, there is competent and reliable scientific evidence that the Challenged Products support prostate health and with a hight degree of probability inhibit the clinical development of prostate cancer and the public has a right to have this information. (RFF 1577-1579, 1584-1922).

G. POM's Erectile Health Claims Are Substantiated By Competent And Reliable Evidence

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. (RFF 1923; 1936-1991; 2065-2119). The mechanism by which this fruit promotes erectile health and function is via its potent antioxidant components and its impact on NO, which is of "paramount importance" to good erectile health and function and is the key molecule that governs penile erections. (RFF 1924; 1936-1991; 2065-2079).

1. The Totality Of POM's *In Vitro* And *In Vivo* Studies Demonstrate The Beneficial Effects Of Pomegranate Juice On Erectile Health And Function

Dr. Louis Ignarro won a nobel prize for his discoveries concerning NO. He conducted an *in vitro* study to evaluate pomegranate juice's capacity to protect NO against oxidative destruction. (RFF 1965). Based on his findings, Dr. Ignarro concluded that pomegranate juice possesses potent antioxidant activity that results in marked protection of NO against oxidative destruction, thereby resulting in augmentation of the biological actions of NO. (RFF 1966-1967). Dr. Ignarro later proclaimed "pomegranate juice was 20 times better than any other fruit juice at increasing nitric oxide." (RFF 2091).

Other studies show similar results. Using an animal model, for example, Dr. Kazem Azadzoi and colleagues found that, due to its high antioxidant capacity, long-term pomegranate juice intake increased intracavernosal blood flow in the penis, improved erectile responses, improved smooth muscle relaxation, and decreased erectile tissue fibrosis. (RFF 1945-1953) (PX0189-0011-0012; PX0051; Goldstein, Tr. 2595-96, 2597).

In addition to these *in vitro* and *in vivo* studies, multiple other significant scientific studies exist that demonstrate, not only the antioxidative powers of pomegranates in enhancing and preserving nitric oxide, but also support the general proposition that antioxidants positively influence erectile health. (RFF 1988-1991).

2. POM's Clinical Study Supports The Conclusion That The Positive Erectile Health Results In The Basic Science Are Borne Out In Human Function

Building on this strong basic scientific foundation, Dr. H. Padma-Nathan performed a RCT of pomegranate juice versus placebo in men with erectile dysfunction, which is the first and only clinical trial of its kind in the field. (RFF 1971-1975; 1978). The study, which had all the same scientific rigors of any drug study, was published in the very reputable International Journal of Impotence Research in 2007. (Hereinafter referred to as the "*Forest/Padma-Nathan RCT Study*"). (PX0189-0012-0013; CX0908; CX1337 (Forest, Dep. at 220-221, 225); CX1338 (Padma-Nathan, Dep. at 195-197)). The 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). Using a global assessment questionaire

("GAQ"), Dr. Padma-Nathan found that participants rated pomegranate juice 50% more effective than placebo at improving erections. (CX0908-0003; PX0352 (Goldstein, Dep. at 109, 144); CX1338 (Padma-Nathan, Dep. at 191-192)). The GAQ results achieved a probability value ("p-value") of 0.058, meaning that the positive results of the study were 94.2% likely to be the result of something other than "chance." (Heber, Tr. 1978; Goldstein, Tr. 2599; Burnett, Tr. 2305). 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. (PX0189-0013; PX0149-0006; CX0908; Heber, Tr. 1979, 2001; Goldstein, Tr. 2598 -99; Burnett, Tr. 2256; PX0349 (Burnett, Dep. at 138-139)).

As set forth below, POM's basic science, animal studies and clinical study are significant as testified to by Respondents' experts, Dr. Burnett and Dr. Goldstein.

3. Respondents' Expert, Dr. Burnett, Has Testified That POM's Studies Are Sufficient To Support The Conclusion That It Is Likely That Pomegranate Juice Has Beneficial Effects On Erectile Health And Function

Dr. Arthur Burnett of Johns Hopkins University Medical School, Respondents' expert regarding nitric oxide, explained 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. (PX0149-0004-0007; PX0349 (Burnett, Dep. at 87-90, 103, 118, 137); Burnett, Tr. 2250-56, 2303). Dr. Burnett testified that the basic scientific studies alone "provide a powerful support for pomegranate juice . . . as antioxidants; that they work with very potent effects on the nitric oxide regulatory mechanism" and that "there's good basic science support that pomegranate juice is a very effective agent factor . . . in vascular function." (PX0349 (Burnett, Dep. at 116-117)). Dr. Burnett also testified that the *Forest/Padma-Nathan RCT Study* demonstrates pomegranate juice is "a potential treatment for ED." (PX0349 (Burnett, Dep. at 116-117, 142)). Dr. Burnett concluded that the 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).

Dr. Burnett indicated that 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). 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. (PX149-0006-0007; Burnett, Tr. 2272-74, 2303; PX0349 (Burnett, Dep. at 118, 137)).

4. Respondents' Expert, Dr. Goldstein, Testified That "Without a Question" Pomegranate Juice Promotes Erectile Health And Function

Not surprisingly, against this scientific backdrop, Dr. Irwin Goldstein, Respondents' expert in the clinical aspects of erectile health, concluded that "without a question," "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." (PX0189-0010, 0014; Goldstein, Tr. 2605). Dr. Goldstein also concluded that reasonable and competent scientific evidence shows that pomegranate juice reduces the risk of or ameliorates erectile dysfunction caused by endothelial dysfunction, blood flow impairment or oxidative stress. (Goldstein, Tr. 2605).

Dr. Goldstein testified that the existing *in vitro* and animal studies definitely show the likelihood that pomegranate juice improves erectile function. (Goldstein, Tr. 2601-02, 2605; PX0352 (Goldstein, Dep. at 37-42)). Dr. Goldstein noted 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 . . . leads to the improvement of erectile function in men with erectile health issues." (PX0352 (Goldstein, Dep. at 133); PX0189-0011; Goldstein, Tr. 2594-95).

Dr. Goldstein also testified that the *Forest/Padma-Nathan RCT Study* showed that, in fact, pomegranate juice did improve erectile function for men who had suffered from erectile dysfunction, and that this "absolutely" had important clinical significance, even though it fell slightly short of statistical significance, generating a 94.2%, rather than 95% confidence level. (PX0189-0013; PX0352 (Goldstein, Dep. at 108-109); Goldstein, Tr. 2598-99). Dr. Goldstein indicated that the study is "clinically significant because it supports the conclusion that the positive results in the basic science are borne out in human function." (PX0189-0013).

Further, Dr. Goldstein concluded that since pomegranate juice is not a pharmaceutical drug, physicians who treat patients concerned with erectile health would not hold pomegranate juice to the standards traditionally required by the FDA for approval of a pharmaceutical drug (including performance of an RCT) before recommending pomegranate juice to their patients. (PX0189-0003; Goldstein, Tr. 2600, 2601-02, 2611, 2620).

Finally, Dr. Goldstein opined that he would recommend pomegranate juice as a management 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). Moreover, Dr. Goldstein opined 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. (PX0189-0005, 0014-0015; PX0352 (Goldstein, Dep. at 37-42); Goldstein, Tr. 2605, 2641).

5. Complaint Counsels' Erectile Expert, Dr. Melman, Demonstrated That His Opinions Were Extreme, Uninformed and Motivated By Bias

Although Complaint Counsels' expert, Dr. Arnold Melman, testified that he did not know the meaning of an "RCT" (Melman, Tr. 1134-35), Dr. Melman asserted, contrary to widespread scientific agreement, that erectile health and function claims can only be substantiated by two large, randomized, double-blind, placebo controlled studies, conducted by two different institutions, with the answers of the participants confirmed by their sexual partners. (Melman, Tr. 1137-43). In addition, for a study to claim any improvement in the participants, the men must have reached orgasm, and that, to be considered at all, each of the two large randomized studies had to reach statistical significance. (Melman, Tr. 1137-43).

Dr. Melman testified that, in requiring such randomized controlled tests, he was applying the FDA standard for drugs because he insisted that pomegranate juice "is a drug," and that, frankly, by his definition "everything is a drug", including water, because it is composed of hydrogen and oxygen molecules. (PX0360 (Melman, Dep. at 17-19); Melman, Tr. 1140, 1141, 1165).

Further, when Dr. Melman was asked whether he would acknowledge that an "improvement" had occurred if a man who had been impotent for five years could finally get an erection and penetrate his sexual partner after trying the product, Dr. Melman responded that he would not recognize an improvement unless the man also reached an orgasm. (Melman, Tr. 1141-47). According to Dr. Melman, short of an orgasm, a mere sustained erection, even if it hadn't occurred in a long while, would not warrant the recognition of a benefit. (Melman, Tr. 1141-47). In that regard, Dr. Goldstein testified that he "couldn't disagree more" with Dr. Melman's statement requiring orgasm as a test of erectile improvement. (Goldstein, Tr. 2604). Dr. Goldstein also testified that Dr. Melman's statement was flatly contrary to all medical thinking in the field as it is contrary to the IIEF. (Goldstein, Tr. 2604).

On cross-examination, Dr. Melman conceded that he had patented a gene transfer therapy for erectile dysfunction called "hMaxi-K," which he hoped to market and make money from doing so, and that he announced to the public, in an interview with the New York Observer, that his "hMaxi-K" product produced spontaneous normal erections in men suffering from erectile

dysfunction, that the men who tried it became like they were young again, that his "hMaxi-K" was "modifying the aging process" and that it was the "the fountain of youth." (Melman, Tr. 1148, 1153-55). Ironically, Dr. Melman's public claims about the wonders of his "fountain of youth" were not supported by the kind of elaborate clinical studies he testified were essential to making such claims or by RCTs of any kind. On the contrary, they were based on an animal study. (Melman, Tr. 1155).

Dr. Melman was given to exaggerated pronouncements such as that pomegranate juice is "a product that doesn't work," and that, before he would suggest pomegranate juice to his patients, he'd tell them to "stop having intercourse". (Melman, Tr. 1171, 1192-94; PX0360 (Melman, Dep. at 31)). The basis of Dr. Melman's claim that pomegranate juice "doesn't work" was, first, that the *Forest/Padma-Nathan RCT Study* used the GAQ questionnaire, which Dr. Melman called a "lousy test" and, second, that the study didn't reach statistical significance. (Melman, Tr. 1171-78). Dr. Melman insisted that if a difference over placebo doesn't reach statistical significance, it's not a difference (Melman, Tr. 1176-78). Surprisingly, Dr. Melman had no experience with the GAQ questionnaire prior to this case, knew nothing about it and made no effort to acquire such knowledge. (Melman, Tr. 1180-82). The GAQ questionnaire, however, is widely used. (Goldstein, Tr. 2602, 2603; Burnett, Tr. 2304; PX0349 (Burnett, Dep. at 127)), and commonly accepted as a standardized instrument among those conducting erectile dysfunction research. (CX1337 (Forest, Dep. at 79)). Dr. Goldstein testified that for Dr. Melman to not know the GAQ is widely used "is a little embarrassing." (Goldstein, Tr. 2602).

Finally, most telling, on cross-examination, Dr. Melman was read the Supreme Court's recent opinion in *Mattrixx*, 131 S.Ct. at 1320 that "medical professionals and researchers do not limit the data they consider to statistically significant evidence." (Melman, Tr. 1178-80). Not realizing that the quote was from the opinion of the United States Supreme Court, Dr. Melman said he completely disagreed with it. (Melman, Tr. 1178-80).

In summary, competent and reliable scientific evidence and clinical evidence supports the conclusion that pomegranate juice provides a benefit to erectile health and function. (Goldstein,

Tr. 2605; PX0189-0014; PX0149-0006-0007; Burnett, Tr. 2255-56; PX0349 (Burnett, Dep. at 103, 116-118, 137); Heber, Tr. 2012). Also, since improving one's erectile function may also help improve one's erectile dysfunction, urologists would recommend pomegranate juice as an option 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 and therefore do not qualify for pharmacologic treatment. (Burnett, Tr. 2303; PX0189-0014-0015; PX0352 (Goldstein, Dep. at 42-45); Goldstein, Tr. 2609; CX2007 (Heber, Dep. at 85)).

Moreover, 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). Therefore, 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, 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. (PX0189-0005, 0014-0015; PX0352 (Goldstein, Dep. at 37-42); Goldstein, Tr. 2605, 2641; PX0190-0006-0007).

X. COMPLAINT COUNSEL FAIL TO SATISFY THEIR BURDEN OF PROVING THAT RESPONDENTS VIOLATED THE FTCA

A. The Legal Standard For Determining What Claims the Challenged Advertisements Convey

To find that an advertisement is deceptive, Complaint Counsel bear the burden of proving that claims (1) are conveyed in the advertisement; (2) [are] "false or misleading;" and (3) "material to prospective consumers." *Kraft, Inc v. F.T.C.*., 970 F.2d 311, 314 (7th Cir. 1992).

In general, advertisements may convey two kinds of claims, express and implied. Express claims "unequivocally" and "directly state the representation at issue," and as a result, that representation necessarily constitutes the meaning of the claim. *In the Matter of Thompson Med. Co.*, 104 F.T.C. 648, 788 (1984), *aff'd*, 791F.2d 189 (D.C. Cir. 1985), *cert. denied*, 479 U.S. 1086 (1987). No further proof of the meaning of an express claim is required because the

express claim itself (rather than a paraphrase about what it "implies") is explicitly stated. *See* Deception Policy Statement, 103 F.T.C. at 176; *Thompson Med.*, 104 F.T.C. at 788.

By contrast, implied claims are claims that the advertisement communicates to reasonable consumers but that are not expressly stated. *See In re Kraft, Inc.* 114 F.T.C. 40, 120 (1991), *aff'd*, 950 F.2d 311 (7th Cir. 1992), *cert. denied*, 507 U.S. 909 (1993); *Thompson Med.*, 104 F.T.C. at 789. Because such claims are not stated explicitly, the Commission must find that the implied claims are likely conveyed to a significant portion of reasonable consumers. In determining whether reasonable consumers are likely to take away an implied claim, the Commission looks at the net impression created by the ad as a whole. *See* Deception Policy Statement, 103 F.T.C. at 179 & n.32; *In re Stouffer Foods Corp.*, 118 F.T.C. 746, 799 (1994).

Complaint Counsel have the burden to prove, by a preponderance of the credible evidence, that a significant portion of reasonable consumers, acting reasonably under the circumstances, would interpret the message of an advertisement to have conveyed the allegedly implied claim. *See In the Matter of Bristol-Myers Co.*, 1983 F.T.C. LEXIS 63, *373 (1983) (Initial Decision; Conclusions of Law) (requiring proof by "preponderance of credible evidence."); *Stouffer*, 118 F.T.C. at 776 (citing *Kraft*, 970 F.2d at 318) (noting that the "standard by which advertising is judged is whether it is likely to mislead reasonable consumers."); *Thompson Med.*, 104 F.T.C. at 320; Deception Policy Statement, 103 F.T.C. at 179.

Solely in the limited circumstances in which an implied claim is "conspicuous, self-evident, or reasonably clear on the fact of the ad," Complaint Counsel are permitted, in meeting their burden of proof, to exclusively rely on their own reasoned analysis to determine what "reasonably clear" implied claims are conveyed by the challenged advertisement. *Stouffer*, 118 F.T.C. at 777 (citing *Kraft*, 970 F.2d at 314, 319). Complaint Counsel must look at the "net impression" created by the ads as a whole, examining "the entire mosaic, rather than each tile separately." *See* Deception Policy Statement, 103 F.T.C. at 179 & n.32; *Stouffer*, 118 F.T.C. at 799; *FTC v. Sterling Drug*, 317 F.2d 669, 674 (2d Cir. 1964).

Complaint Counsel, however, "do] not have a license to go on a fishing expedition to pin liability on advertisers. . . ." *Stouffer*, 118 F.T.C. at 777. Thus, if "the implied claims may not be determined with confidence from the face of the ad, extrinsic evidence must be examined, including consumer surveys and expert testimony." *Id.* (citing *Kraft,* 970 F.2d at 318) (emphasis added). If extrinsic evidence is available, the Commission will consider it, taking into account its relative quality and reliability. *See Kraft*, 114 F.T.C. at 121. Indeed, "[t]he most convincing extrinsic evidence is a survey 'of what consumers thought upon reading the advertisement in question….'" *Kraft*, 970 F.2d at 318 (citing *Thompson Med.*, 104 F.T.C. at 788-89) (noting that other permissible extrinsic evidence includes consumer testimony, expert opinion and copy tests of ads)

B. Complaint Counsel Fail To Meet Their Burden To Prove That The Challenged Advertisements Convey The Alleged Disease Claims

Here, Complaint Counsel claim that in certain of Respondents' advertising and promotional materials for the Challenged Products, 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). Complaint Counsel, however, failed to meet their burden to establish that any of the Challenged Advertisements make either (a) an unequivocal and directly stated express claim or (b) an implied claim that can be "determined with confidence from the face of the advertisement" that is "conspicuous, self-evident, or reasonably clear on the fact of the ad."

As a result, Complaint Counsel are required to present extrinsic evidence (which they failed to do) to establish that any of the alleged claims in the Challenged Advertisements were conveyed to a significant portion of reasonable consumers. *See Stouffer*, 118 F.T.C. at 777 (citing *Kraft*, 970 F.2d at 318).

Moreover, paramount to any analysis of whether the Challenged Advertisements make either express or implied "clinically proven" disease claims is the nature of the product itself.

(Butters, Tr. 2817-18). What consumers might take away from an advertisement of a healthy whole food product – like a pomegranate or pomegranate juice – should be the focal point of the analysis. This is quite different than the lens consumers would use to view advertising for a topical ointment or drug. Complaint Counsel completely ignore this very significant distinction.

1. Respondents' Eight "Outlier" Advertisements, Which Used More Aggressive Imagery and Language and Were Disseminated Only in the Very Early Years, Make Up a Miniscule Percentage of the Total Advertisements Disseminated by Respondents and Are Ancillary to the Remedy Analysis

As a threshold matter, many of the advertisements that Complaint Counsel attack ran in the 2003-2006 time frame and ceased running thereafter. RFF 2252. Such advertisements include what Respondents term "outlier" ads – ads where 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 Respondents.

The "outliers" include these eight ads: (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? (PX0330a47; CX0251_001); (g) Ingredients: pomegranates, $25 million in medical research (CX314_010); and (h) pomwonderful.com "Real Studies" web. RFF 2254-58.

To the extent Complaint Counsel seek relief based on these "outliers," which were discontinued anywhere from three to eight years prior to the Commission bringing this action or even instituting an investigation, the relief sought (an injunction) is not appropriate here. *See, e.g., FTC v. Evans Products Co.,* 775 F.2d 1084, 1087 (9th Cir. 1985) ("'Past wrongs are not enough for the grant of an injunction,' an injunction will issue only if the wrongs are ongoing or likely to recur."). The "outliers" are thus ancillary to the remedy analysis.

With the exception of an inadvertent blood pressure reference on the "Real Studies" web page, the "outliers" were disseminated during the very early years (2003-2006) and ceased running thereafter. RFF 2258. In fact, a few of these outlier ads were issued as the result of staff

mistakes, which were immediately stopped when the mistake was discovered. For example, the reference to the number of "published studies" in the "Imitation May Be Sincere. But Is It Pure?" ad, which according to Complaint Counsel ran one time on November 1, 2008, was simply an inadvertent mistake because some of the studies had not been "published." The ad should have said "$25 million in medical research." RFF 2403. When the mistake was discovered, the word "published" was quickly eliminated, and Respondents never ran the version with the mistake again. RFF 2403.

Such inadvertent mistakes, however, are not likely to occur in the future because Respondents' current advertising review policy is a formalized process, which culminates in legal review. RFF 483. Moreover, Complaint Counsel have presented no evidence that it is probable that Respondents would run these types of ads again. RFF 2405.

Accordingly, because Respondents stopped running the "outlier" ads long ago, corrective measures have been implemented to ensure that the conduct is not repeated, and there is little probability that the conduct in question will occur in the future, the "outlier" ads are ancillary to the analysis of whether a broad order, such as the one proposed by Complaint Counsel, is appropriate here. *See, e.g., Country Tweeds, Inc. v. FTC*, 326 F.2d 144 (2d Cir. 1964):

> We think it advisable again to note that petitioners in this case have ceased to engage in the advertising practice which prompted the order, and voluntarily did so well before the Commission filed its complaint. Cessation of the offending activity, with the likelihood that the petitioner will not again resume it or a related activity, has been one factor which courts have considered in limiting broad Commission orders.

Country Tweeds, 326 F.2d at 148-49 (citing *Grand Union Co. v. FTC*, 300 F.2d 92, 100 (2d Cir. 1962); *Swanee Paper Corp. v. FTC*, 291 F.2d 833, 838 (2d Cir. 1961).

2. The Challenged Advertisements Do Not Convey the Express Claims Complaint Counsel Attribute to the Challenged Advertisements

Complaint Counsel take an aggressive position regarding what Respondents' advertisements convey and apparently contend that, on the face of many of the Challenged Ads, Respondents expressly convey "clinically proven" disease claims that the Challenged Products

"prevent," "treat" or "reduce the risk" of heart disease, prostate cancer and erectile dysfunction. Such contentions are erroneous.

The Challenged Advertisements do not expressly convey the disease messages that Complaint Counsel assert are made in them. RFF 2459-2475. Indeed, 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. RFF 2468. Similarly, nowhere do Respondents expressly (*i.e.*, unequivocally and directly) state that the Challenged Products "prevent," "treat," or "reduce the risk" of heart disease, prostate cancer and erectile dysfunction. RFF 2467. Indeed, by definition, because such advertisements instead use qualified language, such as "promising," "encouraging" or "hopeful," Complaint Counsel cannot maintain that any of the Challenged Advertisements expressly convey claims of being "clinically proven" to prevent, treat or reduce the risk heart disease, prostate cancer or erectile dysfunction. RFF 2469. Appendix of Advertisements.

For example, even the most aggressive "outlier" ads, such as the 2005 "Amaze your cardiologist" ad, which Complaint Counsel contend makes an express claim, *see* PX0267-0006, did not unequivocally and directly state that POM Juice is "clinically proven" to prevent heart disease. The ad read as follows:

> **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). Indeed, in 2005, the NAD agreed with Respondents on this point and 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). RFF 2363.

3. The Challenged Advertisements Do No7t Convey the Implied Claims Complaint Counsel Attribute to the Challenged Advertisements

Complaint Counsel further contend that, in many of the Challenged Ads, Respondents impliedly convey "clinically proven" disease claims that the Challenged Products "prevent," "treat" or "reduce the risk" of heart disease, prostate cancer and erectile dysfunction. Such contentions are erroneous.

Complaint Counsel completely ignore the important distinction that when consumers view Respondents' advertising it is through a different lens than consumers would use if viewing an advertisement for a drug or an over-the-counter medication. Because POM consumers understand that the Challenged Products are wholly derived from the pomegranate fruit (which is a fact heavily emphasized in POM's advertising), 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. Instead, POM consumers view the Challenged Products the way they perceive any other whole food, like broccoli, or blueberries which may help prevent or improve your odds against disease, but which would not "stop" anything and did not involve a single target of action against a particular disease or condition.

a. The Challenged Advertisements, Viewed as a Whole, Do Not Clearly and Conspicuously Convey "Clinically Proven" Disease Claims to a Reasonable Consumer

Complaint Counsel cannot maintain with confidence that such claims are impliedly made based on the face of the advertisements. Indeed, it is wholly impossible for Complaint Counsel to "conclude with confidence" that the Challenged Advertisements convey the "clinically proven" claims, as alleged, on the face of the ads. S*ee Thompson Med.*, 104 F.T.C. at 789. Respondents' 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, or that such Challenged Products are "clinically proven" to do so, under Complaint Counsels' "net impression" analysis or any analysis for implied claims. RFF 2262.

Indeed, to the extent a "treat" claim can conceivably be implied from any of the Challenged Advertisements (which it cannot), the overall net impression of any ad is not (and certainly cannot be determined with confidence from the face of the advertisement) that the Challenged Products are a substitute for conventional medical treatment. RFF 2262. Instead, 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 and exercise "reduce the risk" of disease. (Butters Tr. 2817-18).

Additionally, to the extent a "reduce the risk" claim can be implied from any of the Challenged Advertisements, the overall net impression of any ad is not (and certainly cannot be determined with confidence from the face of the advertisement) 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 broccoli, a healthy diet, or exercise "reduce the risk" of disease. (Butters Tr. 2817-18).

Thus, because Complaint's Counsels' assertions that the Challenged Advertisements impliedly convey that the Challenged Products are "clinically proven" to prevent, treat or reduce the risk of disease cannot be determined with confidence from the face of such advertisements, Complaint Counsel is required to rely on extrinsic evidence. *Stouffer*, 118 F.T.C. at 777 (citing *Kraft*, 970 F.2d at 318); s*ee supra* Part I.A.

b. Complaint Counsel Failed to Present Any Reliable Extrinsic Evidence To Establish The Claims They Attribute To The Challenged Advertisements

Kraft states that "[t]he most convincing extrinsic evidence is a survey 'of what consumers thought upon reading the advertisement in question…'" *Kraft*, 970 F.2d at 318. Here, in

contrast to Respondents, Complaint Counsel presented no evidence on the meaning of the ads or what a reasonable person would take away from them. Instead, they erroneously rely on "creative briefs" and "consumer logs" to supposedly show what Respondents intended their ads to say.

Even, Complaint Counsels' survey expert, Professor Mazis, in stark contrast to work he had previously done for Complaint Counsel, did not conduct any facial analysis of Respondents' ads or offer any expert opinion on them. RFF 2685. Nor did he conduct any survey or copy test of Respondents' ads. *See, e.g., Thompson Med*, 104 F.T.C. at 788-89 (other permissible extrinsic evidence includes expert opinion and copy tests of ads). Likewise, Complaint Counsels' linguist expert, Professor Stewart, conceded that he was not offering any opinion on how consumers would interpret Respondents' ads, but was only criticizing Professor Butters' methodology in doing so. RFF 239. Indeed, Professor Stewart testified that he did not even know if Complaint Counsel had any evidence on the meaning of the ads. RFF 239. Certainly, Complaint Counsel has produced no such evidence. RFF 2200.

Moreover, Complaint Counsel also 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. RFF 2214. *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. RFF 2214. *In re Thompson Med.*, 104 F.T.C. at 788-89 n.6.

The only evidence on the meaning of the Challenged Advertisements was presented by Respondents through the testimony of Professor Butters. Professor Butters viewed all of Respondents' ads in the complaint and all of the additional ads in Complaint Counsels' supplementary responses to interrogatories. RFF 180.

Professor Butters based his opinion not only on what the ads said, but also on what they implied, in the sense, as he put it, of what message a reasonable person would "take away" from the ads. RFF 182. Professor Butters testified that none of Respondents' ads stated or implied

that their products actually prevented or treated any disease. RFF 184. He further testified that the term "treat" would ordinarily mean that the product was a form of "medical treatment" or was a "substitute" for a medical treatment. In that sense of the term, he testified that none of Respondents' ads stated or implied that their products "treated" any disease. RFF 184. If, on the other hand, "treat" means only that the product "can help" with a disease, Respondents' science strongly supports a claim that the Challenged Products can help with heart disease, prostate cancer and proper erectile function.

Dr. Butters acknowledged that his corrected deposition answers to triple compound questions indicated that some people could understand Respondents' ads to mean that their products "reduced the risk" of particular diseases, although he doubted that they would, in fact, reach that understanding. Assuming *arguendo* that such "reduce the risk" claims can be implied in any of the Challenged Advertisements, Respondents' science strongly supports a claim that the Challenged Products do "reduce the risk" of heart disease, erectile dysfunction and even prostate cancer.

Accordingly, because Complaint Counsel failed to present any extrinsic evidence on the meaning of the ads or what a reasonable person would take away from them, they have failed to meet their burden that a preponderance of the credible evidence shows that such implied "clinically proven" disease claims were actually conveyed to a substantial segment of the reasonable consumer. RFF 2262.

c. The Vast Majority of the Challenged Advertisements Fall Into Three Categories, Which Do Not Convey The Implied Claims Complaint Counsel Attribute To The Challenged Advertisements

The vast majority of Respondents' Challenged Advertisements from 2006 through 2010 fall into one or more of three general categories: (a) specific study; (b) "backed by" and (c) antioxidant. RFF 2459. None of the ads in the three categories convey the implied claims Complaint Counsel attribute to the Challenged Advertisements. RFF 2465-75. No matter how such 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. RFF 2465-75.

Respondents' 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.

i. Specific Study Ads Truthfully Describe Scientific Studies

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. Each of these ads were substantiated by competent and reliable scientific evidence. RFF 2478-2506. In fact, while Respondents have sponsored at least one hundred scientific studies on the Challenged Products, Respondents only specifically described six of these studies in the areas of prostate, cardiovascular and erectile health in their ads. RFF 2479.

For example, the "Drink to prostate health" ad described the results of the Pantuck Study (2006), stating:

> 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.

Similarly, the "Antioxidant Superpill" ad summarized the results of the Bev I Coronary Perfusion Study:

> 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. In looking at these ads through the lens that POM Juice and POMx are wholly derived from pomegranates, neither of these ads implies that the Challenged Products prevent, treat or reduce the risk of heart disease or prostate cancer. Moreover, Complaint Counsel presented no evidence that consumers took away the message presumed by Complaint Counsel just because Respondents referred to "prostate cancer," "PSA doubling times," "impaired blood flow," and "improved blood flow" in the Challenged Advertisements. Nor could such a finding be consistent with First Amendment precedent holding that the government may not aggressively suppress the publication of nutrition science on the theory that the science itself may mislead consumers, or when a qualification of some form is sufficient. *See Wallach v. Crawford*, 2005 WL 6054963, at *8-9 (S.D. Cal. Mar. 29, 2005); *see also Edwards v. District of Columbia*, 2011 WL 667950, at *6 (765 F.Supp. 2d 3 (2011); *Enten v. District of Columbia*, 675 F. Supp. 2d 42, 50 (D.D.C. 2009) ("the degree of First Amendment is not diminished merely because…speech is sold rather than given away"); *City of Lakewood v. Plain Dealer Publ'g Co*., 486 U.S. 750, 756 n.5 (1988).

ii. "Backed By" Ads Truthfully Represent the Respondents' Scientific Expenditures

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. RFF ¶ 2507. Examples of the body copy used in the "backed by" ads include:

> 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); and
>
> 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?).

Complaint Counsel presented no evidence that consumers took away the message presumed by Complaint Counsel because Respondents' spent a certain amount of money on science and research. RFF 28-29, 2515. Moreover, Complaint Counsels' assertion that the

"backed by" claims in the ads were overinflated because a number of Respondents' scientific studies had a null or even negative result is without merit. Mr. Tupper testified that Respondents learned a great deal even from the unsuccessful studies, and all of Respondents' studies were important sources of knowledge that allowed them to make informed decisions. RFF 2513. For example, studies on the effect of antioxidants and nitric oxide on blood flow applied to the heart as well as erectile function and probably also to prostate health. RFF 2511. In fact, Respondents substantially understated the dollars spent on research in their advertising because they excluded all overhead items, such as rent and salaries, which were very significant added costs. RFF 2514. These "backed by" ads accurately and truthfully represented the dollars spent by Respondents on the totality of the science on the Challenged Products. RFF 2510.

iii. "Antioxidant" Ads

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 and that antioxidants are good for your health . RFF2518-19. Examples of the body copy used in the four "antioxidant" categories include:

> General Antioxidant:
> The Antioxidant Superpower. CX1426, Exh. A (Super HEALTH Powers);
>
> Comparative Antioxidant:
> 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);
>
> Antioxidant Benefits
> 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); and
>
> Multi-Step Antioxidant

> 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).

As exemplified in the body copy quoted above, the overall net impression of the "antioxidant" ads, especially when viewing them through a "food lens," is not that the Challenged Products are "clinically proven" to prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction. RFF 2523. Indeed, many of these ads were meant to be hyperbolic, humorous and use puffery. For example, Dr. Butters testified that the "superpower" ad were intended to be "a work of fiction" in that they are personifying the pomegranate bottle by comparing the bottle to a superhero. RFF 2524. Similarly, 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. RFF 2540. Dr. Butters testified that this image is a "frivolous exaggeration" and that it is not possible that the IV imagery was conveying drugs and medicine. RFF 2541. Moreover, Complaint Counsel failed to present any evidence to the contrary regarding consumer take away of the antioxidant ads or any expert opinion negating the extensive support for the benefits of antioxidants. RFF 28-29, 811-813.

d. Complaint Counsel Conflate the Terms "Prevent," "Treat" and "Reduce the Risk" and Refuse to Distinguish Among the Terms in Assigning Disease Messages to the Challenged Advertisements, Even Though Their Own Experts Do

Complaint Counsel would have us believe that there are no distinctions between the terms "prevent," "treat" or "reduce the risk" and repeatedly address them as identical and interchangeable terms, even though their own medical experts distinguish between "prevent" and "treat" claims in examining the level of scientific support that might be required for each. (RX5007). Indeed, Complaint Counsels' own expert, Professor Stampfer, opined in an article he authored that that (1) RCTs may not be appropriate for nutrient recommendations to <u>prevent</u> disease, as distinguished from drugs used to <u>treat</u> disease; and (2) recognized 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." RX5007.

i. Prevent

Without any expert opinion or extrinsic evidence to support their claims, Complaint Counsel allege that the Challenged Advertisements convey to reasonable consumers that the Challenged Products prevent, in an absolute and targeted sense, certain diseases, including heart disease, prostate cancer, and erectile dysfunction. Respondents deny that any such message was conveyed at all to any reasonable consumer through any of the Challenged Advertisements. *See*, Appendix of Advertisements. Indeed, to the extent any "prevent" message was conveyed, it was not conveyed to consumers in an absolute or targeted sense, like a drug with a single target of action or a medical treatment such as a coronary bypass surgery. Instead, the evidence shows that the Challenged Advertisements conveyed that the Challenged Products help prevent disease, in the same way that broccoli, or blueberries or a healthy diet, exercise and lifestyle are preventative in the sense that they improve your odds of fending off disease and illness. RFF 29. Indeed, Professor Butters confirmed in his trial testimony that the message conveyed to a reasonable consumer in a food-product advertisement is "different from what they would imply about an advertisement for a five-syllable drug." (Butters Tr. 2817-1818).

There is no question that the Challenged Products are wholly derived from pomegranates, and as such, are entirely harmless food products. RFF 493. POM Juice is a 100% juice product wholly derived from the pomegranate fruit, and POMx has the same content as the pomegranate fruit itself and nothing beyond which provides the same, powerful benefits of drinking POM Juice because it is derived from the exact same fruit. RFF 494. Indeed, Respondents have never advertised their products as a drug, nor intended to advertise their products as a drug. (Tupper Tr. at 3008). Rather, the Challenged Products have always been marketed for what they intrinsically are: whole-food products. *See,* Appendix of Advertisements.

POM Juice is sold in the refrigerated produce section of the grocery store. (CX0967_0014). It is not sold in the "drug" or "over the counter" section, or advertised or marketed in conjunction with or in comparison to any drug product, nor is it sold anywhere near such drug products or any products stating that they prevent some specific medical disease. *Id.* Indeed, the drug aisles of a grocery store may contain products such as "Tough Actin' Tinactin," that state on the product that it "prevents" the specific disease of athlete's foot; or Prilosec, which advertises that "it prevents heartburn before it even starts." Or take Prilosec, "That way, you don't get heartburn in the first place."

By contrast, none of the Challenged Advertisements make any claims that they prevent any specific diseases. Rather, the reasonable consumer would view the Challenged Advertising in the context of a whole-food (*i.e.* broccoli or blueberries) and understand that the Challenged Advertisements do not convey that the Challenged Products prevent a disease, but instead that they promote a healthy lifestyle that improves your odds of staving off illness. (Butters Tr. 2817-1818)

Finally, even if the Challenged Advertisements convey that they prevent a specific disease in the same sense that a drug or over-the-counter medication prevents disease (which they do not), the Challenged Advertisement contain carefully qualified statements that convey accurate messages about the actual health benefits of the Challenged Products, the results of the scientific studies and related information. RFF 2215.

ii. Reduce the Risk

Complaint Counsel contend that the Challenged Advertisements convey the message to reasonable consumers that drinking eight ounces of POM Juice or taking one POMx Pill daily reduces the risk of certain diseases, such as heart disease, prostate cancer or erectile dysfunction, or that they are "clinically proven" to reduce the risk of certain diseases. Contrary to Complaint Counsels' allegations, where Respondents use the phrase "reduce the risk" in the Challenged Advertising, the message conveyed is that the Challenged Products improve your odds of staving off illness. Indeed, the overall net impression to reasonable consumers of ads that use the phrase

"reduce the risk" is that the Challenged Products "reduce the risk" of heart disease, prostate cancer or erectile dysfunction in the same manner that a whole-food like broccoli, blueberries or a healthy diet and exercise reduce the risk of disease. Appendix of Advertisements. As explained above, this is a different standard than reduce the risk in the context of a drug or over-the-counter medication, such as "Tough Actin' Tinactin" or Prilosec. (Butters Tr. 2817-1818). In any event, even if a consumer were to take away such a message, all the Challenged Advertisements use qualifiers and convey accurate messages about the actual health benefits of the Challenged Products. RFF 2214.

iii. Treat

Complaint Counsel also allege without support that the Challenged Advertisements convey to reasonable consumers that the Challenged Products "treat" certain diseases, including heart disease, prostate cancer, and erectile dysfunction. Yet, the clear evidence establishes that no such "treat" claims were conveyed. RFF 30, 43, 116, 184. Indeed, none of the Challenged Advertisements use the word "treat" in the manner in which Complaint Counsel contend. *See* Appendix of Advertisements. Nor do any of the Challenged Advertisements imply that any of the Challenged Products are used to "treat" any disease in any context, even in Respondents' earlier "outlier" ads. *See* Appendix of Advertisements.

To the extent a "treat" claim can be implied from any of Respondents' 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). Indeed, this is common-sense, as a reasonable consumer would not view information regarding whole-food product, like broccoli or pomegranates, as a substitute or replacement for doctor's advice. (Butters Tr. 2817-1818).

Respondents have competent and reliable scientific evidence in the areas of cardiovascular, prostate and erectile health to support claims that patients could benefit from consuming the Challenged Products. As such, had Respondents made "treat" claims, these would be supportable and not a basis for liability under the FDCA.

C. In Any Event, Consumers Do Not Buy POM Products Because They Believe That the Products Will Prevent, Treat Or Reduce the Risk Of Disease

In addition to proving a misrepresentation, Complaint Counsel must show that the misrepresentation was "material" to consumers' purchase decision. *In re Cliffdale Assocs.*, 103 F.T.C. 110, 165 (1984); 1983 FTC Policy Statement on Deception ("FTC Policy Statement"), *appended to Cliffdale Assocs.*, 103 F.T.C. at 182 ("A 'material' misrepresentation or practice is one which is likely to affect a consumer's choice of or conduct regarding a product"). "In other words, it is information that is important to consumers." FTC Policy Statement , 103 F.T.C. at 182. Although the Commission is entitled to apply, within reason, a presumption of materiality to express claims, deliberately made implied claims and claims that involve significant health concerns, *id.* at 182, the "Commission will always consider relevant and competent evidence offered to rebut presumptions of materiality." *Id.* at 182 n.47; *accord Kraft*, 970 F.2d at 323 (recognizing that if the presumption does not apply, "the Commission examines the record and makes a finding of materiality or immateriality.").

Where, however, respondent adduces evidence to rebut the presumption, it disappears, and the ALJ 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). As held in *Novartis*, "Respondents can present evidence … directly contradicting the initial presumption of materiality. This is not a high hurdle … the fact finder next proceeds to weigh all the evidence presented by the parties on the issue … after the presumption drops out, 'the inquiry turns from the few generalized factors that establish [the presumption] to the specific proofs and rebuttals … the parties have introduced.'" *Novartis*, 127 F.T.C. at 686, quoting *St. Mary's Honor Ct.,* 509 U.S. at 516.

Here, Respondents adduced evidence to rebut any presumption of materiality by presenting the expert testimony of Professor David Reibstein, who found in his Survey of POM Wonderful 100% Pomegranate Juice Users ("Reibstein Survey"), that fewer than 1.5% of buyers (i) bought (ii) would buy again or (iii) would recommend to a friend POM Juice because they

believe it cures or prevents a specific disease. RFF . Professor Reibstein further found that less than 1% of pomegranate juice buyers who saw a POM advertisement and who (i) bought (ii) would buy again or (iii) would recommend to a friend pomegranate juice to others because they believe it cures or prevents a specific disease. RFF . Complaint Counsel presented no expert opinion that the asserted implied claims ("Challenged Claims") were material to consumers' purchase decision nor have they submitted their own survey to discredit the Reibstein Survey results. RFF . Complaint Counsel have accordingly failed to show that the Challenged Claims were material. Both *St. Mary's* and *Novartis* hold that rebutting the initial presumption "is not a high hurdle," and Professor Reibstein's testimony and survey certainly surmount it.

1. The Reibstein Survey Proves that Consumers Purchase POM Juice For Reasons Other Than Disease-Related Advertising Claims

a. The Reibstein Survey Used Proper Survey Methodology

The Reibstein Survey was conducted in accordance with generally accepted survey principles. Professor Reibstein surveyed two groups, 406 respondents who purchased POM Juice in the past 6 months and 344 people who purchased brands of pomegranate juice other than POM. (RFF 2663) . The Reibstein Survey was designed to reveal: (1) buyers' motivations for purchasing pomegranate juice; and (2) whether having previously seen POM advertisements in the normal sequence of viewing ads, and not in an artificial setting, the ads affected the buyers' motivations for buying pomegranate juice. (RFF 2660). To find out what motivated the respondents purchasing decision, the groups were asked three primary questions: (1) why they bought the product; (2) would they buy the product again and, if so why; and (3) would they recommend the juice to others and, if so why. (RFF 2664-2667). The participants were also directed to "include as many specific details" in each answer as to why they did or would act as they indicated. (RFF 2664-2667). Because "close-end questions ... suggest the desired answer … [and] also tend to elicit bias" (*Stouffer*, 118 F.T.C. at 781; *accord CKE Rest. v. Jack In The Box, Inc.*, 494 F.Supp.2d 1139, 1144-45 (C.D. Cal. 2007)), all three primary questions were asked in an open-ended format to reduce the likelihood of biased results. (RFF 2672).

Moreover, Question K of the Reibstein Survey asked all 750 participants (both POM and non-POM pomegranate juice buyers) whether they had ever seen a POM Juice advertisement and, if they had, what they remembered about the advertisement. (RFF 2673). Participants were directed to provide "as many specific details" as they could remember about the POM advertisement. (RFF 2673).

2. The Results of the Reibstein Survey Prove The Challenged Claims Are Not Material To Consumers' Purchase Decision

The data from the Reibstein's Survey shows that less than 1.5% of participants bought, would buy again or would recommend to a friend POM Juice because they believe that it cures or prevents a specific disease. (RFF 2623). Moreover, there is also no significant difference in the perception of how pomegranate juice can cure or prevent disease between POM Juice buyers (1.48%) and the control group of non-POM Juice buyers (1.74%). (RFF 2623-2624). Likewise, the results from each of the three primary questions that were asked seeking to understand customer motivation for buying, repeat purchasing, or recommending to friends, shows that there was very little reference (1% or less) to pomegranate juice's impact on any disease. (RFF 2625-2645). This was true for POM Juice buyers and non-POM buyers. (RFF 2625-2645). The statistically signficiant results (RFF 2678) of the Reibstein Survey overwhelmingly prove the unimportance in consumers' purchasing decision of the belief that pomegranate juice cures or prevents specific diseases.

Rather, the data from the Reibstein Survey confirms that POM Juice buyers' purchasing decisions are significantly motivated by other factors such as, among others, taste (43.6%), a general belief that the juice is healthy (35.2%), curiosity (14%), bottle design (8.4%), recommendation from others (7.4%) and price (5.9%). (RFF 2633, 2635). The Reibstein Survey also confirms that taste (74%), a belief that the drink is healthy (35.2%), price (6.1%) and quality (3.3%) would drive POM Juice buyers' repurchasing decision. (RFF 2638-2640). Professor Reibstein found comparable results for participants who answered that they would recommend POM Juice to others. (RFF 2644-2645).

Additionally, the study of the impact of POM's advertisements on buyers' purchasing or recommendation decisions establishes that POM's ads had no impact on buyers' beliefs that pomegranate juice can or will cure or prevent disease. (RFF 2646-2647; 2649-2657). As set forth in the Reibstein Survey, a total of 12 unique respondents out of 750, including non-POM Juice buyers, mentioned a specific disease as a reason they bought, would buy, or would recommend pomegranate juice. (RFF 2646). Among these respondents, only 4 of them have seen a POM advertisement at some point and 8 never have. (RFF 2646). The data, therefore, show that the portion of buyers believing in the curative or preventive attributes of pomegranate juice is very similar between the two groups of buyers: the ones who have seen a POM advertisement and the ones who have not. (RFF 2646-2657). The data in the Reibstein Survey also demonstrates that the amount of money POM spent on its research was not a factor in why respondents purchased POM Juice. (RFF 2656).

Professor Reibstein's testimony and survey not only rebutted the presumption of materiality, they provided powerful evidence that, to the extent any of POM's advertisements may have made claims concerning diseases, those claims were not "material" to consumers' purchase decision. Respondents having rebutted the presumption of materiality, the burden of proving materiality by a preponderance of evidence remains on Complaint Counsel (*see Novartis*, 127 F.T.C. at 686-87), and they have failed to provide evidence to meet that burden.

3. Complaint Counsel Failed to Rebut Respondents' Substantial Evidence Establishing the Immateriality of the Challenged Claims

a. Professor Mazis Offered No Opinion on the Materiality of the Challenged Claims But Conceded that an Advertising Claim is Material Only if It Affects Consumers' Purchasing Decision

Complaint Counsel presented no evidence showing that the Challenged Claims were material to consumers' decision to buy. Complaint Counsels' sole witness on materiality, Professor Michael Mazis, offered no opinion on the materiality of the Challenged Claims in his expert report, deposition, or at trial. (RFF 2680-2688). Complaint Counsels' failure to present evidence on materiality is not surprising because it was not even within the scope of their

expert's assignment to examine this critical issue. (RFF 2680). Rather, Professor Mazis merely evaluated the narrow issue of the "scientific adequacy" of the Reibstein Survey. (RFF 2682). Thus, unlike Professor Reibstein, Professor Mazis did not conduct a consumer survey in this case. (RFF 2684). Professor Mazis also provided no expert opinion based on a facial analysis of POM's ads. (RFF 2685). Nor contrary to his work as a marketing witness for Complaint Counsel in previous cases, did he analyze the impact or "indirect effects" of POM's advertisements on consumers (RFF 2686-2687), or examine POM's ads based on the psychological and consumer behavior theory of "categorization." (RFF 2688).

According to Professor Mazis, "the appropriate measure of materiality" is "the potential impact of the challenged claim on purchase or usage behavior." (RFF 2691). Moreover, he concedes that "an advertising claim may involve information important to consumers, but to be material is has to be important to their decision to buy." (RFF 2690, 2692). Consequently, Complaint Counsels' failure to have Professor Mazis conduct a consumer survey or opine on the materiality of the Challenged Claims is baffling given "materiality" is a critical issue in this case and Professor Mazis's concession that a statement is material only if it is likely to affect a consumer's choice to purchase a product. (RFF 2690, 2692). Of course, given the results of the Reibstein Survey, which decisively demonstrated the lack of materiality of the Challenged Claims, it is not totally surprising that Complaint Counsel failed to seriously address the materiality of the Challenged Claims.

Of course, for an advertising claim to be material requires the advertisement to actually affect consumer behavior. However, Complaint Counsels' expert, Professor Stewart, conceded that it takes "three good exposures" to an advertisement before the ad can have an effect on the consumer (RFF 2696) and that it takes "many exposures" to constitute three good exposures. (RFF 2696). Professor Mazis concurred testifying that a "couple of exposures to an ad" are "probably . . . not going to affect people's belief about a product." (RFF 2697). There is no evidence that any POM advertisement making a disease claim of any nature had more than a single run, much less brining about "many" exposures of the advertisement to any consumer.

(RFF 2698-2701). Therefore, based on the opinions of Complaint Counsels' own experts, Complaint Counsel is unable to credibly argue that the Challenged Claims effected consumer behavior. As to this point, Professor Mazis agrees: "I don't think there's any evidence in the record on that," meaning whether "any POM Juice or POMx advertisement was likely to affect anyone's belief about POM." (RFF2689, 2719-2720).

In sum, given that the Reibstein Survey rebutted the initial presumption of materiality, and Professor Mazis' concession about the lack of evidence in the record on materiality, Complaint Counsels' failure to present any evidence that consumers place any importance on the Challenged Claims is fatal to their ability to prove deception under the FTC Act.

b. Professor Mazis Declined to Rule Out the Reibstein Survey as Probative Evidence of Materiality

Professor Mazis declined to rule out the Reibstein Survey "as probative evidence." (RFF 2718). Indeed, on cross-examination, Professor Mazis admitted that he wrote an article entitled *Use of Consumer Surveys in FTC Advertising Cases* in which he suggested, as one way of proving that an advertisement was immaterial to consumers, a survey asking why the participants buy the advertised product. The open-ended questions Professor Mazis used as examples of how to prove the claim was not material were: (1) "what are the reasons you buy cheese?"; (2) "what are the reasons for your buying individually wrapped cheese food slices?"; and (3) what are "'all the reasons you can think of as to why you buy Kraft singles?'' (RFF 2703). These were almost identical to the open-ended questions asked in the Reibstein Survey. According to Professor Mazis, these open-ended questions have "probative value" in showing an advertisement is immaterial. (RFF 2703).

4. Complaint Counsels' Attempt to Identify An "Intent" Sufficient To Obtain A Presumption Or Rebut Respondents' Survey Expert On Materiality Was Unsuccessful

In an attempt to obtain the initial presumption of materiality and rebut the expert opinions of Professor Reibstein, Complaint Counsel relies on some irrelevant consumer research and

POM's consumer comment logs. However, these documents shed no light on the materiality of the Challenged Claims.

a. The Consumer Research Relied Cited By Complaint Counsel Does Not Address the Materiality of the Challenged Claims

i. The A&U Study is Methodologically Flawed and Unreliable and Should Be Disregarded

Complaint Counsels' reliance on OTX Corporation's Attitude and Usage Study ("A&U Study") is misplaced because it is seriously flawed and unreliable.

First and foremost, Complaint Counsels' expert, Professor Mazis, conceded that the A&U Study does not address whether POM ads were material to the participants' purchase decision. (RFF 2738). That concession is dispositive on the question of whether the A&U Study is relevant to the issues at hand.

Nevertheless, Professor Reibstein testified that the results of the A&U Study are unreliable and inflated because the closed-ended questions are leading in that the participants are given a limited number of choices and/or cued to select from attributes that they may not otherwise have thought of. (RFF 2724). Utilizing closed-end questions also results in the exclusion of potential answers that were not included on the list of choices because survey participants often feel compelled to select one of the answers provided on the list of choices. (RFF 2725-2726). *See, e.,g., Procter & Gamble Pharms., Inc. v. Hoffman-La Roche Inc.*, 2006 WL 2588002, *23 (S.D.N.Y. Sept. 6, 2006) (finding survey flawed where, among other reasons, questions did not offer "don't know" or "no opinion" option). That was the case with the A&U Study, as respondents were forced to select one of the six choices. (RFF 2723).

Professor Mazis conceded at trial that the A&U Study was seriously 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. (RFF 2743). Professor Reibstein concurred that the use of the word "antioxidant" in the screening questions was a serious design flaw. (RFF 2743).

b. The Bovitz Survey Is Flawed, Unreliable and Does Not Address Consumers' Purchasing Decisions

For countless reasons, Complaint Counsel cannot rely on the survey conducted by the Bovitz Research Group comparing consumers' perception of ten billboard advertisements from POM's *Super Hero* and *Dressed Bottle* advertising campaigns ("Bovitz Survey") to establish the materiality in this case of the Challenged Claims. Initially, the Bovitz Survey exposed participants only to POM's billboard advertising; however, Complaint Counsel is not challenging billboard advertisements in this case. (RFF 2720). Thus, the Bovitz Survey is irrelevant to this case.

Respondents presented substantial evidence that the Bovitz Survey is seriously flawed and does not address materiality. (RFF 2754-2755). Moreover Professor Mazis did not consider the Bovitz Survey in preparing his expert report and offered no opinion on it in his expert report. (RFF 2752).

Professor Reibstein testified that the Bovitz Survey is unreliable for measuring consumers' motivations for purchasing POM products because the survey participants were not asked why they purchase POM Juice and 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. (RFF 2760-2761).

The Bovitz Survey is also methodologically flawed because participants were shown specific advertisements in a tightly controlled environment, which is not how consumers normally view advertisements. (RFF 2756, 2762). Thus, the results of the Bovitz Survey cannot be used to determine whether what was observed in the survey applies to a normal advertising viewing context. (RFF 2756). The Bovitz Survey is also had no control and, thus participants might have had preconceived perceptions about pomegranate juice before being exposed to POM's billboard advertisements which could skew their perception of POM's billboard advertisements. (RFF 2757).

Finally, as measured by Question E of the Bovitz Survey, the 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. (RFF 2758-2759). Thus, 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. (RFF 2759).

c. The AccentHealth Study Is Methodological Flawed and Unreliable

The AccentHealth Study of POM's advertising is seriously flawed and unreliable. Complaint Counsel presented no contradictory expert opinion. Indeed, Complaint Counsels' expert, Professor Mazis, did not consider the Accent Health Study in preparing his expert report and offered no opinion on it in his expert report. (RFF 2772).

Professor Reibstein testified that the AccentHealth Study was methodologically flawed and unreliable because the patient was intercepted and interviewed immediately after leaving his urologist's office, heightening whatever issues the patient had about helping his prostate. (RFF 2774-2775). The AccentHealth Study was also flawed and unreliable because it had no control. (RFF 2776). Accordingly, the results of the AccentHealth Study are biased. (RFF 2777).

5. POM's Consumer Comment Logs Do Not Show that the Challenged Claims Were Material to Consumers' Purchasing Decisions

Complaint Counsel have failed to prove that the Challenged Claims were material to consumers' purchasing decision based on POM's consumer comment log. POM has received at least 24,470 consumer comments over the years. (RFF 2779). From the nearly 25,000 consumer comments, Respondents provided Complaint Counsel the 53 consumer comment log entries that referenced a specific disease, health study or POM advertisement. (RFF 2780). Only a handful of these 53 consumer comment log entries actually referenced any health-related advertising claim made by POM, which is entirely consistent with the Reibstein Survey results. (RFF 2623-2624; 2780). Moreover, Complaint Counsel presented no affirmative evidence that anyone listed on the consumer comment logs purchased the Challenged Products as a result of the claims made in the Challenged Advertisements.

D. Some Of The "Advertisements" Complaint Counsel Allege Are Not Actually Advertisements and/or Actionable Under the FTCA.

In their November 9, 2011 Proposed Ad Stipulation, Complaint Counsel contend that four media interviews (three by Mrs. Resnick and one by Mr. Tupper) and one university lecture by Mrs. Resnick allegedly constitute "advertising" in violation of Sections 5 and 12 of the FTCA. The four media interview and one discussion include the following:

(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 promoting the sale of 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).

These four interviews and single university presentation, however, are not actionable under the FTCA because they: (1) do not constitute "advertising"; (2) represent constitutionally protected speech; and (3) in any event, cannot be considered as material to the purchasing decision of any consumers.

1. The Interviews and Presentation Cannot Be Considered Advertisements Under the FTCA.

Although "advertisement" is not defined in the FTCA itself, the FTC "understand [an advertisement] to mean a notice or announcement that is publicly published or broadcast and is paid-for." *In re R.J. Reynolds Tobacco Co.*, FTC Docket No. 9206, 1988 WL 490114, *6 (Mar. 4, 1988) (emphasis added); *Daniel Chapter One I,* FTC Docket No. 9329 (2009), Initial Decision at p. 79 (finding a daily, two-hour radio program to be "advertising" when respondents counseled

listeners, who identified themselves as cancer patients, to use respondents' products as cancer treatments and broadcasted a toll-free phone number for listeners to order their products). There is no evidence that the Respondents, including Matt Tupper, paid to anyone for their participation in the interviews or to allow them to speak about pomegranate juice. (RFF). Thus, using the FTC's own "understanding," the individual Respondents' unpaid media appearances do not constitute actionable advertising. That alone should end the inquiry. But Complaint Counsels' overreaching also fails under a more rigorous commercial speech inquiry.

In deciding whether a statement included in a book, article, or public address is an advertisement or commercial speech, courts have looked to the "main purpose" of the publication or address and to the "primary" motivation of the speaker or writer in making the speech or writing the book. *E.g.*, *Oxycal Labs., Inc. v. Jeffers*, 909 F.Supp. 719, 723 (S.D. Cal. 1995). In *Oxycal*, the Court held that having a commercial motivation to sell books does not make statements in a book about a food product's curative powers an advertisement or commercial speech, even though the author also had an interest in a store that sold such products. *Id.* at 725. Complaint Counsel have not presented any evidence that the individual respondents' "main purpose" or "primary motivation" for participating in the media appearances was to sell Mrs. Resnick's book, *Rubies in the Orchard*, or the Challenged Products. Indeed, the "main purpose" of Ms. Resnick's participation in the Newsweek interview was not to sell "Pom." Her motivation for even agreeing to the interview was that allowing the public to get to know her might help sell her book. The "main purpose" of the interview itself was to provide the viewer or reader with a wide-ranging discussion of Ms. Resnick herself, her views, interests and accomplishments, not to sell Pom or even to propose that people buy her book . (CX1426, Exh. F)

The court in *Oxycal* also considered the length of the targeted statements in comparison to the entire segment. *E.g.*, *Oxycal*, 909 F.Supp. at 725. Each of the references to pomegranate juice were very short and only a miniscule portion of the lengthy appearances which covered a variety of other subjects. For example, Mrs. Resnick's reference to the health benefits of

pomegranate juice was only about 35 sections 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.

Another factor to be considered is whether the speaker's statement was "proactive or reactive." *E.g.*, *Boulé v. Hutton*, 70 F.Supp.2d 378, 389-390 (S.D.N.Y. 1999). Mrs. Resnick's and Mr. Tupper's references to pomegranate juice in the course of their interviews were strictly "reactive." In other words, they were responses to questions posed by the interviewers. For example, Mrs. Resnick's reference to the "medical benefits" of pomegranate juice during the course of her interview with Martha Stewart was strictly "reactive" and was directly in response to a question posed by Martha Stewart. (CX1426, Exh. E-6). In *Boulé,* the court noted that the statements that were found to be not advertisements were "a response to an unsolicited inquiry by a magazine reporter seeking comment on a topic of public concern." *Id.*

Lastly, to be classified as commercial speech and thus as "advertising," speech must, in addition to the requirements listed above, "propose a commercial transaction" and must be "solely related to the economic interests of the speaker and its audience." *Oxycal,* 909 F.Supp. at 724. (emphasis added). Statements that can be classified as commercial speech and thus subject to FTC jurisdiction must be "speech proposing a commercial transaction." *In re R. J. Reynolds,* FTC Docket No. 9206 at 3.

Neither Mrs. Resnick's interviews nor even her specific opinions on the benefits of pomegranate juice "proposed a commercial transaction." Certainly, her Newsweek interview was not "solely related to the economic interests of the speaker and [her] audience." The readers were interested in learning about the life, views and accomplishments of a successful female entrepreneur, not in furthering their own "economic interests." RFF . Similarly, Mr. Tupper's interview discussing the newest superfood was not proposing a commercial transaction. RFF .

2. The Interviews and Presentation Represent Constitutionally Protected Speech

The statements made by Mrs. Resnick and Mr. Tupper at their media appearances are also not actionable under the FTCA because they are statements of opinion and therefore constitutionally protected speech. In *Koch v. F.T.C.*, 206 F.2d 311, 314 (6th Cir. 1953), the Sixth Circuit held that respondent's statements, which were published in a book and made during a public address, promoting the sale of medicinal preparations for cancer, were not "advertisement[s] covered by Sections 5, 12, or 15(a)" of the FTCA because the book "sets forth primarily matter of opinion," and "prohibiting dissemination of such a book . . . would violate the First Amendment. . . ." *Id*. at 317-18. Here, Mrs. Resnick's and Mr. Tupper's responses to questions concerning pomegranate juice are mere expressions of opinion. RFF . Thus, these statements call for First Amendment protection and preclude a finding that these statements are advertising in violation of federal statutes.

3. The Media Appearances Cannot Be Considered Material To The Purchasing Decision Of Any Consumer

Additionally, assuming *arguendo*, that Mrs. Resnick's speech and the interviews were considered "advertising," they were not material to the purchasing decision of POM's consumers. Dr. Reibstein's 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. RFF . And, as discussed above, Complaint Counsel adduced no evidence that showed any causal relationship between any of Respondents' advertising and the consumers' purchase decision. RFF .

Rather than confine themselves to POM's conventional advertisements, Complaint Counsel also allege as violations of the FTCA a handful of media interviews given by Mrs. Resnick and Mr. Tupper. In doing so, however, Complaint Counsel have overstepped their jurisdiction. For "unless [an] advertisement can be classified as commercial speech it is not subject to the Commission's jurisdiction." *In re RJ Reynolds*, FTC Docket No. 9206 (Mar. 4, 1988), Order at 3.

E. POM's Health Claims Are Neither False Nor Lacking in a Reasonable Basis

Complaint Counsel have not produced any evidence or testimony suggesting that POM's claims of health benefits are affirmatively false, *i.e.* that the claimed benefits do not exist, nor can Complaint Counsel carry the heavy burden of proving that all of the alleged claims are expressly conveyed in the ads. ere.

Complaint Counsel completely ignore the considerations and cost benefit analysis required by *Pfizer Inc*., *supra*, 81 F.T.C. 23, including the type of product at issue, the possible consequences of a false claim, and the cost of developing substantiation for the claim. A careful weighing of the relevant factors is not at all what Complaint Counsel advocate. Nor is it the position taken by their experts. Indeed, Complaint Counsel would disseminate or publicize no health information to the public that is not backed by RCT, no matter how great the cost of those studies, or how slight the risk of harm, or what other forms of science support the information, no matter the type of product at issue and regardless if it is entirely safe. Complaint Counsel ignores the required cost benefit analysis under *Pfizer*—precisely because their claims should be rejected under this analysis.

Moreover, this Court should prefer "disclosure over outright suppression." *Pearson I*, 164 F.3d at 657. Where there is doubt as to the completeness or accuracy of an ad, the courts favor providing the information to the public over suppressing it. *Id*. This policy has also been endorsed by federal courts following the command in *Pearson I* stating "that, under the First Amendment commercial speech doctrine, there is a 'preference for disclosure over outright suppression.'" *Alliance for Natural Health*, 714 F.Supp.2d at 52-53; *see also Whitaker v. Thompson*, 248 F.Supp.2d 1, 9 (D.D.C. 2002) (*Whitacker I*) ("in finding that speech is misleading, the government must consider that 'people will perceive their own best interests if only they are well enough informed, and . . . the best means to this end is to open the channels of communication, rather than to close them").

An approach that equates food to drugs makes communicating truthful information regarding the potential health benefits of a whole food product economically impossible to "substantiate." Unlike a drug, wherein the manufacturer receives patent protection and market

exclusivity in return for cost intensive research, producers of natural food products receive no comparable compensation for their investment. Requiring RCTs here will necessarily suppress truthful information. In stark contrast, where the product at issue is a potentially harmful drug, and its expected patent rights and likely high price justifies the massive expense of RCTs, requiring two such studies before informing the public of the drug's potential benefit may be appropriate. For example, Bristol Myers' new melanoma drug Yervoy creates a serious danger of death. Its patent gives the company a monopoly, and the treatment costs $120,000. Under such circumstances, the FDA may have good reasons for requiring RCTs.

On the other hand, where we are dealing with a pure food or juice that creates no risk of harm, has no patent protection, and sells for a few dollars, requiring two enormously costly RCTs, as the only way the public can be given information about the product's health benefits, is contrary to the Commission's previously announced positions and is manifestly bad public policy. As summarized in *Pearson I*, 164 F.3d at 656 n.6, the courts should distinguish between products (*e.g.,* dietary supplements) that do not "in any fashion threaten consumer's health and safety" and "drugs," which "appear to be in an entirely different category," *e.g.*, "wherein the potential harm presumably is much greater." As the Court in *Whitaker I*, reasoned:

> It is especially important to recognize that, in the present case, the potential harm to consumers from deception is severely limited . . . . At worst any deception resulting from Plaintiffs' health claim will result in consumers spending money on a product that they might not otherwise have purchased. This type of injury, while obviously not insignificant, cannot compare to the harm resulting from the unlawful suppression of speech.

Whitacker I, 248 F. Supp.2d at 16.

Respondents' experts in each field support the distinction drawn by the Court of Appeal in *Pearson I* and by the district court in the subsequent *Pearson II* case and in *Whitaker I*. For example, Dr. Miller, an esteemed pediatric oncologist, has testified that where the product is absolutely safe, like the Challenged Products, 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 favor disclosure; and credible evidence is enough. RCT are not required or even necessarily superior.

Notably, Dr. Miller, who previously testified as an expert for Complaint Counsel in *In re Daniel Chapter One*, FTC Docket No. 9329, Initial Decision (Aug. 5, 2009) recognized that in this case—involving a 100% pure fruit juice or wholly-derived pomegranate products, and threatening no material risk of harm—costly RCTs should not be required as a barrier to providing information as to the likely health benefits of pomegranate products to the public. RFF .

Considering all of the relevant factors, RCTs should not be arbitrarily required from Respondents as the only way to justify future advertising about potential nutrient disease effects of pomegranate products. Basic science, *in vivo* and *in vitro* laboratory tests and clinical studies, even if not costly RCT studies, are sufficient. That view is supported by the expert testimony of distinguished scientists in each medical field at issue. RFF .

XI. THE REMEDY COMPLAINT COUNSEL SEEK EXCEEDS THE COMMISSION'S AUTHORITY, IS OVERBROAD, AND VIOLATES THE CONSTITUTION

Complaint Counsel fails to justify the relief that they seek.

A. The FDA Pre-Approval Requirement Sought By Part I Of The Notice Order Exceeds The Commission's Authority And Violates the First Amendment of the Constitution.

In Part I of the proposed Order, Complaint Counsel seek for the first time in this Court relief requiring that Respondents obtain FDA approval before making certain advertising claims concerning the Challenged Products. Complaint Counsels' proposed Order exceeds the Commission's authority and violates the First Amendment of the U.S. Constitution.

The Commission's authority to prohibit false, misleading, deceptive and unfair advertising practices derives from the FTCA. The FTCA permits the Commission to outlaw misleading and deceptive advertising. A claim is not misleading merely because it satisfies the definition of "drug" under the FTCA; rather, the Commission has to demonstrate that the claim made about the product is false, misleading, or deceptive.

Because the Commission's authority is limited to prohibiting misleading, deceptive and false claims, the FTCA also does not allow the Commission to prohibit advertising practices that may not meet FDA approval standards, but which are nevertheless truthful or substantiated. In asking the Commission to enjoin the making of claims merely because the claims have not been approved by the FDA, Complaint Counsel are, in effect, asking that the Commission enforce FDA's standards under the Food, Drug, and Cosmetic Act ("FDCA"). But, nothing in the FTCA gives the Commission the authority for such enforcement and, in any event, the plain language of the FDCA mandates that only the "United States," and not other agencies (such as the Commission), may bring actions to enforce provisions of the FDCA. *Buckman Co. v. Plaintiff's Legal Comm'n*, 531 U.S. 341 (2001).

Were the Commission to issue relief requiring pre-approval by the FDA of certain claims, such relief may well prevent dissemination of truthful claims that for whatever reason have not been reviewed by FDA or even would not meet FDA drug approval standards. The Commission has no authority under the FTCA to prohibit truthful claims, even if such claims do not meet the approval standards of another agency.

Complaint Counsel relies on *Thompson Med.*, *supra*, 104 F.T.C. 648 and other cases for the proposition that Respondents should be required to seek FDA approval in order to make certain health claims. *Thompson Medical*, however, merely determined, based on the record in that case that the proper level of substation for the advertising in that case consistent of two well-controlled clinical trials, which happened to be consistent with the FDA's standards. In that case, which, notably, involved an over-the-counter medicinal cream and not a 100% fruit product, the Commission stated that requiring two well-controlled studies for the health benefit claims at issue there was appropriate. Nowhere in *Thompson Medical* or in any other litigated case has the Commission, or courts for that matter, required a marketer to receive pre-approval from the FDA to make truthful and non-misleading health claims under the FTCA. And, to do so would vastly exceed this Commission's authority.

Part I of the Order also violates the First Amendment of the Constitution. The law is clear that the Commission may not prospectively enjoin Respondents from engaging in speech on the basis that the FDA's pre-approval has not been satisfied without first showing that no qualification is capable of rendering the future nutrient-disease advertising claims non-deceptive on a claim-by-claim basis. *See FTC v. Brown & Williamson Tobacco Corp*., 778 F.2d 35, 45 (D.C. Cir. 1985) (explaining that the Commission's injunction violated the First Amendment because it prevented Brown & Williamson from advertising information "in sufficient quantity to allow consumers to make informed decisions" and "[s]ince [that] would eliminate consumer confusion ... the FTC must bear the affirmative burden of demonstrating any inadequacy, and thus deceptiveness ..."); *Peel v. Attorney Registration and Disciplinary Com'n of Illinois*, 496 U.S. 91 ___, 109-11 (_____) (holding that burden is on the government, not the advertiser, to come up with a less restrictive regulation); *Kraft*, *supra,* 970 F.2d at 325 (collecting cases). Indeed, the government is prohibited from keeping the public in the dark simply because there is a lack of scientific agreement on a particular health issue. The freedom of speech protected by the First Amendment includes the freedom to communicate potential health benefits, appropriately qualified.

Under *Pearson I* and its progeny, unless the Commission can meet its burden of showing that consumers will not understand the limits of scientific evidence bearing qualifications, it may not impose such a prior restraint instead. *See Pearson I*, 164 F.3d at 658 ("[a]lthough the government may have more leeway in choosing suppression over disclosure as a response to the problem of consumer confusion where the product affects health, it must still meet its burden of justifying a restriction on speech"); *Ibanez v. Florida Department of Bus. and Prof. Reg.*, 512 U.S. 136, 146 (1994) ("[i]f the protections afforded commercial speech are to retain their force, we cannot allow rote invocation of the words 'potentially misleading' to supplant the [government's] burden to demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree"); *Edenfield v. Fane*, 407 U.S. 761, 771 (1993) (concerning ban on solicitation by accountants and stating that the government "present[ed] no

studies that suggest personal solicitation of prospective business clients by CPA's creates the dangers. . . ."). The *Pearson III* court explained that the "mere absence of significant affirmative evidence in support of a particular claim ... [is not] negative evidence 'against' it." 141 F. Supp. 2d 105 (citing *Pearson I*, 164 F.3d at 660). Complaint Counsel presented no evidence in this case that there is no scientific evidence in support of the claims or that the evidence is for the claims made is qualitatively weaker than that against it. Without satisfying their burden, the Commission is constitutionally barred from imposing the prior restraint set forth in Part I of the Notice Order on Respondents' future advertising.

B. Parts II and III of the Order Seek Over-Broad Fencing In Relief That Is Not Warranted By The Record

In Parts II and III of the Order, the Commission seeks broad, multi-product "fencing-in" relief that is not justified by the record in this case. Notwithstanding the Commission's broad discretion in fashioning remedies, there must "be some relation between the violations found and the breadth of the order." *See Country Tweeds, Inc. v. F.T.C.*, 326 F.2d 144, 148-149 (2d Cir. 1964) (citing *F.T.C. v. Mandel Bros., Inc.*, 359 U.S. 385 (1959); *F.T.C. v. National Lead Co.*, 352 U.S. 419 (1957); N.*L.R.B. v. Cromption-Highland Mills, Inc.*, 337 U.S. 217 (1949); N.*L.R.B. v. Express Publishing Co.*, 312 U.S. 426 (1941)).

"Multi-products orders should be used with caution because they alter the scheme of penalties and enforcement procedures defined by the Act." *Litton Indus., Inc. v. F.T.C.*, 676 F.2d 364, 371 (9th Cir. 1982) (citing *Standard Oil Co. v. F.T.C.*, 577 F.2d at 661). Here, the proposed Notice Order includes fencing-in provisions directed to a range of the Respondents' business activities that have nothing to do with the Challenged Products. In addition to seeking injunctive relief against POM, Complaint Counsel seek an Order against Respondents' unrelated businesses, including FIJI Water (bottled artesian water), Paramount Citrus (citrus fruits), Paramount Farms (nuts and nut processing), Justin Vineyards (winery) and unrelated products. The record in this case does not justify such broad relief.

To determine whether the fencing-in relief bears reasonable relation to the violations in this case, the Commission considers whether there is a reasonable relationship between the conduct complained of and the requested relief. Traditionally, this ALJ has used three factors to evaluate reasonable relation: (1) the seriousness and deliberateness of the violation; (2) the ease with which the violative claim may be transferred to other products; and (3) whether the respondent has a history of prior violations. *See Stouffer Foods Corp.*, 118 F.T.C. 746, 811 (1994); *Sterling Drug, Inc. v. F.T.C.*, 741 F.2d 1146, 1155 (9th Cir. 1984); *Sears Roebuck & Co. v. F.T.C.*, 676 F.2d 385, 391-392 (9th Cir. 1982); *Standard Oil Co. v. F.T.C.*, 577 F.2d 653, 662 (1978). Balancing these factors, the broad fencing-in relief is impermissibly braod and wholly unwarranted in this case.

As an initial matter, the violations alleged in this case occurred years ago have been corrected. RFF . Thus, the conduct complained of is not sufficiently serious or deliberate to justify a broad sweeping order. *Cf. Litton Indus., Inc. v. .FT.C.*, 676 F.2d 364, 371 (9th Cir. 1982) (upholding multiproduct order when respondents continued practices after Commission had questioned the advertising practices). In addition, Complaint Counsel presented no evidence that any of these businesses, which are wholly separate from POM and the Challenged Products, have improperly advertised their products. Without such evidence, the Commission should reject the broad fencing in provisions proposed by Complaint Counsel.

Moreover, the fencing-in relief also defies common sense, as the other POM-related companies and products that would be subject to Complaint Counsels' proposed Order have nothing to do with the Challenged Products. There is, thus, no reasonable relation between the conduct at issue in this case and the products that Complaint Counsel seek to subject to the proposed Order. *See, e.g., American Home Products Corp. v. F.T.C.*, 402 F.2d 232 (6th Cir. 1968) (finding multi-product order too broad when the only evidence presented in the proceeding concerned Preparation H cream (not the other products subject to the order); *Grove Labs. v. F.T.C.*, 418 F.2d 489 (5th Cir. 1969); *cf. Kraft*, 970 F.2d 311 (upholding multiproduct order

relating to cheese related products); *Western Radio Corp. v. F.T.C.*, 339 F.2d 937 (7th Cir. 1964) (upholding order relating to similar products).

Finally, the Commission has declined to issue broad fencing-in relief in instances, as here, where a party does not have a history of prior violations. [Citations] Respondents in this case have never been party to an FTC proceeding or subject to an FTC order. There is, thus, no basis for issuance of a multi-product order.

XII. LIABILITY SHOULD NOT ATTACH TO ROLL GLOBA LLLC OR RESPONDENT MATTHEW TUPPER

A. Complaint Counsel Have Not Shown That Roll Global LLC and POM Are A Common Enterprise

"In considering allegations of misrepresentations, courts engage in a fact-specific inquiry in which the 'pattern and frame-work of the whole enterprise must be taken into consideration. The factors to be considered include, inter alia: common control, the sharing of office space and officers, whether business is transacted through 'a maze of interrelated companies,' the commingling of corporate funds and failure to maintain separation of companies, unified advertising, and evidence which reveals that no real distinction existed between the Corporate Defendants." *F.T.C. v. Ameridebt*, 343 F. Supp. 2d 451, 462 (D. Md. 2004) (internal quotations and citations omitted). Here, the record is clear that Respondents ROLL Global LLC ("Roll") and POM are not a common enterprise. They maintain separate records and do not comingle their funds. (RFF 70-71). Because ROLL was not involved in the underlying conduct complained of, and because they are a separate enterprise from POM, there is no basis to impose liability on them.

B. Complaint Counsel Failed to Present Sufficient Evidence To Justify Imposition of Relief on Respondent Matthew Tupper

Individual liability is secondary and derivative of corporate liability and can only be imposed if the corporation is first found to have disseminated unfair, deceptive or otherwise misleading advertisements. F.T.C. v. Bay Area Business Council, Inc., 423 F. 3d 627 (7th Cir. 2005). Individual liability cannot be imposed on an officer of a company for participation alone;

instead the ability to control the offending conduct or advertising (i.e., being the ultimate decision maker) is always the key inquiry. S*ee In the Matter of Universal Electronics Corp., et al*., 1971 WL 128754 (F.T.C.) (1971); F*.T.C. v. Swish Marketing et al*., 2010 WL 653486 (N.D. Cal. Feb. 22, 2010); *F.T.C. v. Neovi, Inc. et al*., 598 F.Supp.2d 1104 (S.D. Cal. 2008); *F.T.C. v. Transnet Wireless Corp.*, 506 F. Supp. 2d 1247, 1261-1265 (S.D. Fla. 2007); *F.T.C. v. Verity Int'l, Ltd*., 335 F. Supp. 2d 479, 499 (S.D.N.Y. 2004); *F.T.C. v. Publishing Clearing House*, 104 F. 3d 1168, 1171 (9th Cir. 1997); F*.T.C. v. Amy Travel Service, Inc*., 875 F. 2d 564, 574-575 (7th Cir. 1997); *F.T.C. v. Think Achievement Corp*., 144 F. Supp. 2d 993, 998-1002 (N.D. Ind. 2000); F*.T.C. v. J.K. Publications*, 99 F. Supp. 2d 1176, 1181-1185, (C.D. Cal. 2000); *F.T.C. v. Direct Marketing Concepts, Inc. et al.*, 624 F.3d 1 (1st Cir. 2010). Here, Mr. Tupper did not control the conduct at issue in this case. (RFF 77-78, 80, 82, 99-102). .

Corporate officers may be held individually liable for violations of the FTCA, but only if the officer "owned, dominated and managed" the company and if naming the officer individually is necessary for the order to be fully effective in preventing the deceptive practices which the Commission had found to exist. *F.T.C. v. Standard Educ. Society*, 302 U.S. 112 (1937) (officers/managers and sole shareholders of closely held corporation that was dominated and managed by these individuals were held personally liable and included in cease and desist order because it was anticipated from past conduct that these persons would simply try to evade the FTC's order by setting up another company). Complaint Counsel named POM's President Matthew Tupper as an individual respondent in the Complaint. Mr. Tupper neither owns, dominates, nor ultimately controls POM. (RFF 55-57). . During the relevant period, Mr. Tupper was not involved in final advertising decisions and he worked directly for the owners of the company. (RFF 100-102). . He, therefore, is not subject to liability under the FTCA. *In the Matter of Auslander Decorator Furniture, Inc., Trading As A.D.F., Etc. et al.*, 1974 WL 175916 (F.T.C.) (1974) (finding individual respondents lacked sufficient control or responsibility for liability); *Standard Educ. Society*, 302 U.S. at 119 (officers/managers and sole shareholders of

closely held corporation that dominated and managed the company were included in cease and desist order to ensure compliance with the order as these persons were ultimately in control).

Traditionally, the Commission has imposed individual liability as a method to preclude owners of closely held corporations from dissolving the offending corporation and beginning a new one to avoid a cease and desist order of the FTC. *Standard Educ. Society*, 302 U.S. at 119. This later evolved into allowing non-owner officers to be found liable if they met the above described "ability to control" tests or otherwise "formulated, directed or controlled any of the acts and practices" at issue. *In re Griffin Systems, Inc. et al.*, 117 F.T.C. 515, 563-564 (1994) (finding individual who was vice president, treasurer and director liable for distributing solicitation in violation of the FTCA because he was in charge of the company and was considered the control person by the employees).

Unlike the typical president of a private company, Mr. Tupper's authority was derivative of and subject to private owner individuals above him (the Resnicks) and cannot be seen as a typical ultimate decision maker officer subject to liability in FTC cases. *See e.g. F.T.C. v. Publishing Clearing House*, 104 F. 3d 1168, 1171 (9th Cir. 1997); *F.T.C. v. Neovi, Inc. et al.*, 598 F.Supp.2d 1104 (S.D. Cal. 2008). Mr. Tupper's inclusion in any injunctive or related order, is not necessary to effectuate the cessation of the alleged offending conduct (the primary purpose of such orders), as he does not and never did ultimately control it. (RFF 90, 94, 99); *Standard Educ. Society*, 302 U.S. at 119 (officers/managers and sole shareholders of closely held corporation that dominated and managed the company were included in cease and desist order to ensure compliance with the order as these persons were ultimately in control).

Moreover, Mr. Tupper has resigned from POM and has no plans to return to POM or Roll. Because Mr. Tupper never had control over the alleged offending conduct and he retired from POM and is not planning to return, no liability should be imposed. (RFF 53-54).

XIII. CONCLUSION

Setting aside for the moment the constitutional issues, it is clear that Respondents have abundant competent and reliable preclinical and clinical evidence to support their claims—even

if this Court were to adopt Complaint Counsels' argument that claims beyond supportive health have been made. As summarized in *Whitaker* and *Pearson*, and their progeny, while a complete ban would be reasonable where there was no evidence to support a claim or if there were only "qualitatively weak support" in "one or two old studies," where, as here, there exists ample, significant and credible evidence to support the claim, more disclosure rather than less is the preferred approach. POM's studies are rigorous, scientifically executed studies, published in peer-reviewed scientific journals, which certainly show health benefits from the consumption of POM's pomegranate products. The claims are supported under *Pfizer* and the FTC's "competent and reliable" standard—even those claims which Respondents dispute were conveyed by the advertisements. The advertisements, however, do not convey that the products are "silver bullets" against disease as alleged by the FTC. Consequently, the proposed order against Respondents, including its definition of "Covered Products" is not supportable.

In addition, the mechanism in the order requiring FDA prior approval is not appropriate or warranted by the facts of this case, and is constitutionally flawed. This requirement should be barred outright.

Respectfully submitted,
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UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

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

CERTIFICATE OF SERVICE

I hereby certify that this is a true and correct copy of Respondents' **POST TRIAL BRIEF**, and that on this 11th day of January, 2012, I caused the foregoing to be served by FTC E-File, hand delivery and e-mail on the following:

Donald S. Clark
The Office of the Secretary
Federal Trade Commission
600 Pennsylvania Avenue, NW
H-159
Washington, DC 20580

The Honorable D. Michael Chappell
Administrative Law Judge
Federal Trade Commission
600 Pennsylvania Avenue, NW
Rm. H-110
Washington, DC 20580

I hereby certify that this is a true and correct copy of Respondents' **POST TRIAL BRIEF**, and that on this 11th day of January, 2012, I caused the foregoing to be served by e-mail on the following:

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Dated: January 11, 2012