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' REPLY TO COMPLAINT COUNSEL'S POST-TRIAL BRIEF

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RECORD REFERENCES

References to the record are made using the following citation forms and abbreviations:

Appendix of Advertisements – Respondents' Appendix of Advertisements (submitted with initial Post Trial Brief)

Reply Ad Appendix – Respondents' Reply Appendix of Advertisements

CX – Complaint Counsel exhibit

PX – Respondents exhibit

RPTB – Respondents' Post Trial Brief

RFF – Respondents' Proposed Findings of Fact

RCL – Respondents' Proposed Conclusions of Law

RRFF – Respondents' Reply Findings of Fact

CCPTB – Complaint Counsel's Post Trial Brief

RRCL – Respondents' Reply Conclusions of Law

Tr. – Trial testimony

(CX0000 at 000 (XX, Dep. at xx)) – Citations to deposition testimony from this litigation

(CX0000 at 000 (XX, Dep. at xx), *in camera*) – Citations to *in camera* deposition testimony from this litigation

(CX0000 at 000 (XX, OS Dep. at xx)) – Citations to Deposition Testimony from *POM Wonderful LLC v. Ocean Spray Cranberries, Inc.,* No. CV-09-00565 DDP (RZx) (C.D. Cal.)

(CX0000 at 000 (XX, TCCC Dep. at xx)) – Citations to Deposition Testimony from *POM Wonderful LLC v. The Coca-Cola Co.,* No. CV-08-06237 SJO (FMOx) (C.D. Cal.)

(CX0000 at 000 (XX, Trop. Dep. at xx)) – Citations to Deposition Testimony from *POM Wonderful LLC v. Tropicana Prods., Inc.,* No. CV-09-00566 DSF (CTx) (C.D. Cal.)

(CX0000 at 000 (XX, Welch Dep. at xx)) – Citations to Deposition Testimony from *POM Wonderful LLC v. Welch Foods, Inc.,* No. CV-09-00567 AHM (AGRx) (C.D. Cal.)

Joint Stipulations of Law and Fact, JX0001 (*or* **JX0003**) **¶** - Citation to Joint Stipulations of Fact and Law

CCFF – Complaint Counsel's Proposed Findings of Fact

CCCL – Complaint Counsel's Proposed Conclusions of Law

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"An apple a day keeps the doctor away."

John Pavin Phillips (1866)

A Pembrokeshire Proverb: "Eat an apple on going to bed, and you'll keep the doctor from earning his bread."

I. INTRODUCTION AND STATEMENT OF FACTS

If Complaint Counsel had their way, such phrases would be outlawed without prior FDA approval. It is highly doubtful, too, that apples were subjected to two large RCTs before the Pembrokeshire Proverb hit the Wales presses almost 150 years ago.

Certainly, since the proverb became popular, hundreds of studies have been conducted on apples. Research suggests that apples may reduce the risk of colon cancer, prostate cancer and lung cancer. "Other studies have shown an 'alleviation of oxidative damage and cognitive decline' in mice after the administration of apple juice."[1] However, it is doubtful that, regardless of the number of studies on apples or apple juice, that any human benefit will ever be 100% proven, such that further studies will no longer be warranted or desired. That is the nature of science, particularly in connection with a whole food.[2]

If the public is well-served, however, research on apples and apple juice will continue indefinitely—by both government research agencies and private parties, as well. The government, in fact, regularly discloses the potential health benefits of whole foods based on studies that are far less rigorous than the research at issue in this case. Website pages of the USDA, for example, read "Walnuts: Potential New Link to Heart Health Uncovered" (100 lab hamster study), or "Blueberries, Strawberries, May Forestall Brain Drain" (60 lab rat study); or

[1] http://en.wikipedia.org/wiki/An_apple_a_day.

[2] By "whole food" Respondents refer to a fruit or vegetable, or naturally grown product.

"Blueberries May Help Control Cholesterol and Battle Colon Cancer" (9 lab hamster study).[3] (PX0313-0001-02; PX0311-0002). In a separate article, the USDA announced that "Pomegranate is good for you too" and "It's also high in healthful antioxidants." (PX0306-0001). The National Health Institute (NIH), also, has published a finding that "Pomegranate Extract May Be Helpful for Rheumatoid Arthritis,[4]" claims which POM does not advertise. Based on these claims, it is surprising that Complaint Counsel has not initiated a complaint against the USDA.

Despite the fact that these links between the food and illness may never be 100% proven, the USDA chose to make, in effect, claims that these foods "may prevent" and sometimes "may help treat" diseases. These foods may, or may not help persons as opined by the USDA, but the research was "hopeful," "promising," or "encouraging," so, in the public interest. the USDA chose to make these claims on its website. However, the USDA, by its publication of the benefits of "superfoods," such as blueberries and pomegranates, like Respondents, certainly understands the difference between publicly exclaiming the potential benefits of blueberries in "fighting cancer," and proclaiming such benefits for a drug, or for a compound of 50 ingredients with unknown safety issues, far removed from any natural plant state.

Indeed, the health benefits purportedly claimed by POM are in no way novel. Fruit is good for us. Pomegranates are good for us. Any doctor will tell us that a healthy diet heavy in fruits and vegetables improves our health. Even the claims that Complaint Counsel seek to

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[3] The list of claims on the USDA website based on cell, animal, and epidemiology studies goes on and on. PX0310-0003 ("Blueberry Compound Shows Cancer-Fighting Promise"); PX0315-0002 ("Eating six or more servings of whole grain foods like brown rice or whole-wheat toast every week was associated with slower buildup of artery-narrowing plaque in women already diagnosed with this heart condition."); PX0313-0002 ("Blueberries and Strawberries may help slow the decline in learning and memory that often occurs as we age."); PX0314 ("scientists have found that blueberry extracts helped quell the inflammation that was produced when the brain's immune cells responded to oxidative stress, based on a cell-culture study."); PX0316-0004 ("Plump, juicy Bing cherries, eaten fresh, may help people who suffer from the pain of gout or other forms of arthritic inflammation.").

[4] See, http://nccam.nih.gov/research/results/spotlight/120508.htm. The NIH, which published this potential benefit of POMx, proclaims on its website that one of its missions is to promote the "highest level of scientific integrity" and "social responsibility in the conduct of science."

attach to POM in this case are in no way novel for a whole food: improved heart health, lower risk of disease, decreased arterial plaque, and reduced risk of certain cancers.[5] Consumers know that a diet of fruits and vegetables are good for you and improve health. Consumers also know that they will not cure cancer or act as a "silver bullet" against disease.

This is a critical distinction that Complaint Counsel ignore entirely. They do not acknowledge what several branches of the U.S. Government acknowledge--that there is a significant distinction for consumers (from both a perception and public benefit standpoint) between "treat," "prevent" and "reduce the risk" claims for a fruit, or a wholly-derived fruit product, and the same claims when made for a drug. In an ironic twist of fate, POM is being singled out for advertising that emphasizes the healthfulness of its products by virtue of the products' especially close link to the natural whole fruit, and not by artificial "enhancement" of the products, like an over-the-counter treatment or drug. Indeed, Complaint Counsel's position discourages the marketing of whole food products, or 100% whole food derivatives. Complaint Counsel are, in effect, asking the Commission to decimate the application of *Pfizer* and its progeny, among other authorities, that require the Commission to engage in a flexible analysis, much like other government agencies apparently do, to determine if there exists a sufficiently reasonable basis for a claim, including by considering the type of product and its safety.

To this end, Complaint Counsel dispute critical and obvious distinctions between foods and drugs: consumers do not translate "an apple a day keeps the doctor away" to mean that they can forever "keep the doctor away" by eating apples. Similarly, consumers do not translate "Live Long Enough to Watch Your 401(k) recover" or "Life Support" or "Cheat Death" literally – because like an apple, pomegranate is a fruit. Everyone knows it is *not* a magic elixir; it will not cure your cancer or address your medical condition in a way that will allow you to forgo medical care or allow you to "Cheat Death." Even in the worst case scenario sought by

[5] *See*, PX0315-0002; PX0313-0002; PX0314; PX0316-0004 for references to USDA website.

Complaint Counsel—that POM conveyed in its advertising that the product "treats," "prevents' or "reduces the risk" of disease, consumers would have interpreted these alleged claims only in the same way they interpret an "apple a day keeps the doctor away", *i.e.*, that the products "may be helpful" in reducing the risk, preventing or treating disease, like we suspect and hope blueberries, broccoli, and other whole fruits and vegetables do.

POM should not be barred from continuing to contribute to the dialogue on the health benefits of pomegranate so long as it continues to have a "reasonable basis" for its claims. Fortunately for POM, the "reasonable basis" test is well-established law, and POM's science, much more rigorous than many of the studies cited by the USDA, strongly support its health benefit claims.[6]

As apparent from their Post-Trial Brief, Complaint Counsel is well-aware of the strengths of POM's science in support of its health benefit claims. For this reason, Complaint Counsel seek to construe almost all of POM's advertising as broad "establishment claims" that the products "treat," "prevent," and "reduce the risk of disease," thereby allowing Complaint Counsel to avoid engaging in a "substantiation" analysis for those claims. This is an outrageous and untenable position.

Indeed, having now no choice but to deal with Respondents who have sponsored an impressive array of scientific research, Complaint Counsel also rely on a false RCT standard for substantiation that both the Courts and Complaint Counsel's own scientists have stated is not required.

The stakes could not be higher. The crux of Complaint Counsel's argument appears to be that consumers believe POM's products are a drug. They do not, as is obvious from the advertisements and products themselves. Nor would any reasonable consumer translate any treatment or prevention claims to mean "treat," "prevent," or "reduce the risk" like a drug, as

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[6] *In re Pfizer Inc.*, 81 F.T.C. 23 (1972).

confirmed by Respondents' expert, Professor David Reibstein, and unrefuted by Complaint Counsel. Consumers do not literally believe that "an apple a day will keep the doctor away."

Complaint Counsel effectively seek to treat consumers like children, incapable of reviewing science on human nutrition unless their government has filtered and translated that science for them. In the D.C. Circuit's resounding words:

> As best we understand the government, its first argument runs along the following lines: that health claims lacking "significant scientific agreement" are inherently misleading because they have such an awesome impact on consumers as to make it virtually impossible for them to exercise any judgment at the point of sale. It would be as if the consumers were asked to buy something while hypnotized, and therefore they are bound to be misled. We think this contention is almost frivolous. We reject it.

Pearson v. Shalala, 164 F.3d 650, 655 (D.C. Cir. 1999). Importantly, this is not a case where the product is dangerous, and a more intensive level of regulation may be appropriate. *Id.* at 656 ("It is important to recognize that the government does not assert that appellants' dietary supplements in any fashion *threaten* consumer's health and safety.") (emphasis in original). Instead this case involves a perfectly healthy and safe food product, with extensive important science regarding its benefits. Respondents must be free to speak about that science to the public, as they have done, in a truthful and appropriately qualified way. The FTC's statutory authority does not support Complaint Counsel's new crusade to limit all such commercial speech to FDA-approved statements. The public should be permitted to decide what to eat and drink based on more science, not less.

II. POM'S ADVERTISING IS NOT DECEPTIVE AND DOES NOT VIOLATE SECTIONS 5 AND 12 OF THE FTCA

A. Complaint Counsel's Facial Analysis of the Challenged Ads Is Defective and Fails to Demonstrate that the Challenged Ads Convey the Establishment and Efficacy Claims Complaint Counsel Assign to Them

After months and months of hiding the ball, Complaint Counsel finally unambiguously divulge which of the hundreds and hundreds of POM's ads they assert violate Sections 5 and 12 of the FTCA. (CCPTB at 19). Complaint Counsel's attack boils down to 43 "ads and

promotional pieces" (hereinafter, the "Challenged Ads"), 26 of which pertain to POM Juice and 17 of which pertain to both POMx and POM Juice. (CCPTB at 19-20).

Complaint Counsel assert that a "straightforward" facial analysis of the Challenged Ads demonstrates two categories of claims. First, Complaint Counsel contend that 38 of the 43 Challenged Ads convey express or implied establishment claims that the Challenged Products are "scientifically proven" to treat, prevent, or reduce the risk of heart disease, prostate cancer and erectile dysfunction (hereinafter, "Challenged Establishment Ads"). (CCPTB at 20). To support their assertion, Complaint Counsel rely on the combination of "powerful language," "strong medical imagery," "bold headlines" and "statements touting [Respondents'] science." (CCPTB at 20-21). Such reliance is erroneous because Complaint Counsel ignore, among other elements, the overt puffery, outrageousness and humor in the headlines, sub-headlines and imagery and the fact that the Challenged Products are 100% fruit juice or derived from 100% fruit, and advertised as such. (*See infra* at Part II, Sec. A).

Second, Complaint Counsel contend that 5 of the 43 Challenged Ads convey express or implied efficacy claims that POM Juice "treats, prevents, or reduces the risk of heart disease or prostate cancer" (hereinafter, "Challenged Efficacy Ads"). Similarly, Complaint Counsel depend on POM's alleged "use of strong visual imagery," "dominating headlines" and "strong statement of efficacy" to support this alleged net impression. (CCPTB at 24-25). Despite parroting "net impression" analysis, however, Complaint Counsel do not apply it. Furthermore, Complaint Counsel make no mention of any extrinsic evidence anywhere in their post-trial brief and thus wrongly assume that their interpretation of the alleged establishment and efficacy claims are "conspicuous" and "reasonably clear" from the face of the Challenged Ads. *See, e.g., Kraft, Inc. v. FTC,* 970 F.2d 311, 319 (7th Cir. 1992) ("the Commission may rely on its own reasoned analysis to determine what claims, including implied ones, are conveyed in a challenged advertisement, so long as those claims are reasonably clear from the face of the advertisement.") (emphasis added); *FTC v. QT, Inc.*, 448 F. Supp. 2d 908, 958 (N.D. Ill. 2006)

(internal citations omitted) ("Where implied claims are conspicuous and reasonably clear from the face of the advertisements, extrinsic evidence is not required.").

Here, as forth below and in Respondents' Post-Trial Brief (at 65-82), it is wholly impossible for Complaint Counsel to "conclude with confidence" that the Challenged Ads convey the establishment or efficacy claims, as alleged, on the face of the ads themselves. *See In re Thompson Med. Co.*, 104 F.T.C. 648, 789 (1984), *aff'd*, 791 F.2d 189 (D.C. Cir. 1986). Among many reasons, this is because Complaint Counsel completely overlook the "type" of the product advertised, despite that a true "net impression" analysis would required the "type" of product to be taken into consideration when interpreting the advertising. The Challenged Ads advertise 100% pomegranate juice or a 100% pomegranate-derived extract. (RFF 493-94). Indeed, the fact that the Challenged Products are wholly-derived from the pomegranate fruit is heavily emphasized in the body copy and visual imagery of the Challenged Ads as well as on the products themselves. (RRFF 325-615; Reply Ad Appendix). Moreover, what consumers take away from an advertisement of a healthy whole food product – like a pomegranate, pomegranate juice or pomegranate extract – is markedly different than the lens consumers would use when viewing advertising for an over-the-counter medication or drug, like Prilosec or Lipitor. *See Removatron Int'l Corp. v. FTC,* 884 F.2d 1489, 1497 (1st Cir. 1989) (looking to "common-sense" net impression of an allegedly false and deceptive advertisement). Complaint Counsel, however, completely disregard this very significant, common-sense and critical distinction in their facial analysis, rendering virtually all "superfoods" advertising as unlawful without FDA approval. Taken to its logical end, Complaint Counsel would contend that the universal proverb "An apple a day keeps the doctor away" is actionable if apple growers were to use this tagline in their advertising. This is certainly not the right result.

1. The Challenged Establishment Advertisements, Viewed as a Whole, Do Not Clearly and Conspicuously Convey the Broad "Clinically Proven" Claims Complaint Counsel Seeks to Attach to Them

Complaint Counsel contend that 38 of the 43 Challenged Ads[7] convey establishment claims and assert that a simple facial analysis of each of the Challenged Establishment Ads demonstrates that the ads convey the net impression that the Challenged Products are "scientifically proven" or "clinically proven" to treat, prevent or reduce the risk of heart disease, prostate cancer and erectile dysfunction. (CCPTB at 20-21). Yet, as described below, Complaint Counsel go through many elaborate steps and jump to many illogical inferences to prove this assertion, when the alleged "clinically proven" claims should be "conspicuous, self-evident, or reasonably clear" on the face of the ads if they are so self-evidently susceptible to Complaint Counsel's interpretation. *See In re Stouffer Foods Corp.*, 118 F.T.C. 746, 777 (1994). *Compare Thompson Med. Co.*, 104 F.T.C. at 799 (with respect to ads, CX 7, 10 and 11, "we conclude that the language in the headline ('Aspercreme . . . concentrates all the strong relief of aspirin . . .') is readily susceptible to the interpretation that Aspercreme contains aspirin and the language would be so interpreted by consumers") *with Thompson Med. Co.*, 104 F.T.C. at 800 (with respect to ad CX 8,"[w]e are not able to conclude with adequate confidence by looking

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[7] The 38 Challenged Ads were previously defined as the "Challenged Establishment Ads." Of the 38 Challenged Establishment Ads, Respondents contend that six of these ads are not at issue. First, Respondents contend that the three interviews by Mrs. Resnick and Mr. Tupper (CX0473/CX1426, Exh. E-7 (Tupper Interview on Fox Business, June 2008); CX0472_0003 (Lynda Resnick Interview on *The Early Show*, February 2009) and CX0473/CX1426, Exh. F (Newsweek Interview with Lynda Resnick, March 2009)) 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. (RPTB at 92-96; RFF 2252 at 268, 2545-51, 2567-95, 2610-21). Second, the "Lucky I have super HEALTH POWERS" ad, which was disseminated in August 2009, (CX0379_0001) and September 2009 (CX0372_0001/ CX0380_0001), and the "I'm off to save prostates!" ad, which was disseminated in February 2009, (CX0274/CX1426, Exh. C), are not at issue because Professor Mazis admitted that Complaint Counsel were only challenging POM Juice print ads that ran at least twenty-two months before the execution of the Reibstein Survey - that is, those ads disseminated prior to December 2008. (RFF 2238-42, 2252 at 266-67). Similarly, the "Super HEALTH Powers!" hang tag is not at issue because Complaint Counsel failed to present any specific evidence of when this hang tag was disseminated. (RFF 2248-51, 2252 at 267). However, even assuming *arguendo*, that the ALJ accepts the September 2009 dissemination date proffered by Complaint Counsel in the Complaint (CX1426 at ¶ 9.A.), as true, even though there is no evidence of this, Professor Mazis testified that Complaint Counsel were only challenging ads disseminated prior to December 2008. (RFF 2238-42).

solely at evidence from the ad itself whether or not one message conveyed to consumers by CX 8[8] is that Aspercreme contains aspirin" because the "general tone of the ad contrasts Aspercreme with aspirin, emphasizing the supposed difference between the products rather than their similarities."). For these reasons and those set forth below, Complaint Counsel's facial analysis is defective. Indeed, instead of demonstrating that the Challenged Establishment Ads convey "clinically proven" claims, a facial analysis has just the opposite effect.

First, Complaint Counsel fail to accurately describe what an "establishment claim" is. Their interpretation of an establishment claim improperly renders any reference, implied or explicit, to something "scientific" or "medical" in nature, as a broad "clinically proven" establishment claim that the product treats or prevents diseases. Specifically, Complaint Counsel imprecisely characterize an establishment claim as a "claim[ ] that the . . . representation[] [is] based on scientific proof." (CCPTB at 20). While it is true that "establishment claims" are "statements to the effect that scientific tests establish that a product works," *Removatron Int'l Corp. v. FTC*, 884 F.2d at 1492 n.3, and "[c]ommon examples include statements such as 'tests prove,' 'doctors recommend,' or 'studies show,'" *FTC v. Direct Mktg. Concepts, Inc.*, 569 F. Supp. 2d 285 (D. Mass. 2008) (citations omitted), "[a]n establishment claim is one that says, in substance, that 'tests or studies prove' a certain fact." *Gillette Co. v. Norelco Consumer Prods. Co.*, 946 F. Supp. 115, 121 (D. Mass. 1996) (emphasis added).

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[8] The headline in CX 8 stated:

There's always been aspirin ...

Now there's ASPERCREME

Works faster, safer than aspirin – relieves pain in minutes.

Thompson Med. Co., 104 F.T.C. at 800. The next sentences (in much smaller print than the headline) stated: "Aspirin has been helping sufferers of minor arthritis pain for years. Now there's a different way to get relief. ASPERCREME." In addition, there was a visual depiction of an Aspercreme tube in its display packaging on the ad, stating in print slightly smaller than the text of the ad: "An effective aspirin-like analgesic for temporary relief of occasional minor pain …." *Thompson Med. Co.*, 104 F.T.C. at 800.

Here, POM never states, expressly or by implication, conspicuously on the face of any of the Challenged Establishment Ads that scientific tests "prove" that the Challenged Products "prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction," as alleged by Complaint Counsel. (RFF 2210(a); Appendix of Advertisements). Complaint Counsel certainly cannot point to any advertisement that directly states (or even implies) such a claim. Instead, Complaint Counsel cobble together the "statements touting [Respondents'] science" in an effort to artificially stretch the meaning of the ads. (*See* CCPTB at 21-22). For example, Complaint Counsel attempt to read "clinically proven" "prevent and treat" claims into the ads by relying on the following underlined snippets from some of the Challenged Establishment Ads.[9] Notably, Complaint Counsel have failed to quote the relevant body copy, which is set forth below:

- "Medical studies have shown that drinking 8 oz. of POM Wonderful pomegranate juice daily minimizes factors that lead to atherosclerosis," (CX0016 ("Drink and be healthy"); CCPTB at 21);
- An initial UCLA study on our juice found hopeful results for prostate health, reporting "statistically significant prolongation of PSA doubling times," according to Dr. Allen [sic] J. Pantuck in *Clinical Cancer Research,*'06, (CX0280 ("Live Long Enough to Watch Your 401(K) Recover"); CX0328 ("Your New Health Care Plan"); CX0331 ("Healthy, ~~Wealthy~~ & Wise"); CX0337 ("The First Bottle You Should Open in 2010"); CCPTB at 21);
- "Pomegranate juice consumption resulted in significant reduction in IMT (thickness of arterial plaque) by up to 30% after one year," said D. Michael Aviram, *Clinical Nutrition,* '04, (CX0280 ("Live Long Enough to Watch Your 401(K) Recover"); CX0328 ("Your New Health Care Plan"); CX0331 ("Healthy, ~~Wealthy~~ & Wise"); CX0337 ("The First Bottle You Should Open in 2010"); CCPTB at 21);
- "An additional study at the University of California, San Francisco included 45 patients with impaired blood flow to the heart. Patients who consumer 8 oz. of POM Wonderful 100% Pomegranate Juice daily for three months experienced a 17% improvement in blood flow," (CX1426, Exh. I ("Antioxidant Superpill"); CCPTB at 22); and
- "An additional human study showed that consuming pomegranate juice reduces another enzyme: ACE (angiotensin converting enzyme). Inhibition of ACE lessens the progression of atherosclerosis and it is this enzyme that is targeted by blood pressure medications. Pomegranate juice inhibited ACE by 36% after two weeks of juice consumption," (CX0013 (1/09/03 Press Release); CCPTB at 22).

[9] Respondents refer to the Challenged Ads which summarize Respondents' scientific studies on the Challenged Products as "specific study" ads. (RFF 2460, 2478).

From these snippets from the "specific study" ads, Complaint Counsel make the broad generalization that the underlined "[r]eferences to clinical testing, research and case studies are express claims that Respondents' representations are supported by scientific evidence." (CCPTB at 22-23). From this initial statement, Complaint Counsel next illogically and baldly conclude that the reference to (1) "statistically significant prolongation of PSA doubling times" communicates the much broader claim that POM Juice and POMx prevent, treat or reduce the risk of prostate cancer; (2) "significant reduction in IMT (thickness of arterial plaque) by up to 30%" communicates the broader claim that POM Juice and POMx prevent, treat or reduce the risk of cardiovascular disease; and (3) "17% improvement in blood flow" communicates the broader claim that POM Juice and POMx prevent, treat or reduce the risk of cardiovascular disease. (CCPTB at 21-22). On the contrary, to the extent any establishment claim is made in Respondents' "specific study" ads (which Respondents deny), the broadest establishment claim remotely apparent would be that the Challenged Products may help (1) "lengthen PSA doubling times;" (2) "result in a reduction in IMT by 30% after one year" and (3) "improve blood flow by 17%." (*See* Reply Ad Appendix).

Moreover, ignoring for the moment, the very significant fact that the product is 100% fruit juice or 100% fruit derived, nowhere do Complaint Counsel explain how they make the logical (or rather, illogical) leap from (1) "statistically significant prolongation of PSA doubling times" to "prevents, treats or reduces the risk of prostate cancer," and (2) "significant reduction in IMT by up to 30%" and/or "17% improvement in blood flow" to "prevents, treats or reduces the risk of heart disease." These purported inferences are, in fact, contrived. It is not what the advertisements actually say, expressly or implicitly, conspicuously on their face, and there is absolutely no evidence of it.[10]

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[10] Complaint Counsel also imprecisely characterize *In re Metagenics, Inc.*, No. 9267, 1996 WL 615822, at *11,16, 62 (Initial Decision Oct. 11, 1996), to support their very broad approach to establishment claims and imply that the Commission in *Metagenics* undertook a facial analysis of the ads when, in fact, it did not. (*See* CCPTB at 21). In *Metagenics*, the Commission claimed that Metagenics, Inc. and one of its officers (collectively, "Metagenics") had represented, directly or by implication, and without substantiation that microcrystalline hydroxyapatite ("MCHC") (continued…)

Nor do Complaint Counsel describe how they make the leap, for example, from "statistically significant prolongation of PSA doubling times" to (1) "prevents prostate cancer," (2) "treats prostate cancer" or (3) "reduces the risk of prostate cancer." They purposely conflate the three terms "prevent," "treat" and "reduce the risk,"[11] except in a few cases, (*see* Appendix A to CCPTB), where Complaint Counsel have not explained how or why they distinguish among the terms, 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.[12] (*See* RX5007) (Complaint Counsel's own expert, Professor Stampfer, opined in an article he authored that (1) RCTs may not be appropriate for nutrient recommendations to prevent disease, as distinguished from drugs used to treat disease; and (2) recognized that, because RCT study designs may not be "available" (economically or scientifically) for nutrients, "nutrient related decisions [to prevent disease] could be made at a level of certainty somewhat below that required for drugs.").[13] Even drugs

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"reduces or eliminates pain associated with bone ailments." *Id.* at *1. One of Metagenics' ads stated that "MCHC has been reported to improve fracture healing and relieve back pain in women with post-menopausal bone loss." *Id.* at *11. Metagenics, however, conceded that this ad represented that MCHC reduced or eliminated pain associated with bone ailments and failed to deny that the ad represented that Metagenics had scientific proof to substantiate their claim. *Id.* at *62-63. In effect, Metagenics conceded that the ad made an establishment claim regarding pain reduction. The Commission accordingly concluded, without a facial analysis or review of extrinsic evidence, that the ad "report[ing] to . . . relieve back pain in women with post-menopausal bone loss" was an establishment claim. *Id.*

[11] Complaint Counsel further confuse the issue by obscuring whether they contend that the Challenged Ads convey that the Challenged Products "prevent, treat and reduce the risk" of disease or "prevent, treat or reduce the risk" of disease. *Compare* Appendix A to CCPTB ("✓ = The ad makes prevention (P), risk reduction (R), and treatment (T) claims, unless otherwise noted in superscript.") *with* CCPTB at 20-21; CCFF 335, 348, 362, 388 (net impression is that POM Juice "treats, prevents, or reduces the risk of heart disease"). At this late juncture, Respondents should not be forced to guess what claims Complaint Counsel are attacking. Their actions are severely prejudicial.

[12] Nor do Complaint Counsel acknowledge anywhere that "reduce the risk" is closer to "help prevent" than to "treat". (Burnett, Tr. 2274; PX0349 (Burnett, Dep. at 70)).

[13] Complaint Counsel's own expert, Meir Stampfer, acknowledged:

> Similarly, it is judged that the level of confidence needed in defining nutrient requirements or dietary recommendations to prevent disease can be different from that needed to make recommendations to treat disease.

(continued…)

that reduce the risk of breast cancer do not necessarily "treat" breast cancer. *See generally Zeneca, Inc. v. Eli Lilly & Co.*, No. 99 CIV. 1452 (JGK), 1999 WL 509471, at *43 (S.D.N.Y. July 19, 1999) (no discussion of "treat" claim within discussion of the claim that raloxifene has been proven to reduce the risk of breast cancer).

Indeed, case law demonstrates just how unreasonable and illogical it is for Complaint Counsel to read "clinically proven" "prevent, treat or reduce the risk" claims into the Challenged Establishment Ads. *See, e.g., Direct Marketing Concepts,* 569 F. Supp. 2d at 294, 300 (finding no question that the net impression of the Coral Calcium infomercial,[14] which was much more aggressive than the language asserted here, would lead a reasonable viewer to believe that scientific research published in the Journal of the American Medical Association ("AMA") and the New England Journal of Medicine supported the proposition that calcium supplements are able to prevent, reverse, or cure cancer); *FTC v. Nat'l Urological Grp.*, 645 F. Supp. 2d 1167, 1195 (N.D. Ga. 2008) (Thermalean brochure,[15] on its face, conveyed the net impression that the

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(RX5007 at 478) (emphasis added).

[14] The Coral Calcium infomercial stated, in pertinent part:

> Kevin Trudeau: Now, the medical community would say to say that calcium is a cure for cancer is ridiculous.
>
> Robert Barefoot: Then why did the Journal of the AMA this year quote the Strain (phonetic) Cancer Research Institute and [say] that *calcium supplements reverse cancer*. That's a quote from the Journal of the AMA and they quoted how much. They said 1,500 milligrams a day is enough to *reverse colon cancer* and they said other cancers will grow back to normal."

Direct Marketing Concepts, 569 F. Supp. 2d at 294 (emphasis in original).

[15] The Thermalean brochure stated:

> Clinical studies show the active components in Thermalean yield the following extraordinary results:
>
> -Loss of 19% total body weight
>
> -Increase metabolic rate by 76.9% without exercise
>
> -Reduction of 40-70% overall fat under the skin
>
> -Loss of 20-35% of abdominal fat.
>
> * * *

(continued…)

supplement was clinically proven to enable users to lose 19% of their total body weight, lose 20-35% of abdominal fat, reduce their overall fat by 40-70%, decrease their stored fat by 300% and increase their metabolic rate by 76.9%); *FTC v. Removatron Int'l Corp.*, 111 F.T.C. 206, 297-98 (1988) (Commission found "RESEARCH PROVES REMOVATRON METHOD DESTROYS HAIR FOLLICLE" to be an express establishment claim); *Thompson Med.*, 104 F.T.C. at 814-15 (Commission found express claim that Aspercreme's active pain reliever "is clinically proven to give strong, effective relief at the point of arthritis pain" to be "scientifically proven").

In stark contrast to the above-cited cases, the Challenged Establishment Ads merely describe or summarize qualified results or outcomes about specific scientific research.[16]

> In their precise rations, the thermogenic components used in Thermalean have achieved the following results in University-sponsored clinical trials (all of these statistics have been reported in such professional journals as the International Journal of Obesity, American Journal of Clinical Nutrition, and The New England Journal of Medicine):
>
> -300% decrease in stored fat vs. placebo
>
> -29% greater weight loss vs. REDUX
>
> -600% increase in total weight loss vs. placebo
>
> -42% reduction in body fat in a specified time period

National Urological Grp., 645 F. Supp. 2d at 1195.

[16] To further buttress their ill-contrived claims, Complaint Counsel also erroneously argue that POM's use of qualifiers, such as "preliminary," "hopeful," "pilot" and "emerging" to describe the scientific studies are "inadequate to offset the overarching message" because they are in smaller font and blend in with the rest of the body copy. (CCPTB at 24). First, Complaint Counsel blatantly misrepresent this fact because the vast majority, if not all, of POM's qualifiers are in the same size font as the rest of the ad's body copy. (RFF 2465-66, 2506, 2517, 2534, 2542; *e.g.,* CX 109 ("Heart therapy") ("helps guards," "emerging science suggests," and "encouraging results"); CX 0260 ("Drink to prostate health") ("recently published preliminary medical study"); CX0120 ("One small pill for mankind") ("an initial UCLA medical study," "hopeful results," "preliminary human research suggests")). Second, Complaint Counsel's reliance on *In re Daniel Chapter One*, No. 9329, 2009 WL 2584873 (Initial Decision Aug. 5, 2009) and *FTC v. Medlab, Inc.*, 615 F. Supp. 2d 1068 (N.D. Cal. 2009), is misplaced. Unlike Respondents' qualifiers, which were part of the main body copy and used to convey qualified and very couched health messages, the cases cited by Complaint Counsel examined disclaimers that appeared at the conclusion of TV commercials or in miniscule type at the bottom of print ads, both of which potentially "create[d] confusion with messages that contradict[ed] the advertisements' overall messages." *Daniel Chapter One*, 2009 WL 2584873, at *83 (quotations omitted) (Commission found the disclaimer: "These statements have not been evaluated by the FDA. This product is not intended to diagnose, treat, cure or prevent disease," which appeared at the bottom of respondents' web pages to be inadequate to avoid liability because it was inconspicuous as well as inconsistent and contradictory to the content of the advertising). *See, e.g., Medlab*, 615 F. Supp. 2d at 1077 ("Defendants cannot inoculate themselves from the representations that appear in the body of the text by including [] cautionary statements [*i.e.*, 'Results will vary from one individual to another .... To achieve best results, you should follow the caloric abatement (continued…)

(RFF 2478-2506). For example, some of the POMx Pill ads[17] described the Pantuck Study as "[a]n initial UCLA study . . . [that] found hopeful results for prostate health" and reported "statistically significant prolongation of PSA doubling times." This is quite different than stating the Pantuck Study (2006) proved that POMx prolongs PSA doubling times and is clinically proven to prevent, treat or reduce the risk of prostate cancer. The same analogy can be made with respect to any of the Challenged Establishment Ads that summarized the Aviram Study (2004), which reported a 30% reduction in IMT, and the Bev I Coronary Perfusion Study, which reported a 17% improvement in blood flow. Indeed, in 2005, the NAD found that the statement "Just eight ounces a day can reduce plaque up to 30%!" was not an establishment claim (*i.e.*, a "clinically proven" claim). (RFF 2363, 2386).

Similarly, Complaint Counsel engage in an even more aggressive and illogical effort to construct broad establishment claims from POM's "backed by" advertising. However, the fact that POM advertised the amount of money Respondents spent on scientific research does not convey the net impression that the Challenged Products are "clinically proven to prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction." (RFF 2507-19; RPTB at 76-77.) What the "backed by" ads actually convey is that Respondents are committed to the science and learning the truth about pomegranates:[18]

> 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.

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recommendations, increase activity level and not rely on pill use alone'] at the foot of their advertisements."); *Thompson Med.*, 104 F.T.C. 778 ("The record also shows that the brand name 'Aspercreme' is misleading and that the kind of fleeting aspirin disclaimers (such as 'Does not contain aspirin' super displayed for a few seconds) or equivocal ingredient statements (such as 'contains salicyn, a strong non-aspirin pain reliever') in Aspercreme ads are not sufficient and more effective, straight-forward aspirin disclaimers are needed.").

[17] The ads include CX0280 ("Live Long Enough to Watch Your 401(K) Recover"), CX0328 ("Your New Health Care Plan"), CX0331 ("Healthy, ~~Wealthy~~ & Wise") and CX0337 ("The First Bottle You Should Open in 2010").

[18] L. Resnick, Tr. 251; conceded by Complaint Counsel at CCFF 309, 310.

(CX0192 ("What gets your heart pumping?")). Contrary to Complaint Counsel's implication, it is completely illogical to infer from the fact that a certain amount of money was invested in research to the conclusion that the Challenged Products are proven to prevent, treat or reduce the risk of disease. Again, this is another one of Complaint Counsel's ill-defined, "logical leaps" from "backed by $23 million of initial scientific research" to "backed by $23 million in research that proved the Challenged Products prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction." Indeed, Complaint Counsel presented no evidence that consumers took away the message presumed by Complaint Counsel because Respondents spent a certain amount of money on science and research. (RFF 28-29, 2515). Moreover, the "backed by" ads accurately and truthfully represented the dollars spent by Respondents on the totality of the science on the Challenged Products. (RFF 2510).

Second, Complaint Counsel completely ignore their own recitation of the "net impression analysis," which requires the "entire mosaic to be viewed rather than each tile separately," (CCPTB at 15), as well as an examination of "the interaction of all the different elements in an ad." *Stouffer Foods*, 118 F.T.C. at 777. Instead, they erroneously rely on the "impact of each or a few elements" for their overall view of the net impression of an ad, (CCPTB at 20-22), and seemingly neglect a significant element that is key to any facial or common-sense net impression analysis – that the advertisements are of products wholly-derived from pomegranates. (RFF 493).

Throughout its advertising, POM highlights that POM Juice is a 100% juice product wholly-derived from the pomegranate fruit, and that POMx has the same content as the pomegranate fruit itself and is 100% derived from the exact same fruit. (RFF 494; Reply Ad Appendix). Moreover, Respondents have never advertised their products as a pharmaceutical drug, nor intended to advertise their products as drugs. (RFF 495-96). Rather, Respondents have always marketed the Challenged Products for what they intrinsically are: whole-food products. These facts are heavily and repeatedly emphasized throughout POM's advertising, both visually and in the body copy:

- Prevalent visual imagery of one or several deep, ruby red pomegranates;[19]
- Dominant image of deep, ruby red pomegranate juice in bottle shaped like two pomegranates stacked on top of one another;[20]
- Pervasive image of POMx Pill bottle shaped like a pomegranate fruit;[21]
- The words "100% Pomegranate Juice" displayed on face of the POM Juice bottle depicted in the Challenged Ads;[22]
- Repeated textual reference to "POM Wonderful 100% Pomegranate Juice;"[23]

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[19] *See, e.g.,* Reply Ad Appendix; RRFF 325-615; CX0016 ("Drink and be healthy"); CX0348_0001/CX0350_0001 ("24 Scientific Studies "); CX1426, Exh. I ("Antioxidant Superpill" brochure"); CX0331/CX1426, Exh. J ("Healthy, ~~Wealthy~~ & Wise"); CX0280 ("Live Long Enough to Watch Your 401(k) Recover"); CX0314_0004/CX0314_0008 ("POM Wonderful and Prostate Health"); CX0279 ("Science, not fiction"); CX0029 ("Studies Show that 10 out of 10 People Don't Want to Die"); CX0342/CX0353 ("Take Out a Life Insurance Supplement"); CX0180/CX1426, Exh. K ("The Antioxidant Superpill"); CX0337 ("The First Bottle You Should Open in 2010"); CX0351/CX0355 ("The Only Antioxidant Supplement Rated X"); CX0169/CX1426, Exh. L ("The power of POM in one little pill"); and CX0328 ("Your New Healthcare Plan").

[20] *See*, *e.g.,* Reply Ad Appendix; RRFF 325-615; CX0026 ("Drink and be healthy"); CX0031 ("Floss your arteries"); CX0034 ("Amaze your cardiologist"); CX0188_0001 ("Cheat Death"); CX1426, Exh. B ("Drink to prostate health"); CX0109 ("Heart therapy"); CX0379_0002 ("Holy Health! 32 million in medical research"); CX0274/CX1426, Exh. C ("I'm off to save prostates!"); CX0379_0003/CX0372_0003/CX0380_0003 ("KA-POM!"); CX0379_0001/CX0372_0001/CX03801_0001/CX0380_0005/CX0380_0007 ("Lucky I have super HEALTH POWERS!"); CX0314_0004/CX0314_0008 ("POM Wonderful and Prostate Health"); CX0122 ("Science, not fiction"); CX0279 ("Science, not fiction"); CX0029 ("Studies Show that 10 out of 10 People Don't Want to Die"); CX1426, Exh. A/CX0475 ("SUPER HEALTH POWERS!" Hang Tag); CX0180/CX1426, Exh. K ("The Antioxidant Superpill"); CX0314_0006 ("The Antioxidant Superpower"); CX0337 ("The First Bottle You Should Open in 2010"); CX0351/CX0355 ("The Only Antioxidant Supplement Rated X"); CX0169/CX1426, Exh. L ("The power of POM in one little pill"); CX0314_0005 ("The proof is in the POM"); CX0192 ("What gets your heart pumping?"); and CX0328 ("Your New Healthcare Plan").

[21] *See*, *e.g*., RRFF 325-615; Reply Ad Appendix; CX0348_0001/CX0350_0001 ("24 Scientific Studies "); CX1426, Exh. I ("Antioxidant Superpill" brochure"); CX0331/CX1426, Exh. J ("Healthy, ~~Wealthy~~ & Wise"); CX0280 ("Live Long Enough to Watch Your 401(k) Recover"); CX0120 ("One small pill for mankind"); CX0122 ("Science, not fiction"); CX0279 ("Science, not fiction"); CX0342/CX0353 ("Take Out a Life Insurance Supplement"); CX0180/CX1426, Exh. K ("The Antioxidant Superpill"); CX0337 ("The First Bottle You Should Open in 2010"); CX0351/CX0355 ("The Only Antioxidant Supplement Rated X"); CX0169/CX1426, Exh. L ("The power of POM in one little pill"); and CX0328 ("Your New Healthcare Plan").

[22] *See*, *e.g.,* Reply Ad Appendix; RRFF 325-615; CX0026 ("Drink and be healthy"); CX0031 ("Floss your arteries"); CX0034 ("Amaze your cardiologist"); CX0103 ("Decompress"); CX0188_0001 ("Cheat Death"); CX1426, Exh. B/CX0314_0003 ("Drink to prostate health"); CX0109 ("Heart therapy"); CX0379_0002/CX0372_0002/CX0380_0002 ("Holy Health! $32 million in medical research"); CX0274/CX1426, Exh. C ("I'm off to save prostates!"); CX0379_0003/CX0372_0003/CX0380_0003 ("KA-POM!"); CX0379_0001/CX0372_0001/CX03801_0001/CX0380_0005/CX0380_0007 ("Lucky I have super HEALTH POWERS!"); CX0120 ("One small pill for mankind"); CX0314_0004/CX0314_0008 ("POM Wonderful and Prostate Health"); CX0122 ("Science, not fiction"); CX0279 ("Science, not fiction"); CX0029 ("Studies Show that 10 out of 10 People Don't Want to Die"); CX0180/CX1426, Exh. K ("The Antioxidant Superpill"); CX0314_0006 ("The Antioxidant Superpower"); CX0337 ("The First Bottle You Should Open in 2010"); CX0169/CX1426, Exh. L ("The power of POM in one little pill"); CX0314_0005 ("The proof is in the POM"); CX0192 ("What gets your heart pumping?"); and CX0328 ("Your New Healthcare Plan").

- Statements touting that POMx is "made from the same pomegranates we use to make our POM Wonderful 100% Pomegranate Juice;"[24]
- Statements that POMx is "made from the very same pomegranates as POM Wonderful 100% Pomegranate Juice;"[25]
- Statements that POMX is "[m]ade from pomegranates and nothing else;"[26]
- Statements that "POM is the only brand guaranteed contain 100% real pomegranate juice;"[27]
- Statements that POM Juice is nothing but "100% PURE POMEGRANATE JUICE;"[28]
- Statements touting that POM Juice "contains the juice of five whole pomegranates;"[29]
- Reference to the fact that the Challenged Products are from pomegranates grown in California: "California-grown pomegranate juice," "California-grown" with visual image of pomegranate tree or "California-grown, Wonderful variety pomegranates;"[30] and

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[23] *See, e.g.*, Reply Ad Appendix; RRFF 325-615; CX0348_0001/CX0350_0001 ("24 Scientific Studies"); CX1426, Exh. B/CX0314_0003 ("Drink to prostate health"); CX0331/CX1426, Exh. J ("Healthy, ~~Wealthy~~ & Wise"); CX0379_0002/CX0372_0002/CX0380_0002 ("Holy Health! $32 million in medical research"); CX0379_0003/CX0372_0003/CX0380_0003 ("KA-POM!"); CX0280 ("Live Long Enough to Watch Your 401(k) Recover"); CX0120 ("One small pill for mankind"); CX0314_0004/CX0314_0008 ("POM Wonderful and Prostate Health"); CX0122 ("Science, not fiction"); CX0279 ("Science, not fiction"); CX0342/CX0353 ("Take Out a Life Insurance Supplement"); CX0180/CX1426, Exh. K ("The Antioxidant Superpill"); CX0314_0006 ("The Antioxidant Superpower"); CX0337 ("The First Bottle You Should Open in 2010"); CX0351/CX0355 ("The Only Antioxidant Supplement Rated X"); CX0314_0005 ("The proof is in the POM"); CX0192 ("What gets your heart pumping?"); CX0328 ("Your New Healthcare Plan"); CX14726, Exh. M ("Heart Newsletter"); and CX1426, Exh. N ("Prostate Newsletter").

[24] S*ee, e.g.*, Reply Ad Appendix; RRFF 325-615; CX0348_0001/CX0350_0001 ("24 Scientific Studies"); CX0331/CX1426, Exh. J ("Healthy, ~~Wealthy~~ & Wise"); CX0280 ("Live Long Enough to Watch Your 401(k) Recover"); CX0120 ("One small pill for mankind"); CX0342/CX0353 ("Take Out a Life Insurance Supplement"); CX0337 ("The First Bottle You Should Open in 2010"); CX0351/CX0355 ("The Only Antioxidant Supplement Rated X"); and CX0328 ("Your New Healthcare Plan").

[25] *See, e.g.*, Reply Ad Appendix; RRFF 325-615; CX1426, Exh. I ("Antioxidant Superpill" brochure"); CX0122 ("Science, not fiction"); CX0279 ("Science, not fiction"); CX0120 ("One small pill for mankind"); CX0180/CX1426, Exh. K ("The Antioxidant Superpill"); and CX0169/CX1426, Exh. L ("The power of POM in one little pill").

[26] *See, e.g.*, Reply Ad Appendix; RRFF 325-615; CX1426, Exh. I ("Antioxidant Superpill" brochure").

[27] *See, e.g.*, Reply Ad Appendix; RRFF 325-615; CX0379_0003/CX0372_0003/CX0380_0003 ("KA-POM!"); and CX0314_0005 ("The proof is in the POM").

[28] *See, e.g.*, Reply Ad Appendix; RRFF 325-615; CX1426, Exh. A/CX0475 ("SUPER HEALTH POWERS!" Hang Tag).

[29] *See, e.g.*, Reply Ad Appendix; RRFF 325-615; CX0379_0003/CX0372_0003/CX0380_0003 ("KA-POM!"); and CX0314_0005 ("The proof is in the POM").

[30] *See, e.g.*, Reply Ad Appendix; RRFF 325-615; CX0120 ("One small pill for mankind"); CX0122 ("Science, not fiction"); CX0169/CX1426, Exh. L ("The power of POM in one little pill"); and CX14726, Exh. M ("Dreher Heart Newsletter").

- Textual reference that POM Juice is "available in your supermarket produce section."[31]

Similarly, POM emphasizes throughout its advertising that the Challenged Products are a concentrated source of antioxidants and that the Challenged Products' effectiveness is based, at least in significant part, on the products' abundant antioxidants:

- Statements referencing "naturally occurring antioxidant[s];"[32]
- A chart comparing the antioxidant potency of various beverages;[33]
- Statements touting that POM has "a higher level of antioxidants than any other drink;" [34]
- Widespread reference to POM Juice as "The Antioxidant Superpower,"[35] or to POMx as "Antioxidant Superpill;"[36]
- Statements that Wonderful pomegranates are "renowned for their superior antioxidants;"[37]
- Statements that POM Juice has "uniquely high levels of powerful antioxidants;"[38]

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[31] *See, e.g.*, Reply Ad Appendix; RRFF 325-615; CX0314_0004/CX0314_0008 ("POM Wonderful and Prostate Health").

[32] *See, e.g.*, Reply Ad Appendix; RRFF 325-615; CX0016 ("Drink and be healthy"); CX0029 ("Studies Show that 10 out of 10 People Don't Want to Die"); CX0031 ("Floss your arteries"); CX0034 ("Amaze your Cardiologist"); CX0314_0006 ("The Antioxidant Superpower") and CX0033 ("Life support").

[33] *See, e.g.*, Reply Ad Appendix; RRFF 325-615; CX0016 ("Drink and be healthy"); CX0314_0005 ("The Proof is in the POM") and CX0379_0003/CX0372-0003/ CX0380_0003 ("KA-POM!").

[34] *See, e.g.*, Reply Ad Appendix; RRFF 325-615; CX0029 ("Studies Show that 10 out of 10 People Don't Want to Die").

[35] *See, e.g.*, Reply Ad Appendix; RRFF 325-615; CX0016 ("Drink and be healthy"); CX0029 ("studies show that 10 out of 10 People Don't Want to Die"); CX0031 ("Floss your arteries"); CX0034 ("Amaze your cardiologist"); CX0103 ("Decompress"), CX0109 ("Heart therapy"); CX0192 ("What gets your heart pumping?"); CX0274/CX1426_0029, Exh. C ("I'm off to Save Prostates"); CX0314_0005 ("The Proof is in the POM"); CX0314_0006 ("The Antioxidant Superpower"); CX0379_0001/CX0372_0001 (CX0380_0005/ CX0380_0001 ("Lucky I have super HEALTH POWERS"); CX0379_0003/ CX0372_0003/ CX0380_0003 ("KA-POM!"); CX0380_0006/CX0372_0004 ("100% Pure"); CX0379_0004 ("Risk your health in this economy?"), CX0380_0004 ("Have no health fear"); CX0033 ("Life support") and CX1426_0037, Exh. H ("I'm off to Save Prostates").

[36] *See, e.g.*, Reply Ad Appendix; RRFF 325-615; CX0169/CX1426_0045, Exh. L ("The Power of POM in one little pill"); CX0180 ("The Antioxidant Superpill"); and CX0280 ("Live Long Enough to watch your 401(k) Recover").

[37] *See, e.g.*, Reply Ad Appendix; RRFF 325-615; CX0314_0005 ("The Proof is in the POM"), CX0379_0003, CX0372_0003, CX0380_0003 ("KA-POM!").

[38] *See, e.g.*, Reply Ad Appendix; RRFF 325-615; CX0314_0005 ("The Proof is in the POM") and CX0379_0003/ CX1426_0045, Exh. L/CX0380_0003 ("KA-POM!").

- Statements that POMx contains a "powerful blend of . . . polyphenol antioxidants;"[39]
- Statements that POMx provides "more concentrated . . . antioxidants than any other pomegranate supplement;"[40]
- Statements referring to POMx as an "ultra-potent antioxidant extract;"[41] and
- Statements referencing "the unique and superior antioxidant power of pomegranates."[42]

These statements clearly convey that the pomegranates are superfoods and chock-full of antioxidants, like blueberries, Goji berries, walnuts and green tea. Moreover, in 2006, the NAD noted that its decision did not preclude POM from making truthful claims regarding the state of the science on antioxidants and free radicals or to accurately describe the encouraging results of preliminary research regarding the impact antioxidants may have on heart health, cancer and other diseases. (RRFF 670). Indeed, the NAD agreed that it is undisputed that antioxidants may be beneficial to health. (RRFF 670; CX0055_0039) ("NAD takes no issue with the advertiser discussing and/or educating the public as to the state of this science or promoting the fact that its product is an excellent source of antioxidants which, undisputedly, may be beneficial to one's health.") (emphasis added).

Despite the prevalence and pervasiveness in POM's advertising of these "whole-food" graphics and emphasis in the body copy that the Challenged Products are wholly derived from pomegranates, one of the super foods containing abundant antioxidants, Complaint Counsel

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[39] *See, e.g.*, Reply Ad Appendix; RRFF 325-615; CX0120 ("One small pill for mankind"); CX0122/ CX1426_0045, Exh. L ("Science, not fiction"); CX0180/CX01426_0039, Exh. I ("The Antioxidant Superpill") and CX0169/ CX1426_0045, Exh. L ("The Power of POM in one little pill").

[40] *See, e.g.*, Reply Ad Appendix; RRFF 325-615; CX0120 ("One small pill for mankind"); CX0122/ CX0279 ("Science, not fiction") and CX0180/ CX1426_0044, Exh. K/ CX01426_0039, Exh. I ("The Antioxidant Superpill").

[41] *See, e.g.*, Reply Ad Appendix; RRFF 325-615; CX0280 ("Live Long Enough to Watch Your 401(k) Recover"); CX0328 ("Your New Health Care Plan"); CX0331/ CX1426_0043, Exh. J ("Healthy. ~~Wealthy~~ & Wise"); CX0337 ("The First Bottle you Should Open"); CX0342/CX0353 ("Take Out a Life Insurance Supplement"); CX0348/CX0353 ("24 Scientific Studies") and CX0351/CX0355 ("The Only Antioxidant Supplement Rated X").

[42] *See, e.g.*, Reply Ad Appendix; RRFF 325-615; CX0280 ("Live Long Enough to Watch Your 401(k) Recover"); CX0328 ("Your New Health Care Plan"); CX0331/CX1426_0043, Exh. J ("Healthy. ~~Wealthy~~ & Wise"); CX0337 ("The First Bottle you Should Open"); CX0342/CX0353 ("Take Out a Life Insurance Supplement"); CX0348/CX0350 ("24 Scientific Studies") and CX0351/CX0355 ("The Only Antioxidant Supplement Rated X").

completely ignore these key elements in their facial analysis. This is because Complaint Counsel know that consumers view POM's advertising through a different lens than they would if they were reading an advertisement for a drug or an over-the-counter medication. *See Removatron Int'l Corp. v. FTC,* 884 F.2d at 1497 (focusing on "common-sense" reading of the ads). Because POM consumers understand that the Challenged Products are wholly-derived from the pomegranate fruit, no reasonable consumer or even a "significant minority of reasonable consumers" would reasonably take away the message as interpreted by Complaint Counsel from the face of the Challenged Establishment Ads. *See generally In re Telebrands Corp.*, 140 F.T.C. 278, 291 (2005), *aff'd*, 457 F.3d 354 (4th Cir. 2006) ("An ad is misleading if at least a significant minority of reasonable consumers are likely to take away the misleading claim.").

Instead, it is far more logical that POM consumers would view the Challenged Products the way they perceive any other whole food, like broccoli, blueberries, grapes or tomatoes, which may help prevent or improve your odds against disease, but which would not act like a drug with a single target of action against a particular disease or condition.[43] At the very minimum, however, the emphasis in the advertising on the fact that the Challenged Products are a concentrated and potent source of antioxidants that are 100% fruit derived (with nothing else added) directly counter the medical imagery that Complaint Counsel rely so heavily on. *See, e.g.*, *Thompson Med. Co.*, 104 F.T.C. at 800 ("[w]e are not able to conclude with adequate confidence by looking solely at evidence from the ad itself whether or not one message conveyed to consumers by CX 8[44] is that Aspercreme contains aspirin" because the "general tone of the ad contrasts Aspercreme with aspirin, emphasizing the supposed difference between the products rather than their similarities."). Even the Commission would require more from Complaint

[43] Indeed, Professor Reibstein's survey found that very few consumers purchased POM Juice because they believed it would cure or prevent any specific disease. (*See* RFF 2623-79).

[44] The headline and body copy for CX 8 are set forth in full in footnote 7.

Counsel if they were attacking claims by the apple industry that "an apple a day keeps the doctor away."

Third, Complaint Counsel also completely ignore the puffery that is implicit in some of the imagery, headlines and body copy. The Commission has long recognized that highly subjective claims that consumers are not likely to take seriously and are incapable of measurement are non-actionable "puffery." *See, e.g., In the Matter of Bristol-Meyers C*o, 102 F.T.C. 21, 321 (1983), *aff'd*. 738 F.2d 554 (2d. Cir. 1984); ***Summit Tech., Inc. v. High-Line Med. Instruments Co.***, 933 F. Supp. 918 (C.D. Cal. 1996) ("Puffery is often described as 'involving outrageous generalized statements, not making specific claims.'") (citing ***Metro Mobile CTS, Inc. v. Newvector Commc'ns, Inc.***, 643 F. Supp. 1289 (D. Ariz. 1986), ***rev'd without opinion***, 803 F.2d 724 (9th Cir.1986)). Under their analysis, however, Complaint Counsel have attempted to bootstrap all puffery, which by definition is non-actionable, to "actionable" puffery by alleging that the use of humor and puffery in ads somehow makes consumers more susceptible to the contrived health claims asserted by Complaint Counsel. Indeed, just the opposite is true. *See, e.g., Removatron Int'l Corp,.* 884 F.2d at 1497 (applying "common-sense" net impression analysis to advertising claims).

For example, Complaint Counsel attempt to turn POM's puffing (***i.e.***, what Complaint Counsel refers to as "strong medical imagery"[45] and "bold headlines") on their heads in a feeble attempt to illustrate that a facial analysis of the Challenged Ads shows that the ads convey the net impression that the Challenged Products are "clinically proven to treat, prevent or reduce the risk of disease." (CCPTB at 21, 23-24). While POM acknowledges that some of its advertisements have included humorously exaggerated headlines, such as "Amaze your cardiologist," "Live Long Enough to Watch Your 401(k) Recover," and "The Only Antioxidant Rated X" and imagery of a POM Juice bottle donned with medical devices, such as a blood

[45] Nor does Respondents' alleged use of "medical imagery" and "medical messaging" convey Respondents' intent to make the challenged establishment or efficacy disease claims. (*See infra* Part II.C.).

pressure cuff or electrocardiogram ("EKG") leads, or dressed-up in a bikini or a superhero cape, (*see, e.g.,* CX0034, CX0103, CX0280, CX0351, CX0355, CX0192, CX0314_0006), POM denies (and its witnesses have denied) that the utilization of such headlines or imagery was to convey claims that the Challenged Products treat or prevent disease. Nor do Complaint Counsel articulate how "strong medical imagery" and "bold headlines" in conjunction with the other elements, convey, clearly and conspicuously on the face of the Challenged Ads, the net impression that the Challenged Products are "clinically proven to prevent, treat or reduce the risk of disease."[46] Once again, Complaint Counsel's purported inferences are, in effect, contrived.

More specifically, Complaint Counsel's facial analysis of the "Amaze your cardiologist" ad is flawed. The "Amaze your cardiologist"[47] featured an image of the POM Juice bottle with EKG sensors attached to it. (CX0344). The body copy stated:

> Ace your EKG: just drink 8 ounces of delicious P♥M Wonderful P♥megranate Juice a day. It has more naturally occurring antioxidants than any other drink. Antioxidants fight free radicals . . . nasty little molecules that can cause sticky, artery clogging plaque. A glass a day can reduce plaque by up to 30%!* Trust us, your cardiologist will be amazed.
>
> **P♥M Wonderful P♥megranate Juice. The Antioxidant Superpower**.

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[46] As discussed below and in Respondents' Post-Trial Brief (at 72-74), Complaint Counsel failed to present any reliable extrinsic evidence to corroborate this assertion or that consumers even construed the Challenged Establishment Ads, including the imagery and headlines, as conveying that the Challenged Products are "clinically proven to prevent, treat or reduce the risk of disease." Indeed, several of POM's witnesses, including Mr. Tupper, Mr. Perdigao, Ms. Leow, Mrs. Resnick, Mr. Resnick and Dr. Butters, testified that such much of the imagery and headlines were meant to be humorous, hyperbolic or tongue-in-cheek. (*See, e.g.,* RFF 2276-80, 2364, 2392, 2454, 2540-41; Appendix of Advertisements, Reply Ad Appendix). Even Complaint Counsel's own expert, Dr. Stewart, testified that the "bold" headline "Amaze your cardiologist" was not to be taken literally. (RFF 2932).

[47] Four of the 38 Challenged Establishment Ads (CX0016 ("Drink and be healthy"), CX0103 ("Decompress"), CX0031 ("Floss your arteries")), including this one, are outliers, meaning they are older ads that used more aggressive body copy and imagery. (RFF 2255, 2258). As set forth in Respondents' Post-Trial Brief (at 67-69), because these ads were discontinued anywhere from three to eight years prior to the Commission bringing this action or even instituting an investigation, (RFF 2258), and Complaint Counsel have presented no evidence that it is probable that Respondents would run these types of ads again, (RFF 2260-61), injunctive relief 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.

*Aviram, M. *Clinical Nutrition*, 2004.

(CX0034). Complaint Counsel, however, ignore the (1) outrageousness of the headline, (2) silliness of the "dressed bottle," and (3) fact the product is 100% fruit juice, (RRFF 344-48; RFF 2374-99), to assert that:

> The copy and images in this advertisement draw a clear association with cardiovascular disease diagnosis and treatment, particularly the bottle "dressed" as an EKG patient, references to a cardiologist and "ac[ing] your EKG," and specific citations to a study purportedly showing 30% reduction of arterial plaque. This advertisement conveys the net impression that drinking eight ounces of POM Juice daily treats, prevents, or reduces the risk of heart disease, including by reducing arterial plaque, and that this benefit is clinically proven.

(CCFF 348).

Viewing the ad as a whole, including the interaction of headlines, body copy and visual imagery, among other elements, Complaint Counsel's assertion is plainly wrong. First, Complaint Counsel's net impression analysis ignores the overt puffery and humor in the ad. (*See* RFF 2392-93). The imagery of the bottle dressed-up in EKG sensors is humorous and does not necessarily portray a "heart-diseased" EKG patient. A doctor could order a baseline EKG for a patient before any problems develop or to check how well certain medicines are working and whether they are causing side effects that affect the heart. The headline "Amaze your cardiologist" and phrases "Ace your EKG" and "Trust us your cardiologist will be amazed" are also humorous puffing – *i.e.*, exaggerated advertising and incapable of being measured. (RFF2392). They make no mention of "heart disease." *Cf. In re Daniel Chapter One*, No. 9329, 2009 WL 2584873, at *69 (Initial Decision Aug. 5, 2009) ("the title of the publication, 'How to fight cancer is your choice,' . . . sets the stage [that the Challenged Products treat or cure cancer] by strongly implying if not expressly stating, that the products described in the newsletter will "fight" cancer."). Second, the ad makes clear on its face that it is for a wholly-derived fruit product and that POM Juice contains abundant antioxidants. The POM Juice bottle is filled with deep, ruby red pomegranate juice, the shape of the bottle resembles two pomegranates stacked on

top of one another, the face of the bottle prominently displays "100% P♥MEGRANATE JUICE" and the body copy states that POM Juice "has more naturally occurring antioxidants than any other drinks." (RRFF 344-48; Reply Ad Appendix). Third, there is absolutely no evidence that consumers took away any "heart disease" message from the P♥M logo.[48] (*See* RFF 2395-96.) It is very plausible (perhaps, even more plausible) that consumers interpreted the P♥M logo as "I love POM" or "I heart POM."[49] Last, the phrase, "A glass a day can reduce plaque by up to 30%" is a qualified, quantified performance claim. (RFF 2350, 2382). Even the NAD agreed with Respondents on this point and found that the statement was not an establishment claim (*i.e.*, a "clinically proven" claim). (RFF 2386). Contrary to Complaint Counsel's facial analysis, the overall net impression of the ad accordingly is not that "drinking eight ounces of POM Juice is 'clinically proven' to prevent, treat or reduce the risk of certain disease, such as heart disease." (RFF 2388, 2394).

Similarly, Complaint Counsel's facial analysis of a 2009 print ad for POMx Pills, for example, with the headline "Live Long Enough to Watch Your 401(k) Recover" is also flawed because they assert that the net impression is that "taking one POMx Pill daily [or 'drinking eight ounces of POM Juice daily'] treats, prevents, or reduces the risk of cardiovascular disease and prostate cancer, and that those health benefits are clinically proven." (CCFF 418). Again, Complaint Counsel ignore the (1) outrageousness of the headline, (2) puffery in the headlines

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[48] Indeed, "the purpose of ad interpretation is to determine the claims that consumers – particularly the target audience – take away from an ad, whether or not an advertiser intended to communicate those claims." *In re Telebrands Corp.*, 140 F.T.C. 278, 291-92 (2005), *aff'd*, 457 F.3d 354 (4th Cir. 2006).

[49] Indeed, Complaint Counsel's interpretation that consumers would associate a heart symbol with heart disease would render vast swaths of advertising as making implied disease claims. (CCFF 290). This is certainly an implausible and dubious theory, given the prevalence and popularity of heart symbols in advertising. For example, the use of a heart symbol in logos was made popular and common-place by the "I Love New York" logo, I ♥ NY which has "been used since the mid-1970s to promote tourism in New York City and later to promote New York State as well." http://en.wikipedia.org/wiki/I_Love_New_York. Additionally, Unilever, the world's biggest ice cream manufacturer, markets the bulk of its ice cream business internationally under its "Heartbrand" brand umbrella, the brand with the big red heart logo, known in the United States as Good Humor GOOD HUMOR, who was using the Heartbrand logo until just recently. http://www.unilever.com/brands/foodbrands/heartbrand/index.aspx. It would be ludicrous to think that Unilever was conveying anything about heart disease or health by its logo.

and sub-headlines, (3) qualifiers used to convey couched health messages and (4) fact the product is 100% fruit derived and a concentrated source of antioxidants. (RRFF 415-18; Appendix of Advertisements 278-93).

The body copy of the ad stated:

> Antioxidants are a necessity.
>
> Not a luxury.
>
> Emerging science suggests that antioxidants are critically important to maintaining good health because they protect you from free radicals, which can damage your body. Taking one P♥Mx pill a day will help protect you from free radicals and keep you at your healthy best. Even when you're going through your worst.
>
> Recession-proof your health
>
> with P♥Mx.
>
> P♥Mx – an ultra-potent antioxidant extract made from the same pomegranates as P♥M Wonderful 100% Pomegranate Juice – is the most potent natural antioxidant supplement available. Each 1000 mg P♥Mx pill has the antioxidant power of a full glass of P♥M Wonderful 100% Pomegranate Juice.
>
> $25 million in medical research.
>
> A sound investment.
>
> P♥Mx is made from the only pomegranates backed by $25 million in medical research at the world's leading universities. Not only has this research documented the unique and superior antioxidant power of pomegranates, it has revealed promising results for prostate and cardiovascular health.
>
> Hope for the future.
>
> Yours.
>
> Our P♥Mx pills are made from the same pomegranates we use to make our P♥M Wonderful 100% Pomegranate Juice, on which each of the following medical studies was conducted.
>
> An initial UCLA study on our juice found hopeful results for prostate health, reporting "statistically significant prolongation of

> PSA doubling times," according to Dr. Allen *[sic]* J. Pantuck in *Clinical Cancer Research*, '06.
>
> Two additional preliminary studies on our juice showed promising results for heart health. "Stress-induced ischemia (restricted blood flow to the heart) decreased in the pomegranate group," Dr. Dean Ornish reported in the *American Journal of Cardiology*, '05.
>
> "Pomegranate juice consumption resulted in significant reduction in IMT (thickness of arterial plaque) by up to 30% after one year," said Dr. Michael Aviram, *Clinical Nutrition*, '04.

(CX0280) (footnotes omitted).

First, as with the "Amaze your cardiologist" ad, Complaint Counsel overlook the blatant, humorous puffing in the headline, "Live Long Enough to Watch Your 401(k) Recover," and sub-headlines, "Antioxidants are a necessity. Not a luxury," "Recession-proof your health with P♥Mx," "$25 million in medical research. A sound investment," and "Hope for the future. Yours." (Appendix of Advertisements 289-91; Reply Ad Appendix). Second, nowhere in the ad do the medical studies that are described state that the studies "prove" that POM Juice or POMx "prevent, treat or reduce the risk of heart disease and prostate cancer." (RFF 2209-11; Reply Ad Appendix). Indeed, the studies merely described specific results and facts using qualified phrases, such as "initial UCLA study," "hopeful results for prostate health," "preliminary studies" and "promising results for heath health." (Appendix of Advertisements 285). *Cf., In re Removatron Int'l Corp.*, 111 F.T.C. at 297-98 (Commission held that references to clinical testing and research, such as "[C]linically tested and endorsed," and "MEDICALLY ENDORSED … GOVERNMENT APPROVED-TESTED," were express claims that the respondents promised a scientific level of substantiation); *Medlab*, 615 F. Supp. 2d at 1079 (internal quotations omitted) (court upheld Commission's finding that the statement, "Fast, Immediate Results … Guaranteed! Clinical studies prove it." made "clinically proven" claims). Third, despite the fact that the ad makes clear on its face that it is an advertisement for a wholly-derived pomegranate product, Complaint Counsel completely disregard these textual references and images. For instance, there is (1) a picture of a POMx Pill bottle shaped like a pomegranate front and center (2) images of five small, ruby red pomegranates inside a cracked, transparent

pill; (3) another picture of a slightly larger pomegranate near the bottom of the ad; (4) repeated references to "P♥M Wonderful 100% Pomegranate Juice" throughout the body copy; and (5) a further reference that the "pills are made from the same pomegranates we use to make our P♥M Wonderful 100% Pomegranate Juice." (CX0280; RRFF 415-18; Reply Ad Appendix). Fourth, the ad emphasizes that POMx is "an ultra-potent antioxidant extract" and that it has the "antioxidant power of a full glass" of POM Juice. (CX0280; RRFF 415-18; Reply Ad Appendix). Clearly, the ad viewed as a whole, through headlines, sub-headlines, product descriptions, textual references and visual imagery, does not convey the net impression, like a drug, that POM Juice or POMx Pills are "'clinically proven' to prevent, treat or reduce the risk of certain diseases, such as heart disease or prostate cancer." (Appendix of Advertisements 285; Reply Ad Appendix).

As set forth in the examples above, the Appendix of Advertisements, Reply Ad Appendix, RFF 2264-2452 and RRFF 325-615, Complaint Counsel's facial analysis is wholly defective in demonstrating the "clinically proven" (or "efficacy") claims Complaint Counsel assign to the Challenged Establishment Ads. Clearly, the interaction of the advertisement headlines, sub-headlines, visual images and textual references, among other elements, are inadequate to "conclude with confidence" that the Challenged Establishment Ads make the claims alleged by Complaint Counsel. *See Kraft,* 970 F.2d at 314. Extrinsic evidence is thus necessary to interpret the claims. *Stouffer*, 118 F.T.C. at 777 (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") (citing *Kraft*, 970 F.2d at 318) (emphasis added).

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

Complaint Counsel contend that 5 of the 43 Challenged Ads[50] convey efficacy claims only – that is, that "POM Juice is effective for treating, preventing, or reducing the risk of heart disease or prostate cancer without stating directly the level of science that substantiates the claims." (CCPTB at 25). The Challenged Efficacy Ads include: CX0033 ("Life support" print ad); CX0036/CX0188 ("Cheat death" print ads); CX0463 ("Heart therapy" banner ad); CX0466/CX1426, Exh. H. ("I'm off to save PROSTATES!" banner ad);[51] and CX0473/CX1426, Exh. E-6 (Lynda Resnick interview on *The Martha Stewart Show*).[52] As with the ads Complaint Counsel contend make establishment claims, Complaint Counsel rely on "strong visual imagery," "dominating headlines" and "strong statements of efficacy" for their conclusion that a simple facial analysis demonstrates that the Challenged Efficacy Ads convey the net impression that POM Juice treats, prevents or reduces the risk of heart disease, prostate cancer and erectile dysfunction. (CCPTB at 25). Complaint Counsel's facial analysis of the Challenged Efficacy Ads fails for the same reasons their analysis fails with respect to the Challenged Establishment Ads.

Once again, Complaint Counsel rely on the "captivating images" but ignore the overt puffery, humor and frivolous exaggeration in the imagery, headlines and body copy. (RFF 2540-41). For example, the "Life Support" print ad depicts a dominant image of a POM Juice bottle

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[50] The 5 Challenged Ads were previously defined as the "Challenged Efficacy Ads."

[51] Respondents contend that this banner ad is not at issue because Complaint Counsel presented no specific dissemination information. (RFF 2252 at 267). In their proposed findings of fact, Complaint Counsel contend that this ad was disseminated on February 2009 and cite to CX0466 as evidence of this contention. CX0466, however, does not prove this contention because no dissemination is included on the face of the exhibit. (*See* CX0466).

[52] Respondents contend that Mrs. Resnick's interview on The Martha Stewart Show (CX0473/CX1426, Exh. E-6, November 2008) is not actionable under the FTCA, and therefore not at issue here, because it: (1) does not constitute "advertising"; (2) represents constitutionally protected speech; and (3) in any event, cannot be considered as material to the purchasing decision of any consumers. (RPTB at 92-96; RFF 2252 at 268, 2552-66). Moreover, Mrs. Resnick adamantly believes the opinion that she expressed regarding POM Juice and prostate cancer. (RFF 2559-60).

with the words "100% Pomegranate Juice" on the face of bottle, which is shaped like two pomegranates stacked on top of each other. (RRFF 341-43; CX0033). The bottle is filled with ruby red pomegranate juice and is dangling upside down from an intravenous pole ("IV") with juice running through the IV line at the bottom of the bottle. (CX0033; RRFF 041-43). The headline "Life support" appears in bold letters with the following body copy in much smaller lettering:

> P♥M Wonderful P♥megranate Juice fills your body with what it needs. On top of being refreshing and delicious, this amazing juice has more naturally occurring antioxidants than any other drink. These antioxidants fight hard against free radicals that can cause heart disease, premature aging, Alzheimer's, even cancer. Just drink eight ounces a day and you'll be on life support – in a good way.
>
> **P♥M Wonderful P♥megranate Juice. The Antioxidant Superpower.**

(CX0033.) From this imagery of the "POM bottle 'dressed' as an [IV] line" and the "references to specific diseases juxtaposed with the recommendation to drink eight ounces a day for 'life support,'" Complaint Counsel assert that the ad conveys the "net impression that drinking eight ounces of POM Juice daily prevents or reduces the risk of heart disease, among other diseases." (CCFF 343).

An examination of the ad as a whole, including the interaction of headlines, body copy and visual imagery, among other elements, however, demonstrates that Complaint Counsel's net impression analysis is plainly wrong. Their net impression analysis completely disregards the blatant puffery and humor (*see* RFF 2540-41), as well as the fact that the ad's body copy and imagery focus on the fact that the product is a 100% juice product wholly-derived from the pomegranate fruit. (RRFF 341-43; Reply Ad Appendix). The phrases, "POM Wonderful Pomegranate Juice fills your body with what it needs" and "Just drink eight ounces a day and you'll be on life support – in a good way" are further humorous, non-actionable puffing. (RRFF 341-43; Reply Ad Appendix). Additionally, without specifying how they make this logical leap, Complaint Counsel assert that the body copy: "These antioxidants fight hard against free

radicals that can cause heart disease, premature aging, Alzheimer's, even cancer" translates to an efficacy claim that POM Juice "prevents or reduces the risk of heart disease." (CCFF 343; CCPTB at 26.) This is, yet again, another example of Complaint-Counsel's ill-contrived inferences. Even *assuming arguendo*, that the IV imagery is a "symbol for drugs and medicine," (*see* CCFF 342), Complaint's Counsel's inference is overreaching, in light of the explicit references to the fact that the ad is for 100% pomegranate juice and that POMx contains abundant antioxidants. (*See* Appendix of Advertisements 268, 274; RRFF 341-43; Reply Ad Appendix).

A facial analysis of the Cheat Death ads (CX0188/CX0036)[53] also is analogous to that of the "Life Support" ad. Both "Cheat Death" ads prominently display a POM Juice bottle that resembles two-stacked pomegranates filled with ruby red pomegranate juice. (RRFF 349-56; Reply Ad Appendix). The words "100% Pomegranate Juice" appear on the face of the bottle with the P♥M logo in prominent letters. (CX0118/CX0036; RRFF 349-56; Reply Ad Appendix). A broken noose also dangles from the bottle's neck with the headline "Cheat Death." The body copy of the 2008 "Cheat Death" ad stated:

> You need more than luck to live longer. You need antioxidants. And P♥M Wonderful 100% Pomegranate Juice is loaded with them. It helps guard your body against free radicals, unstable molecules that emerging science suggests aggressively destroy healthy cells in your body and contribute to disease. P♥M Wonderful 100% Pomegranate Juice is supported by $23 million of medical scientific research from leading universities, which has uncovered encouraging results in prostate and cardiovascular health. So drink a glass a day and cheat death. Live life.
>
> **P♥M Wonderful 100% Pomegranate Juice. The Antioxidant Superpower.**

[53] CX0036 is older, outlier version of the "Cheat death" print ad with the text POM "can help prevent" certain diseases that has not run in over five or six years. (RFF 2268-70). As set forth in Respondents' Post-Trial Brief (at 67-69), because this ad was disseminated so long ago and there is no evidence that Respondents are likely to run this ad in the future, the ad provides no basis for injunctive relief. (RFF 2270-72). As quoted above, the 2008 version of the "Cheat Death" ad (CX0188) uses different body copy than the older version of the ad and contains no reference to POM helping to prevent any diseases. (RFF 2269).

(CX0188).

As with the "Life Support" ad, the headline "Cheat Death," the image of the POM Juice bottle with a broken noose around its neck and the phrases "You need more than luck to live longer" and "So drink a glass a day and cheat death. Live Life." are hyperbolic, humorous, edgy and provocative.[54] (RFF 2276-77, 2279-80, 2288). Coupled with the fact that the body copy and imagery makes clear that the product is 100% juice wholly-derived from pomegranate fruit and "loaded" with antioxidants, no one would ever believe that drinking POM Juice would enable you to literally "cheat death." Disregarding the blatant puffery, however, Complaint Counsel assert that the net impression is that "drinking eight ounces of POM Juice daily prevents or reduces the risk of heart disease." (CCFF 356). How Complaint Counsel reach this conclusion from the interactions of the headline, body copy and visual imagery, among other elements, is not only perplexing, especially in light of the fact that the ad expressly states that "scientific research . . .has uncovered encouraging results in prostate and cardiovascular health," (CX0188), but completely at odds with the common-sense approach to net impression analysis. *See Removatron Int'l Corp.,* 884 F.2d at 1497 (looking to "common-sense" net impression of an allegedly false and deceptive advertisement); *FTC v. Davison Assocs., Inc.*, 431 F. Supp. 2d 548, 559-60 (W.D. Pa. 2006) ("In determining whether a practice is likely to mislead, the fact finder must consider the overall, common sense, net-impression of the practice on a reasonable consumer."); *FTC v. Minuteman Press,* 53 F. Supp. 2d 248, 262 (E.D.N.Y. 1998) (common-sense net impression analysis controls).

[54] The "Cheat death" headline and phrase "So drink a glass a day and cheat death. Live Life." is analogous to the old proverb, "An apple a day keeps the doctor away." If apple growers were to use that tagline in marketing, would the Commission go after them? Like many of POM's headlines and phrases, this is obvious puffery. No consumers actually believe that they will not get sick or will not have to go to the doctor if they eat an apple – a whole fruit just like the pomegranate – every day. What they do take away is that an apple a day is healthy; it is good for you. Indeed, this is what POM's ads convey – drink 100% pomegranate juice, it is good for you and it is good for your heart. (RFF 2275, 2278, 2280, 2281; Appendix of Advertisements 92, 97-99; Reply Ad Appendix).

Even more perplexing are the efficacy claims Complaint Counsel assign to the "Heart therapy" (CX0463) and "I'm off to save PROSTATES!" (CX1426 Exh. H/CX0466) banner ads. The "Heart therapy" ad featured a deep, ruby red POM Juice bottle resembling two stacked pomegranates reclining on a chaise lounge with animation and sound effects, using the "heart" symbol in the POM logo to expand and contract. (CX0463; RRFF 536-38; Reply Ad Appendix). The face of the bottle contained the words "100% Pomegranate Juice" and the limited body copy said "Backed by $25 million in medical research" as well as a "Learn more" click through. (CX0463).

The "I'm off to save PROSTATES!" internet banner ad began with a white speech balloon set against a burgundy background with the phrase "HURRY! Prostates everywhere are in danger!" (CX0466). An animated, deep burgundy POM Juice bottle resembling two stacked pomegranates then flew up and down the screen like a superhero, ultimately ending with an image of a POM Juice bottle surrounded by an aura and a speech bubble, stating "I'm off to save PROSTATES!" and the words "Antioxidant Superpower" and a "learn more" click through outside the speech bubble. The face of the bottle prominently displayed the words "100% Pomegranate Juice" on the front. (CX0466; Reply Ad Appendix).

Complaint Counsel's facial analysis, which presumably includes the humorous, comical and hyperbolic images, together with the text, sound effects and animation, somehow concludes that the net impression of the "Heart Therapy" banner ad is that "POM Juice prevents or reduces the risk of heart disease." (CCFF 538). Similarly, Complaint Counsel contend that the net impression of the "I'm off to save PROSTATES!" banner ad is that "POM Juice prevents or reduces the risk of prostate cancer." (CCFF 540). As described above, however, an evaluation of all the elements in the ads as a whole, does not support these conclusions. (RRFF 536-540; Reply Ad Appendix). Nor are the alleged implied efficacy claims "conspicuous, self-evident, or reasonably clear" on the face of the ads. *See Stouffer*, 118 F.T.C. at 777. In effect, the alleged "efficacy" claims are so far-fetched that they could not even be considered "barely discernible." Respondents' interpretation, which examines all the elements of each Challenged Efficacy Ads

as whole, including, among other elements, the (1) outrageous and puffing headlines and sub-headlines, (2) humorous visual images and (3) fact that the product is 100% fruit juice, is thus the most common-sense approach. *See Removatron Int'l Corp.,* 884 F.2d at 1497 (looking to "common-sense" net impression of an allegedly false and deceptive advertisement); *FTC v. Minuteman Press,* 53 F. Supp. 2d at 262 (common-sense net impression analysis controls).

B. Complaint Counsel Failed to Present Any Reliable Extrinsic Evidence to Establish the Claims They Attribute to the Challenged Advertisements

As set forth above, Complaint Counsel rely on blunt, unproveable assertions and inferences about what consumers "must" have taken away from the Challenged Ads and make no effort to shore up their deficient facial arguments with any reliable empirical analysis, such as consumer surveys or expert opinion. Notably, Complaint Counsel make no mention of any extrinsic evidence on the meaning of the ads or what a reasonable person would take away from them in their post-trial brief. Case law, however, makes clear that Complaint Counsel "[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 copy tests of ads and expert testimony." *Id.* (citing *Kraft*, 970 F.2d at 318) (emphasis added).

Even Complaint Counsel's survey expert, Professor Mazis, in stark contrast to work he had previously done for Complaint Counsel in other cases, did not conduct any facial analysis of Respondents' ads or offer any expert opinion on them. (RFF 2622, 2685). Nor did he conduct any survey or copy test of Respondents' ads. (RFF 2684). *Cf. In re Telebrands Corp.,* 140 F.T.C. 278, 307 (2005), *aff'd*, 457 F.3d 354 (4th Cir. 2006) (examining extrinsic evidence despite conclusion that facial analysis of Respondents' Ab Force ads "clearly conveyed the claims alleged in the Commission's complaint):

> Although extrinsic evidence is not necessary to reach our decision, consistent with our practice we have examined the extrinsic evidence that the parties have offered about the meaning of the challenged Ab Force ads. *See*, *e.g.*, *Stouffer*, 118 F.T.C. at 799. This includes (1) Dr. Mazis's expert testimony and report regarding how respondents' TV ads would be perceived by

> consumers; (2) a copy test that Dr. Mazis designed, based on the most widely disseminated TV ad; and (3) a critique by respondents' expert, Dr. Jacob Jacoby, of the methodology that Dr. Mazis adopted.

Id. at 307 (emphasis added); *In re Novartis Corp.*, 127 F.T.C. 580, 603 (1999), *aff'd*, 223 F.3d 783 (D.C. Cir. 2000) ("In prior expert testimony that has been accepted by the courts, [Professor Mazis] has on a number of occasions analyzed advertising and marketing materials on the face of the ad and offered an opinion with regard to what reasonable consumers are likely to take away from such advertising or promotional materials."). Unlike *Telebrands* and *Novartis*, there is no such copy test or advertising analysis by Professor Mazis (or any of Complaint Counsel's experts) in this case. (RFF 2622, 2684-85).

Complaint Counsel's rebuttal expert, Professor Stewart, also 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). In fact, Professor Stewart testified that he did not even know if Complaint Counsel had any evidence on the meaning of the ads. (RFF 239). Nor have Complaint Counsel presented any reliable extrinsic evidence or expert opinion rebutting the fact that many of the ads were meant to be hyperbolic, puffery and humorous.[55] (RFF 2214). *See, e.g.*, *Sterling Drug, Inc. v. FTC*, 741 F.2d 1146, 1150 (9th Cir. 1984). Even Complaint Counsel concede that Professor Stewart testified that "although some humorous headlines like 'Amaze your cardiologist' and "Floss your arteries' might not [sic] be taken literally, they [can] still communicate serious health messages, such as that POM Juice offers significant cardiovascular health benefits." (CCFF 608). That "POM Juice offers significant cardiovascular health benefits," however, is a far cry from "POM Juice prevents, treats or reduces the risk of cardiovascular disease."

[55] Indeed, many of the statements in the majority of the Challenged Ads were not meant to be taken literally and cannot be objectively verified, and thus constitute puffery. (RFF 2214; Appendix of Advertisements; Reply Ad Appendix). *In re Thompson Med.*, 104 F.T.C. at 788-89 n.6.

The only apparent extrinsic evidence about "advertising communication" proffered by Complaint Counsel is thus the flawed Bovitz Survey, conducted by the Bovitz Research Group in early 2009. (CCFF 579, 588). Even Complaint Counsel give little, if any credence, to the Bovitz Survey. It is not mentioned one time in their post-trial brief. Nor did their own survey expert, Professor Mazis, consider the Bovitz Survey or offer any expert opinion on it. (RFF 2752).

Despite these obvious concessions by Complaint Counsel regarding the import and reliability of the Bovitz Survey, Respondents address the Bovitz Survey (because Complaint Counsel propose some findings of fact regarding it (*see* CCFF 579-96), only to demonstrate the survey's irrelevance and unreliability.

The Bovitz Survey compared consumers' perception of ten billboard advertisements[56] from POM's Super Hero and Dressed Bottle advertising campaigns (hereinafter, "Bovitz Stimuli"):[57]

- Super Hero campaign ads:
    - Holy Health! $25 million in medical research!
    - I'm off to save PROSTATES!
    - 100% PURE pomegranate juice to the rescue!
    - BACK OFF …impostor juices!
    - Risk your health in this economy? NEVER!
- Dressed Bottle campaign ads:
    - Cheat Death.
    - The Antioxidant Superpower.
    - Decompress.
    - Heart therapy.
    - Forever young.

[56] Billboard advertisements are out-of-home advertising that have no body copy – that is, they consist entirely of headlines. (RFF2236).

[57] Each of the Bovitz Stimuli also included a tagline, such as "The Antioxidant Superpower" or the "The antioxidant power of pomegranate juice" or something to that effect. (PX0223-0411-12; RRFF 583).

(PX0223-0411-12; RFF 2752; RRFF 583). Contrary to Complaint Counsel's assertions, Complaint Counsel cannot rely on the Bovitz Survey as relevant extrinsic evidence on the meaning of the Challenged Ads or what a reasonable person would take away from them because Complaint Counsel is not challenging billboard advertisements (*i.e.,* ads without body copy) in this case. (RFF 2234, 2770; RRFF 585). Complaint Counsel, however, erroneously attempt to analogize the conclusions regarding the Bovitz Stimuli to certain of the Challenged Ads that have the same headlines, even though the Challenged Ads are not billboards and contain body copy. (*See* CCFF 585). For example, Complaint Counsel assert that the following Challenged Ads are comparable to the Bovitz Stimuli simply because they have the same headlines:

Bovitz Stimuli	Body Copy in Bovitz Stimuli?	Challenged Ad	Body Copy in Challenged Ad?
"Heart therapy" billboard ad (PX0223-0412/PX0295a15-0011)	No	"Heart therapy" banner ad (CX0463)	Yes[58]
		"Heart therapy" print ad (CX0109)	Yes
	No	"Decompress" print ad (CX0103)	Yes
	No	"Cheat death" print ads (CX0036/CX0188)	Yes
"I'm off to save PROSTATES!" billboard ad (PX0223-0411/PX0295a15-0010)	No	"I'm off to save PROSTATES!" banner ad (CX0466)	Yes[59]
		"I'm off to SAVE PROSTATES!" print ad (CX0274)	Yes

[58] The "Heart therapy" banner ad contains less body copy than the print ad with the identical headline. (*Cf.* CX0463 *with* CX0109). The banner ad includes the "Heart therapy" headline, plus the body copy, "Backed by $25 million in medical research." There is no additional body copy. (CX0463).

[59] As with the "Heart therapy" banner ad, the body copy in the "I'm off to save PROSTATES!" banner ad contains less body copy than the print ad with the identical headline. (compare CX0CX 0274 *with* CX466). The "banner ad includes the "I'm off to save PROSTATES!" headline, plus the body copy, "Hurry! Prostates everywhere are in danger!" There is no additional body copy. (CX466).

(CCFF 585). As evidenced in the chart above, any comparisons between the Bovitz Stimuli and the Challenged Ad with the same headline is completely irrelevant because the Challenged Ads with the same headlines all have body copy, and the body copy of an ad drastically changes the meaning of an ad or what a reasonable person would take away from it. (RRFF 584). Indeed, a simple facial comparison of the "I'm off to save PROSTATES!" Bovitz Stimuli to the "I'm off to save PROSTATES!" Challenged Ad (print ad version), both of which are depicted below in Figures 1 and 2, respectively, aptly illustrates this obvious point.

Figure 1
Challenged Ad (CX0274).

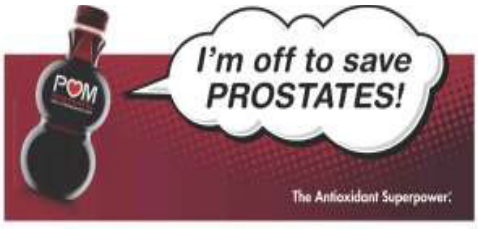

Figure 2
Bovitz Stimuli (PX0223-0411).

Moreover, even the results from the Bovitz Survey do not stand for the proposition that Complaint Counsel says they do. For example, Complaint Counsel contend that the "I'm off to save PROSTATES!" print and banner ad communicate a message that "POM Juice treats, prevents, or reduces the risk of prostate cancer" because 43% of the general population and 48% of the POM population in the Bovitz Survey allegedly stated that the "main idea" of the "I'm off to save PROSTATES" billboard ad was that it was "good for prostates." (CCFF 588). This is yet another example of Complaint Counsel's illogical inferences. Nowhere do Complaint Counsel explain how they make the leap from POM Juice is "good for prostates" to "POM Juice

treats, prevents, or reduces the risk of prostate cancer," especially in light of the fact that the Bovitz Survey also allegedly found that 31% of the general population and 48% of the POM population said the "main idea" of the "I'm off to save PROSTATES!" billboard was "healthy/health benefits/juice is good for you." (PX0295a15-0017, 45; RRFF 588).

Similarly, Complaint Counsel assert that the "Decompress" print ad creates the net impression that "POM Juice treats, prevents, or reduces the risk of heart disease" because allegedly 14% of the general population and 17% of the POM population in the Bovitz Survey said the "main idea" of the "Decompress" billboard ad was that it "helps/lowers blood pressure." (CCFF 588). Complaint Counsel, however, fail to mention that the Bovitz Survey also allegedly concluded that (1) 64% of the general population and 73% of the POM population stated the "main idea" of the "Decompress" billboard was "healthy/health benefits/juice;" (2) 16% of the general population and 20% of the POM population responded that "antioxidants" were the "main idea" and (3) 6% of the general population and 13% of the POM population said the "main idea" of the billboard was "calming, relieves stress/relaxing." (PX0295a15-0018, 46; RRFF 588). Complaint Counsel's assertion that the "Decompress" print ad conveys the net impression that "POM Juice treats, prevents, or reduces the risk of heart disease, including by reducing blood pressure" according makes no sense, in light of all those alleged findings. To the extent, the "Decompress" print ad, which does not use the words "blood pressure" or say anything at all about "blood pressure" (RFF 2329) makes any claim about blood pressure (which Respondents dispute that it does),[60] it is that POM Juice may reduce the risk of heart disease, like a healthy diet of fruits and vegetables and exercise "may reduce the risk" of heart disease, for all the reasons summarized above. (RFF 2326).

[60] Respondents contend that the net impression of the "Decompress" print ad is that POM Juice is healthy, healthy for your heart and good for cardiovascular health. (RFF 2337). Regardless of the net impression, Respondents further contend that the ad provides no basis for injunctive relief, (*see* RFF 2257, 2321), because they have not run the ad in at least four years, (RFF 2318-19), and Complaint Counsel have presented no evidence that it is probably that Respondents would run this type of ad again. (RFF 2319-20).

Even assuming *arguendo*, that the Bovitz Survey is relevant to the meaning of any of the Challenged Ads (which it is not), Respondents presented substantial evidence that the Bovitz Survey is seriously flawed and, therefore, unreliable extrinsic evidence. (RFF 2753-71). The fact that Professor Mazis did not consider the Bovitz Survey in preparing his expert report and offered no opinion on it in his expert report is, in effect, an attestation to that fact. (RFF 2752).

First, the Bovitz Survey was seriously and fatally flawed by screening Question E, which imposed extremely stringent "healthy-living" or "health-conscious lifestyle" requirements on survey participants. (PX0223-0393; RFF 2758). Question E, which is set forth fully below, asked respondents to answer ten questions, five of which were health-related statements.

Question E. Listed below are some statements that may or may not describe you. Using the scale provided, please indicate the extent to which each of the following statements describes you.

(RANDOMIZE ROWS)	**Describes me perfectly**	**Describes me well**	**Describes me somewhat**	**Describes me a little**	**Does not describe me at all**
1. I use my diet to manage my health	5	4	3	2	1
2. High fiber foods are a regular part of my diet	5	4	3	2	1
3. I regularly work out to stay fit	5	4	3	2	1
4. I try to include plenty of fruits and vegetables in my diet	5	4	3	2	1
5. I believe that what I eat can directly affect my health	5	4	3	2	1
6. I am the first of my friends to try new gadgets and technology	5	4	3	2	1
7. I prefer to watch movies at home instead of a theater	5	4	3	2	1
8. I am adjusting my lifestyle to be conscious of the environment	5	4	3	2	1
9. I enjoy cooking and trying new	5	4	3	2	1

(RANDOMIZE ROWS)	Describes me perfectly	Describes me well	Describes me somewhat	Describes me a little	Does not describe me at all
recipes that I find online					
10. I like to stay up on current events	5	4	3	2	1

(PX0223-0393). To qualify for participation in the survey, respondents had to respond with a "5" or a "4" on the rating scale with respect to at least three of the five health-related statements (*i.e.*, Questions 1 through 5). (PX0223-0393). Based on the screening criteria in Question E, the average healthy person would not qualify. (RRFF 582). Because the participants in the Bovitz Survey were not just "health-conscious" but health nuts, they were not a good representation of the overall consumer population. This stringent screening criteria therefore created an overall bias in the survey towards extremely health-focused people and led to participants that were much more likely to be focused on health issues than the general population. (RFF 2759; RRFF 582).

Second, Professor Reibstein testified that the survey is a completely unreliable method for measuring the meaning of POM's billboard advertisements because the participants were shown these ads in a tightly controlled environment (*i.e.,* a forced exposure or viewing), which forces a consumer to zero in on an ad in a way he or she would never do in the real world. (RFF 2756, 2762). Last, the Bovitz Survey also is unreliable for determining consumer's perceptions because the sample was too small (RFF 2760-61), and because it lacked a control, meaning that participants might have had preconceived perceptions about pomegranate juice before being exposed to the Bovitz Stimuli which could skew their perception of the billboard stimuli. (RFF 2757).

Because the Bovitz Survey is flawed, irrelevant and, therefore, unreliable and both Professors Mazis and Stewart conceded they were not offering any expert opinion on how consumers would interpret any of the Challenged Ads. (*See* RFF 239, 2622, 2685). The only reliable extrinsic evidence on the meaning of the Challenged Ads was presented by Respondents

through the testimony of Professor Butters. (RPTB at 72-74). 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 183-84). 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, 2302). 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. (RFF 143, 552, 1210-11, 1774, 1783, 2099, 2907, 2107, 2112). And, although Dr. Butters acknowledged that his corrected deposition answers to triple compound questions indicated that some people could interpret the Challenged Ads as conveying that the Challenged Products "reduced the risk" of particular diseases, he doubted that they would, in fact, reach that understanding. (RFF 2274). Moreover, 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. (RFF 1206, 1783, 2119).

Accordingly, because Complaint Counsel failed to present any reliable extrinsic evidence on the meaning of the ads or what a reasonable person would take away from them, they have failed to meet their burden that a preponderance of the credible evidence shows that the implied establishment or efficacy disease claims as alleged were actually conveyed by the Challenged Ads to a substantial segment of the reasonable consumer. (RFF 2262; Appendix of Advertisements; RRFF 325-615; Reply Ad Appendix). *See, e.g., Thompson Med.*, 104 F.T.C. at 789 ("If our initial review of evidence from the advertisement itself does not allow us to conclude with confidence that it is reasonable to read an advertisement as containing a particular

implied message, we will not find the ad to make the implied claim unless extrinsic evidence allows us to conclude that such a reading of the ad is reasonable.").

C. Respondents Did Not Intend to Convey Establishment and Efficacy Claims That the Challenged Products Treat, Prevent or Reduce the Risk of Heart Disease, Prostate Cancer, and Erectile Dysfunction

Unable to show that the Challenged Ads expressly or impliedly convey the Challenged Claims (*see supra* Section II.A-B),[61] Complaint Counsel argue that Respondents "intended" to convey them and, thus, the claims were in fact communicated to consumers. Of the tens of thousands of pages in the record, no such evidence of such intent exists. To the contrary, Mr. Resnick, Mrs. Resnick, and Mr. Tupper testified that POM never intended to convey the claim that the Challenged Products treat, prevent or reduce the risk of disease. (RFF 496, 531, 535, 537-38, 540, 545-50, 2280; CX1375 (L. Resnick, Trop., Dep. at 0079-81). Complaint Counsel presented no evidence directly contradicting their testimony. Instead, they fixate on irrelevant issues and misstated facts in a failed attempt to show Respondents intended to make the Challenged Claims.

1. Inclusion of Studies and Health Claims in POM's Ads Does Not Show Respondents Intended to Convey the Claims That the Products Treat, Prevent or Reduce the Risk of Disease

Complaint Counsel falsely argue that Respondents' intent to convey the Challenged Claims is evident based on two separate and unconnected arguments: (1) POM highlighted its scientific research and conveyed "serious" health messages in its advertising; and (2) Mr. and Mrs. Resnick's deposition testimony regarding their genuine belief in the preventive and curative attributes of pomegranate juice amounts to purported "admissions" of Respondents' intent to convey these claims. Complaint Counsel are wrong on both counts. First, as discussed *supra*, POM's citation to scientific research in its advertising does not support the argument that POM conveyed that its Challenged Products treat, prevent, or reduce the risk of heart disease, prostate

[61] The "Challenged Claims" refers to the claims Complaint Counsel seek to attribute to the Challenged Ads, i.e., that they treat, prevent or reduce the risk of heart disease, prostate cancer and erectile dysfunction.

cancer, and erectile dysfunction. There were many other elements to the advertisements, including the product itself, that make obvious to reasonable interpreters that the products are not a "silver bullet" against disease. Second, Complaint Counsel cannot take the Resnicks' personal beliefs about the health benefits of pomegranates as proof they intended to convey in POM's advertising the claims that the Challenged Products treat, prevent or reduce the risk of disease. This is illogical and a severely attenuated argument the fails to satisfy Complaint Counsel's burden. Under Complaint Counsel's perverse logic, they prevail if they show the individual Respondents do not believe in the health benefits of the product, and prevail if the Respondents do believe in those health benefits. It cannot be both.

Respondents genuinely believe in the health benefits of the Challenged Products and in the integrity of POM's research program. (RFF 502-520). For example, Mr. Resnick personally believes that pomegranates are a uniquely healthy food and that the consumption of pomegranate juice is beneficial in the fight against cardiovascular disease and POM's research supports his belief. (RFF 506, 515). Likewise, Mrs. Resnick personally believes "with all her heart" that if you lead a healthy lifestyle and consume pomegranate juice, you will be healthier. (RFF 518). Indeed, Mrs. Resnick considers POM Juice to be "health in a bottle" because of the medical benefits of the juice revealed by both POM's research and the 8,000 year history of pomegranates. (RFF 517). Similarly, based upon POM's research studies, Mr. Tupper advises family members with prostate cancer to consume pomegranate juice. (RFF 503, 508). Respondents' belief in the science is justified by the high level of scientific integrity in POM's science program and in the studies themselves. (RFF 269, 314-17, 333-45, 393-94, 436-39, 521-523, 959-86, 1066-68, 1086, 1147-1174, 1683-93, 1702-17). Thus, it is not surprising that POM's ads summarize certain of Respondents' scientific research on the Challenged Products in the areas of cardiovascular, prostate, and erectile health and talk about the healthful properties of POM's products, including that the Challenged Products contain abundant antioxidants and that they are wholly derived from pomegranate fruit. (RFF 493-99, 2478-2505, 2518-44). But this aspect of POM's marketing philosophy alone does not show that Respondents intended to

convey the broad, pharmaceutical-style "prevent or treat" claims Complaint Counsel attributes to the Challenged Ads.

For example, while Respondents have developed a truly unprecedented amount of scientific research on the Challenged Products that would support claims based on the more aggressive personal beliefs held by the Resnicks and Mr. Tupper, Respondents testified that POM never intended to convey the claim that the Challenged Products treat, prevent or reduce the risk of any specific disease, and certainly not in the same sense that a drug treats, prevents, or reduces the risk of disease. (RFF 496, 535, 538, 540, 545-50, 2280; CX1375 (L. Resnick, Trop., Dep. at 0079-81).

Moreover, Lynda Resnick testified that the headline, "I'm off to save PROSTATES!" was "absolutely not" intended to mean that POM Juice would prevent prostate cancer. (RFF 531). Mrs. Resnick further testified that the intent of the ad was not to communicate to consumers that POM would treat prostate cancer, but rather to convey the message that POM Juice is good for your prostate or at most improves prostate health. (L. Resnick, Tr. 217-19). Nor did Mrs. Resnick intend to use Dr. Pantuck's prostate cancer study to communicate to consumers that POM Juice would treat prostate cancer. (RFF 537). Even Mrs. Resnick's development of the logo P♥M, with a heart in place of the "O," was merely intended by her to tell consumers that the juice is generally heart healthy, not convey the totally different message ─ which she has expressly disavowed ─ that POM Juice can treat, prevent or reduce the risk of disease. (CCFF 290).

As to Mr. Resnick, he testified that POM publicizes its research to provide consumers with information to allow them to evaluate for themselves the nature of the Challenged Products' health benefits, not to convey the claim that pomegranate juice treats or prevents disease. (RFF 542-43, 545). Mr. Resnick also testified that POM's advertisements were never intended to convey the message that the Challenged Products can treat or "prevent any health conditions." (RFF 538, 547). Nor did he ever intend to convey that POM products are a substitute for recommended medical treatment. (RFF 524).

Confronted with evidence showing Respondents never intended to convey the Challenged Claims, Complaint Counsel resort to grossly mischaracterizing the evidence. For example, Complaint Counsel twist Mrs. Resnick's statements that POM's "unique selling proposition" is the fact that its products are healthy into an "admission" that Respondents intended to convey the claim that the Challenged Products treat, prevent or reduce the risk of disease. *See* CCPTB at 17, citing CCFF 154-56, 281-82, 289-91, 296-97. This is both an outrageous and illogical inference. Mrs. Resnick's statements merely reflect her marketing philosophy that POM should highlight in advertising that pomegranate juice is a healthy food product, not some unspoken desire to convey "an FDA drug" message that never appeared in the Challenged Ads.[62] *See supra* Section II.A-B.

Additionally, none of the Challenged Ads state that scientific tests "prove" that the Challenged Products prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction, or even that they prevent, treat or reduce the risk of heart disease, prostate cancer or erectile dysfunction. (RFF 2210-11, 2459-75; Reply Ad Appendix; *see supra* Section II.A-B). Throughout its advertising, POM highlights that POM Juice is a 100% juice product wholly-derived from the pomegranate fruit, and that POMx has the same content as the pomegranate fruit itself and is 100% derived from the exact same fruit. (RFF 493-94). Indeed, Respondents have never advertised their products as a pharmaceutical drug, nor intended to advertise their products as drugs. (RFF 495-96). Rather, Respondents have always marketed the Challenged Products for what they intrinsically are: whole-food products. (RFF 497-99).

Even where research is mentioned in POM's ads, the ads generally convey the qualified message that the studies' results are merely "promising," "encouraging," or "hopeful" for prostate, cardiovascular and erectile health or state that the Challenged Products "may" help with

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[62] Likewise, Complaint Counsel illogically imply that because Liz Leow and Fiona Posell stated POM's ads had a "medical component" or "medical message;" Respondents therefore intended to make disease prevention claims. *Id.*, citing CCFF 292-93. However, Complaint Counsel presented no evidence that either of these employees believed that Respondents intended to convey or that POM actually conveyed the Challenged Claims.

a particular condition or that the Products are "fighting" for better health in a particular area. (RFF 2466, 2506, 2517, 2534, 2542). Such restrained language is inconsistent with Respondents' purported "intent" to convey the far more aggressive claim that the Challenged Products treat, prevent or reduce the risk of heart disease, prostate cancer and erectile dysfunction or are "clinically proven" to do so. However, the restrained language is consistent with Respondents' testimony directly refuting the alleged intent to make the "curative and preventive" claims Complaint Counsel attributes to the Challenged Ads. (RFF 531, 535, 537-38, 540, 545-47, 549-50, 2280; CX1375 (L. Resnick, Trop., Dep. at 0079-81).

Puffery can also be found in some of the imagery and headlines of POM's ads. *See supra* Section II.A-B. Such humorously exaggerated headlines and imagery were never intended to convey the message that the Challenged Products treat, prevent or reduce the risk of disease. For example, Mrs. Resnick testified that the purpose of the "Cheat death" ad was not to communicate to consumers that POM Juice is a "silver bullet" against disease, but rather "make you laugh. And what we're saying here essentially with puffery is that you'll live longer if you -- you can cheat death, which we all know you can't." (RFF 535). Mrs. Resnick further testified that the intent of the "Cheat death" ad was to get reader's attention, remember the shape of the bottle, and remember that POM Juice is a healthy product. (RFF 2280; Appendix of Advertisements ¶ 97). Mr. Tupper confirmed that the "Cheat death" advertisement was puffery that was obviously never intended to be interpreted literally. (RFF 2279). Similarly, Mrs. Resnick, Mr. Tupper and Ms. Leow each testified that the "Decompress" ad was intended to be a tongue-in-cheek way to let people know that POM Juice is a healthy and natural product, not that it reduces blood pressure. (RFF 2332-35).

In sum, the record evidence is overwhelming that Respondents never intended to convey to consumers via the Challenged Ads the claims that the Challenged Products treat, prevent or reduce the risk of heart disease, prostate cancer and erectile dysfunction.

2. Citation to Money Spent on Research in POM's Ads Does Not Show Respondents Intended to Convey the Claims That the Products Treat, Prevent or Reduce the Risk of Disease

The mere fact that POM's ads state it spent a particular amount of money on scientific studies on the Challenged Products does not suggest that Respondents intended to convey the claims that the products will treat or ward off disease. On this point, Complaint Counsel presented no evidence that Respondents harbored such intent. Instead, Mrs. Resnick testified that the purpose of including the amount of money related to medical research in the advertising was to convey a message about the company, and its level of dedication to learning the truth about pomegranates. Mrs. Resnick said "[Respondents wanted] a very direct of communicating to the consumer that here was a natural food that had gone through rigorous scientific testing and that we cared enough to do this and we wanted to tell people that we had and continue to do scientific research." (L. Resnick, Tr. 251). Complaint Counsel concede, in fact, that "POM's intention in disseminating the 'backed by' advertisements was to convey its commitment to the science program, the seriousness, breadth, and depth of the science, and to distinguish itself from other food and supplement companies." (CCFF 310; *accord* 309).

Even where medical research was referenced in advertising, the ads conveyed qualified messages about the health benefits of the Challenged Products, not definitive claims that the products will treat, prevent or reduce the risk of heart disease, prostate cancer or erectile dysfunction. (RFF 2517; *see also supra* Section II.A-B). This critical fact negates Complaint Counsel's implication that Respondents intended to convey the claims Complaint Counsel attributes to the Challenged Ads. Accordingly, the evidence overwhelmingly shows that Respondents' intent was merely to communicate *POM's dedication to research*, not convey the claims that the Challenged Products treat, cure or reduce the risk of any particular disease.

3. POM's Focus on Health Conscious Buyers Does Not Prove Respondents Intended to Convey the Claims that the Products Treat, Prevent or Reduce the Risk of Disease

Complaint Counsel contend that Respondents targeted health-conscious consumers and, thus, intended to convey the Challenged Claims. However, neither the medium in which POM

advertised nor its creative briefs establish Respondents' intent to convey the claims that the Challenged Products treat, prevent or reduce the risk of heart disease, prostate cancer and erectile dysfunction.

a. The Medium in Which POM Advertised Does Not Show Respondents' Intent to Convey the Challenged Claims

A focus on health-conscious consumers, including those concerned about illness ─ the very type of consumers that would purchase the magazines *Men's Fitness* or *Prevention* ─ is hardly evidence of a desire to make claims that the Challenged Products "treat," "prevent" or "reduce the risk" of disease as interpreted by Complaint Counsel. These magazines are replete with nutritional suggestions, health tips, guides to healthy living, effective exercise tips and techniques, and any number of articles to assist those focused on proactively maintaining their health and, therefore, reducing the risk of disease ─ but not like a drug does, with increased efficacy (*e.g.*, Lipitor and Prilosec) and safety risks. Instead, the typical article in these magazines may focus on, for example, "5 unexpected reasons to drink more water," the benefits of tomatoes, and why "an apple a day may keep the doctor away." This month's *Men's Fitness*, for example, discusses "Healthy Fried Food?" and asks "What Makes Red Wine Healthy?" Statements in this magazine (and others) that blueberries contain resveratrol, "a heart disease- and cancer-fighting antioxidant found in red grapes and red wine"[63] is not a statement that it will in fact prevent these diseases; Complaint Counsel depicts such language as drug claims. The audience of *Men's Fitness* (and target audience of POM's products as argued by Complaint Counsel) do not receive the message that blueberries (or pomegranates) "prevent" diseases like a drug prevents the buildup of bad cholesterol, or like foot powder prevents fungus with their single effective target of action. Instead, at most, they receive the message that consumption may help reduce the risk of (or help prevent) disease like a healthy diet and exercise do. This is

[63] *See* http://findarticles.com/p/articles/mi_m1608/is_9_17/ai_80309781/?tag=content;col1.

obvious from the magazine type itself. And there is credible evidence for these claims, including under the FTC's "competent and reliable" standard. *See supra* Section II.A-B.

Similarly, the audience of *Prevention* magazine, with its sections on "Health," "Fitness," "Weight Loss," "Food," "Beauty" and "Shopping" do not take away the more severe interpretations that Complaint Counsel advocate here. This fact is obvious from the nature of the magazine itself, as well as from Dr. Reibstein's survey, where less than 1.9% of participatory POM buyers mentioned a disease or specific medical condition of the body when responding to the questions as to why they bought, would buy again or would recommend POM Juice to a friend. (RFF 2623, 2630).

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

In addition, the message conveyed to a reasonable consumer by such ads would also not change merely because the superfoods (blueberries, broccoli, etc.) are branded. If anything, it is more logical that branding would make a consumer even more skeptical of claims. Again, this

likelihood was borne out at trial by the testimony and survey of Professor Reibstein. (Reibstein, Tr. 2495-2502; RFF 2623-28, 2630-32, 2636-37, 2641-42).

In addition, Respondents' "intent" is just as convincingly revealed in where they sold the products. POM Juice is generally sold in the produce aisle of the grocery store, with all the fresh fruit and vegetables. (RFF 498-500). While POMx is not sold in the produce section, it is advertised as 100% fruit derived, nutritional substitute for POM Juice and caters to juice customers primarily. (RFF 494-95, 501). POMx's relationship to the juice and that it is also 100% fruit derived is explained in the advertising. (RFF 494-95, 501). As exemplified in the magazines in which POM advertised and the produce aisles where the juice can be purchased, there is a clear distinction, with a difference, between saying that a product is good for you or may impact or reduce the risk of disease, like certain "superfoods," fruits, vegetables and a healthy diet do, and saying that consumption of a product will, in fact, prevent disease, or treat it, like a drug. Yet, Complaint Counsel ignore these distinctions entirely. Complaint Counsel, in fact, appears to seek a ruling that would, at a minimum, seek to require pharmaceutical type studies for all health benefit claims of any "superfood," even if the claim is that the superfood may help prevent or "reduces the risk" like a healthy diet does - - the type of claim frequently seen in magazines such as *Time*, *Men's Fitness*, *Prevention*, *Sports Illustrated* and others. Complaint Counsel goes too far in refusing to address either 1) the differences in the type of product at issue and how those differences affect the claims; or 2) the differences in "prevent," "reduce the risk" and "treat" claims goes too far. Complaint Counsel have not provided here the basis for any blanket findings that Respondents intended to make "prevent," "treat" and "reduce the risk" claims as defined by Complaint Counsel. The record and all the available evidence support the contrary.

b. POM's Creative Briefs Are Irrelevant to Show Respondents' Intent to Convey the Challenged Claims

Specific language in POM's creative briefs do not counter the available evidence on Respondents' intent in POM's advertising. Creative briefs were typically prepared by junior

POM marketing employees. (Perdigao, Tr. 2790; Tupper, Tr. 921; CX1356 (Leow, Dep. 40)). Mrs. Resnick and Mr. Tupper seldom, if ever, saw, reviewed or provided feedback on creative briefs. (CX1359 (L. Resnick, Dep. 102-03, 109); Tupper, Tr. 923-24; CX1353 (Tupper, Dep. 224); Perdigao, Tr. 623-24, 2790-91; (CX1348 (Perdigao, Dep. 170, 268); Leow, Tr. 459-60; CX1356 (Leow, Dep. 54-55)). Mrs. Resnick testified that she typically did not discuss any particular creative brief with POM marketing employees. (CX01359 (L. Resnick, Dep. 109). There is no evidence that Mr. Resnick has ever seen a creative brief. (Perdigao, Tr. 2791). Indeed, the evidence shows that he had very little involvement in the marketing of POM's products and no day-to-day involvement. (RFF 75-76; Perdigao, Tr. 604; Leow, Tr. 419, 465-66).

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

Once Fire Station received a creative brief, a creative team or teams was assigned to develop concepts for the proposed advertisement. (Perdigao, Tr. 619, 621-22; CX1348 (Perdigao, Dep. 54); Leow, Tr. 453). The concepts were then shown to Liz Leow, Fire Station's Creative Director, who might like them, dislike them, adjust them, or send them back to the

drawing board. (Perdigao, Tr. 621-22; CX1348 (Perdigao, Dep. 55); Leow, Tr. 458-59). If Ms. Leow liked the concepts, they went to Mr. Perdigao for review and then to POM marketing for comment. (Perdigao, Tr. 615; CX1348 (Perdigao, Dep. 55); Leow, Tr. 459). There were often multiple rounds of revisions to the concepts at this stage of the creative process. (Leow, Tr. 459). Sometimes the larger creative concepts were rejected by POM and Fire Station had to start the creative process from the beginning. (Leow, Tr. 460; CX1356 (Leow, Dep. 42-43)).

In sum, because the ad that actually ran typically did not reflect the creative brief prepared by the junior POM marketing employee, it is not accurate to describe creative briefs as reflective of the "intent" behind an advertisement. (Perdigao, Tr. 2791).[64] Accordingly, creative briefs provide no basis to infer Respondents' intent to convey the Challenged Claims.

D. The Challenged Claims Are Not Material To Consumers' Decisions to Purchase POM Juice

Complaint Counsel utterly failed to sustain their burden of proving that the Challenged Claims were material to prospective consumers because they (1) never offered any affirmative proof or expert opinion to support a finding that the Challenged Claims were material (*see* RFF 2680-89), and (2) failed to discredit Professor Reibstein's Survey of POM Wonderful 100% Pomegranate Juice Users ("Reibstein Survey"), which directly contradicted the initial presumption of materiality. *See In the Matter of Novartis Corp.*, 127 F.T.C. 580, 686 (1999)

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[64] Mr. Michael Perdigao, head of Firestation advertisement agency, was asked several questions about the use of the "creative brief" at Firestation, in connection with POM:

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

Perdigao, Tr. 2790-2791.

(rebutting the presumption "is not a high hurdle"), citing *St. Mary's Honor Ctr. v. Hicks*, 509 U.S. 502, 506 (1993). Because the presumption of materiality has dropped out, "'the inquiry … turns from the few generalized factors that establish [the presumption] to the specific proofs and rebuttals … the parties have introduced.'"[65] *Novartis*, 127 F.T.C. at 686 (quoting St. Mary's Honor Ctr., 509 U.S. at 516). Complaint Counsel, however, adduced no "specific proofs and rebuttals" that give rise to their initial presumption that the Challenged Claims were material. This total lack of evidence is fatal to Complaint Counsel's ability to prove deception under the FTC Act.[66]

Confronted with this fatal flaw in their case, Complaint Counsel instead raise spurious arguments that shed no light on the alleged materiality of the Challenged Claims.

First, Complaint Counsel contend that the Reibstein Survey did not rebut the initial presumption of materiality because it "did not expose consumers to the challenged ads or to the challenged claims" and failed to probe what the survey respondents meant by their "healthy" responses. (CCPTB at 29; CCFF 658, 660). Complaint Counsel's assertions are erroneous. Not only was the Reibstein Survey methodologically sound in measuring materiality, it took an approach recommended by Complaint Counsel's own survey expert, Professor Mazis, in an article he wrote entitled *Copy-Testing Issues In FTC Advertising Cases*, as one way of proving that an ad was not material to consumers. (RFF 2703; *see infra* pp. 58). The Reibstein Survey also thoroughly and reliably probed respondents' responses. Moreover, the Reibstein Survey demonstrates, among other things, that 1% or less of POM Juice buyers bought or would buy again because they believe the juice prevents or cures any specific disease. (RFF 2631-32, 2636-37, 2646-57).

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[65] As with any factual issue, the ALJ now weighs the evidence on materiality presented by each side to determine whether Complaint Counsel have met their burden of providing a preponderance of evidence on the issue. *See In the Matter of Novartis Corp.*, 127 F.T.C. at 686.

[66] *See* FTC Policy Statement on Deception ("FTC Policy Statement") (stating that a claim "must be a material one for deception to occur" under the FTC Act), *appended to In re Cliffdale Assocs.*, 103 F.T.C. 110, 165 (1984) (holding the materiality of a claim to a consumer's purchase decision is an essential element under the FTC Act).

Second, Complaint Counsel contend that the Attitude and Usage study conducted by OTX ("A&U Study") and Online Juice Survey conducted by Zoomerang.com ("Zoomerang Survey") show that the Challenged Claims are material to consumers. (CCPTB at 28). However, these two surveys fail to address materiality and/or are so methodologically flawed that they are not reliable evidence of materiality. (RFF 2722-25, 2279, 2232-33, 2238, 2743-44; RRFF 648-50).

Third, Complaint Counsel contend that Professor Reibstein testified that the Challenged Claims would motivate POM's consumers to purchase POM Juice. (CCPTB at 29). Complaint Counsel's assertion is utterly false. Indeed, just the opposite is true. Professor Reibstein never testified that the Challenged Claims were material to consumer purchase decisions. (RRFF 338). Moreover, his survey establishes that very few consumers buy POM Juice to cure or prevent a specific disease. (RFF 2623, 2630-31, 2635-36, 2640).

Fourth, Complaint Counsel contend that materiality should be inferred because Respondents purportedly continued advertising allegedly deceptive claims after being put on notice that their claims were deceptive. (CCPTB at 29). The alleged "warnings" cited by Complaint Counsel were, in reality, rulings and inquiries. (RRFF 402, 662-63, 667, 675, 677-78, 681, 686-91). Moreover, they provide no basis to infer materiality because, among other reasons: (1) Respondents dispute the appropriateness of the adoption by these third-party letters and rulings of FDA-type pharmaceutical drug approval requirements, including requiring RCTs for making health claims regarding fruits or whole fruit products; and (2) several of the rulings and inquiries never took issue with POM's underlying science or claimed that POM's ads were false or misleading.

1. Respondents Rebutted Any Initial Presumption of Materiality Because the Reibstein Survey Unequivocally Demonstrates that the Challenged Claims Are Not Material Because Consumers Purchase POM Juice For Non-Disease Related Reasons

Complaint Counsel falsely argue that the Reibstein Survey is an improper measure of materiality because it did not expose consumers to the Challenged Ads or Challenged Claims and

only asked broad open-ended questions with no probing when respondents said they purchased POM Juice because it was "healthy." (CCPTB at 29). Both contentions lack merit. (CCFF 660-61).

Professor Reibstein testified that it was not necessary to show respondents advertisements because his survey was not a copy test designed to establish what messages the Challenged Ads conveyed, but to discover purchase motivations – *i.e.*, why consumers buy POM Juice.[67] (RFF 2660, 2675). For example, the introduction to the survey questionnaire stated that respondents will be asked questions about what types of beverages they drink and "the reasons why [they] drink them." (PX0237-0001). The key open-ended questions were also designed to elicit information about consumers' purchase decisions by asking "Why did you purchase," "Would you consider purchasing again" and "Would you recommend" POM Juice to a friend. (RFF 2665-67; *see also* RFF 2669-71). Thus, the Reibstein Survey exclusively focused on the information which actually affected respondents' choice of, or conduct regarding POM Juice, which is the essence of materiality. *See American Home Prods. Corp.*, 98 F.T.C. 136, 368 (1981) (claim is material if it is a "factor in the consumer's decision to purchase the product"), *aff'd*, 695 F.2d 681 (3d Cir. 1982); *In re Cliffdale Assocs.*, 103 F.T.C. at 165 (a claim is material if it affects a consumer's purchase decision); FTC Policy Statement, 103 F.T.C. at 182 (same).

Additionally, the Reibstein Survey contained sufficient probing into the respondents' decision-making process. For example, by asking respondents in each of the key primary questions to "*include as many specific details*" in each answer as to why they did or would act as they indicated (RFF 2665-67), the Reibstein Survey proactively sought to probe the specific reasons underlying the respondents' responses. (Reibstein, Tr. 2546). Moreover, Professor Reibstein's survey design was more impactful and reliable because he effectively asked the

[67] Moreover, Complaint Counsel's proposed approach of exposing consumers to the challenged claim or the challenged ad is a completely artificial approach because it is a forced exposure and inaccurately reflects how consumes react to ads or advertising claims in the real world. (RRFF 655, 657-59; RFF 2756, 2762-63). Professor Reibstein also testified that ad testing would not measure materiality. (Reibstein, Tr. 2525; RRFF 2756, 2762-63).

same question three different ways: (1) Question E: Why did you purchase POM; (2) Question F: "Would you consider purchasing POM Wonderful 100% Pomegranate Juice again" and "Why" and (3) Question G: "Would you recommend POM Wonderful 100% Pomegranate Juice to a friend" and "Why".[68] (Reibstein, Tr. 2554, 2585-86; RFF 2665-67). Indeed, Professor Reibstein testified that his triangular approach was a very reliable design and, in effect, asked follow-up questions:

> Q. Okay. So you asked why they bought, if they would repurchase, and if they would recommend to a friend and why in three different sets of questions.
>
> A. Right.
>
> Q. Okay. So why did you ask so many similar-sounding questions with --
>
> A. So I wanted to try and triangulate and to give them as many opportunities as possible to articulate what their motivations were for purchasing. And it is often common in doing marketing research that what you want to do is have multi-questions, not identical questions but sort of surrounding the same area so that you could gain some reliability in the answers that you have.
>
> * * *
>
> Q. Without follow-up questions and without closed-ended questions, your 35.2 percent may be a very low estimate of the percentage of purchasers who are motivated by health reasons; correct?
>
> A. I don't think that is really a fair way to characterize what I believe because I -- you said "without follow-up questions." There really are follow-up questions. And the follow-up questions are, you know, I ask why do you buy, and then I also ask sort of related questions that are follow-ups. So, first of all, I ask why do you buy and please provide all the detail, and then I ask follow-up questions that say would you buy again and why, and so that's giving them more opportunity to be expansive, and would you recommend this to a friend and why, and so in each of

[68] Questions H, I and J asked non-POM Juice pomegranate juice buyers the same questions as Questions E, F and G, respectively. (RFF 2669-71).

> those cases it really is follow-up and follow-up with an opportunity for them to be expansive without saying, Well, you're wrong in your previous answer and you're going to have to be providing us some more. So I'm going to say that's incorrect as you characterized it of having no follow-up questions.

(Reibstein, Tr. 2492, 2553-54) (emphasis added). Likewise, if curing or preventing heart disease, prostate cancer or erectile dysfunction were important factors in respondents' decision to buy POM Juice, Professor Reibstein testified that his survey gave them more than ample opportunity to express that belief by asking them in multiple ways what information was likely to affect their choice of, or conduct regarding POM Juice. (Reibstein, Tr. 2585-86; RRFF 655, 657-59).

Despite Complaint Counsel's faulty criticisms of the Reibstein Survey, it is noteworthy that Complaint Counsel's expert, Professor Mazis, declined to rule out the Reibstein Survey "as probative evidence" on materiality. (RFF 2718). Nor could he have discounted it given his own article entitled *Copy-Testing Issues In FTC Advertising Cases* in which he suggested, as one way of proving that an ad was not material to consumers, a survey asking why the participants buy the advertised product. (RFF 2713). The open-ended questions Professor Mazis used as examples of how to prove the claim was not material were almost identical to those asked in the Reibstein Survey: (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 2665-2671, 2713). Significantly, Professor Mazis did not suggest asking any follow up questions to these open-ended questions. Professor Mazis testified that, while these open-ended questions might underestimate the importance of calcium in selecting cheese, they would nevertheless have "probative value" in proving that the ads in question were not material. (RFF 2713).

Finally, the Reibstein Survey demonstrates that the Challenged Claims are not material because very few consumers purchase, repurchase or recommend pomegranate juice because they believe it prevents or cures any specific disease. (RFF 2623-2628). Specifically, only

1.48% of POM Juice buyers and 1.74% of non-POM Juice buyers bought, would buy again or would recommend to a friend POM Juice because it prevents or cures disease. (RFF 2623-24, 2630). In fact, in response to the key question why did you buy POM Juice, only 1% of respondents volunteered that they bought because the juice would prevent or cure disease. (RFF 2631, 2635). Similar results were found for why would you buy POM Juice again and why would you recommend the juice to a friend. (RFF 2636, 2640-41, 2645). The Reibstein Survey also shows that that less than 1% of pomegranate juice buyers who saw a POM advertisement purchased the juice because they believe it cures or prevents a specific disease. (RFF 2646, 2650, 2652). Based on these findings, the Reibstein Survey establishes that very few consumers of pomegranate juice purchase the product because of its "curative and preventive" properties. Accordingly, the Reibstein Survey effectively and reliably shows that the disease claims Complaint Counsel attribute to the Challenged Ads are not material to consumers' purchase decisions.[69]

2. The Non-Expert Consumer Research Relied Upon By Complaint Counsel Do Not Show That the Challenged Claims Are Material

a. The A&U Study is Methodologically Flawed and Sheds No Light on the Materiality of the Challenged Claims

Complaint Counsel's reliance on the A&U Study to show the materiality of the Challenged Claims is misplaced.

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[69] "When evaluating surveys that measure whether consumers are confused or misled, an issue that federal courts have primarily addressed in the context of trademark surveys, "figures below 20% become problematic because they can only be viewed against the background of other evidence weighing for and against a conclusion of likely confusion." 6 J. Thomas McCarthy, *McCarthy on Trademarks and Unfair Competition*, § 32:188 (evidence of likelihood of confusion). Yet even where such other evidence is very strong, the rock-bottom level of consumer confusion or deception that has been found sufficient to serve as evidence of consumer deception was 8.5%: "[t]he lowest reported figure is 8.5% …where other evidence was also strongly supportive." *Id.* In fact, "[w]hen the percentage results of a confusion survey dip below 10%, they can become evidence which will indicate the confusion is not likely." *Id*., § 32:189. The Seventh Circuit, reviewing cases that found low percentage results, found that a finding of 7.6% consumer confusion is "a factor weighing against [trademark] infringement." *Henri's Food Prods. Co. v. Kraft, Inc.*, 717 F.2d 352, 220 U.S.P.Q. 386, 391 (7th Cir. 1983)." Here, the results of the Reibstein Survey are far below the minimum 8.5% figure.

First, the results of the A&U Study do not stand for the proposition that Complaint Counsel says they do. For example, in response to the question "You said you drink pomegranate juice / antioxidant fruit juices because it's healthy / good for your health. Which specific health reasons below describe why you personally drink pomegranate juice / antioxidant fruit juices?," Complaint Counsel assert that A&U Study respondents cited "contains naturally occurring antioxidants" (91%), "helps promote heart health" (57%) and "helps protect against prostate cancer" (47% (males only)) as the top three reasons why respondents drank pomegranate juice when asked to choose from a list of twelve choices. (*See* CCFF 643; PX0223-0334; PX0223-0352). Complaint Counsel erroneously assert that these results show that "consumers would find claims that drinking POM Juice treats, prevent or reduces the risk of heart disease or prostate cancer to be important to their purchase or use decisions" – *i.e.*, material. (*See* CCFF 646; RRFF 643, 646). This conclusion, however, is yet another example of Complaint Counsel's illogical inferences. Just because a certain percentage of consumers allegedly drink POM Juice because it "contains naturally occurring antioxidants" and "helps promote heart health" does not mean the Challenged Claims (*i.e.*, prevent, treat or reduce the risk of disease) were material to consumers. (RRFF 643, 646-47). To the extent any conclusion can be drawn from the unreliable A&U Study, it is certainly not that the Challenged Claims are material to consumers. (RRFF 643, 646-47). While it is plausible that claims that the product is <u>healthy or full of antioxidants</u> may be important to consumers, the inferences Complaint Counsel attempt to draw from the A&U Study regarding the Challenged Claims are markedly different and plainly incorrect.

Second, as testified to by Professors Reibstein and Mazis, the A&U Study was methodologically flawed and therefore no reliable conclusions could be drawn from it. For example, both Professors Reibstein and Mazis testified at trial that the A&U Study "primed" the respondents to think more about health issues by repeatedly referencing "antioxidants" and "antioxidant juices" in the beginning of the survey before asking them why they drink pomegranate juice. (RFF 2732, 2743). By improperly putting the suggestion of health in

respondents' mind, this serious flaw leads to biased and unreliable results. (RFF 2731, 2743). The A&U Study is also methodologically flawed and unreliable because the sample size of 200 POM Juice users was too small to reach statistical significance. (RFF 2733). Although Dr. Mazis half-heartedly attempted to justify this exceedingly small sample size in, he ultimately agreed on cross-examination that the results of the A&U Study are not statistically significant. (RFF 2739).

The results of the A&U Study are also unreliable and significantly inflated because the questions were close-ended and leading in that the respondents were admittedly given limited choices, forcing respondents to select from attributes they may not otherwise have thought of.[70] (RFF 2723-24, 2728-29; Reibstein, Tr. 2551-52). Closed-ended questions also result in the exclusion of potential answers that were not included on the list of choices because respondents often feel compelled to select one of the answers provided on the list of choices. (RFF 2725). The cuing, leading questions significantly biased the outcome of the A&U Study as testified to by Professor Reibstein. For example, when questions are open-ended as in the Reibstein Survey, many other reasons for purchase are given that are not listed in A&U Study, including recommended/others like it, price/on sale, mixer, quality and bottle design. (RFF 2730; PX0223-0006-07; PX0227-0006). Moreover, when cued as in the A&U Study, the survey answers are inflated. (Reibstein, Tr. 2518-19). For instance, in the A&U Study, 88-91% of the respondents answered that they drink pomegranate juice because it had antioxidants, which contrasts significantly with the Reibstein Survey, which showed that less than 10% of respondents purchase pomegranate juice for that reason. (RFF 2731).

[70] Even Complaint Counsel's expert, Professor Mazis, admits that some of the results of the A&U Study are peculiar when examined against POM's advertisements. In particular, although a substantial number of A&U Study respondents cited "helps protect against urinary tract infections" (38%) and "provides immunity from colds and flu" (45%), Professor Mazis admitted that none of the respondents could have gotten these "benefits" from POM's ads since POM never advertised those "benefits." (RFF 2749-50).

The results of the A&U Study are also biased because the use of closed-ended questions heightened "yea saying," which is the tendency to give a yes or more socially desirable response in an effort to be agreeable to the exclusion of potential answers not included on the list.[71] (RFF 2725, 2741; Stewart, Tr. 3218-19). Although yea-saying can be mitigated through the use of a control question offering a "don't know" or "no opinion" type of option, (*Procter & Gamble Pharms., Inc. v. Hoffman-La Roche Inc.*, 2006 WL 2588002 at *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); *L&F Prods. v. Procter & Gamble Co.*, 845 F. Supp. 984, 998-99 (S.D.N.Y. 1994) (discounting results of closed-ended question that lacked "don't know/no opinion" option)), the A&U Study failed to include such a control question. (RFF 2727).

Complaint Counsel also misleadingly cite the results of Question B2 of the A&U Study, which they claim show that "helps promote heart health" (57%) and "helps protect against prostate cancer" (47%) were important reasons respondents drank POM Juice. (*See* CCPTB at 28). As Complaint Counsel's experts testified, however, to eliminate the effect of yea-saying, the responses to the control group are subtracted from the responses to the test group. (RFF 2735, 2745). When the responses of the control group of non-POM Juice drinkers are subtracted from the responses of the test group of POM Juice drinkers in regard to Question B2, the percentage of POM Juice drinkers who mentioned "promotes heart health" and "helps protect against prostate cancer" is exceedingly low at only 8% and 7%, respectively. (RFF 2736-37). Moreover, with respect to the survey participants' responses to Question B2, Professor Reibstein testified that this type of question was a leading, biased question because it directed participants to select a "specific health reason" which pressures them to identify a "specific health reason" even if they did not perceive any of the choices as a "particular benefit" of drinking POM Juice. (RFF 2767-68; PX0227-0006).

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[71] *In re Stouffer Foods Corp*., 118 F.T.C. 746 781 (1994) ("close-end questions ... suggest the desired answer … [and] also tend to elicit bias"); *CKE Rest. v. Jack In The Box, Inc*., 494 F. Supp. 2d 1139, 1144-45 (C.D. Cal. 2007).

Finally, Professor Mazis conceded that the A&U Study does not state whether "POM ads were material to [consumers'] purchase decision[s]." (RFF 2722, 2738, 2748). His concession negates Complaint Counsel's groundless assertion that the A&U Study shows that health claims for the Challenged Products were material to consumers' purchase decisions. *See American Home Prods.*, 98 F.T.C. at 368 (claim material only if it affects a consumer's choice of, or conduct regarding a product); *In re Cliffdale Assocs.*, 103 F.T.C. at 165 (same).

b. The Zoomerang Survey is Methodologically Flawed and Sheds No Light on the Materiality of the Challenged Claims

Similarly, the Zoomerang Survey is woefully deficient in methodology and is utterly irrelevant to the materiality of the Challenged Claims. For example, instead of examining consumers' purchase decisions regarding POM Juice, the objective of the Zoomerang Survey was to understand, among other irrelevant issues, consumers "consumption habits," an entirely different concept. (CX0136_0003; CX0292_0025-26; RRFF 648-50). Thus, the survey respondents were not asked why they purchase POM Juice or what factors would be important to their purchase decision. (CX0136_0003, 0006; RRFF 648-50). This fact seriously and fatally undermines the suggestion by Complaint Counsel that the Zoomerang Survey is relevant to determine the materiality of the Challenged Claims. (RRFF 648-50).

Moreover, the Zoomerang Survey provides no credible evidence on materiality because it used highly suggestive close-ended questions that contributed to biased and unreliable results. (CX136_0006). In particular, respondents were presented with only six "benefits" of drinking pomegranate juice and forced to rank them by importance to them personally. (CX0136_0006-07; CX0292_0025; RRFF 649). Thus, the results of the Zoomerang Survey are unreliable and inflated because by so severely narrowing the choices, respondents were forced to rank health benefits they may not otherwise have thought of or which they personally did not believe were benefits. (RFF 2724; Reibstein, Tr. 2551-52; RRFF 648-50). The use of the close-ended question also resulted in the exclusion of potential health benefits that were not included on the

list of choices because respondents were compelled to rank only the health benefits listed. (RFF 2725).

Additionally, the results of the Zoomerang Survey fail to support Complaint Counsel's materiality argument. When forced to rank six health "benefits" of drinking pomegranate juice, Complaint Counsel assert that Zoomerang Survey respondents ranked cardiovascular health, prostate health, anti-aging and as the top three "important" "benefits." (CCPTB at 28; CCFF 649). Complaint Counsel mistakenly assert that these findings show that the Challenged Claims "were material to consumers' purchasing decisions" – *i.e.*, material. (CCPTB at 28). Complaint Counsel's contention is meritless. Even if consumers allegedly consider cardiovascular health, prostate health and anti-aging "important" benefits of drinking POM Juice, that does not denote that the Challenged Claims are material (*i.e.*, prevent, treat or reduce the risk of disease) to consumers. Complaint Counsel presented no evidence tying the unreliable Zoomerang Survey to the Challenged Ads or Challenged Claims. Of course, as Dr. Mazis conceded at trial, even if one of the listed health benefits was "important" to the survey respondent, "to be material it has to be important to their decision to buy." (RFF 2692; *see also* RFF 2693). On that issue, however, Complaint Counsel presented no evidence that any of the six health benefits were a factor in the respondents' purchase decisions and, thus, failed to show they were material. (RRFF 648-50).

3. Dr. Reibstein Never Testified That the Challenged Claims Would Motivate Consumers to Buy the Challenged Products

Complaint Counsel falsely argue that Professor Reibstein testified that the Challenged Claims would motivate a certain segment of POM's target audience to buy POM's products. This hypothetical question was not within the scope of his expert opinion and report, and although Professor Reibstein testified that a claim that drinking a bottle of POM Juice a day prevents or treats heart disease, prostate cancer, or erectile dysfunction "might be" "important" to consumers, (PX0356 (Reibstein, Dep. at 117-19), he never testified that such a claim would be material. Moreover, Professor Reibstein had no evidence before him to draw this conclusion sought by Complaint Counsel, and there is no foundation for him to reliably answer this

question. Indeed, he testified that it is unknown whether consumers would actually believe or act on such a claim. (PX0356 (Reibstein, Dep. at 118-19). Complaint Counsel concedes that Dr. Reibstein's testimony is relevant to materiality only if he opined that the "challenged claim would motivate the target audience to purchase a product." (*See* CCPTB at 29) (emphasis added) (citing *Novartis*, 127 F.T.C. at 689-90) (in crediting expert testimony on materiality, noting one expert testified that the claim was the "primary reason" consumers buy the product and the other expert testified that the claim would "motivate" back pain sufferers "to purchase a product"). Here, unlike the experts in *Novartis*, Professor Reibstein never testified that the Challenged Claims motivate or are a reason why consumers purchase the Challenged Products. (PX0356 (Reibstein, Dep. at 117-19).

4. Materiality of the Challenged Claims Cannot be Inferred From the Notices Respondents Received about Their Science and Advertising

Unable to present any evidence to support a finding that the Challenged Claims are material, Complaint Counsel resort to arguing that materiality can be inferred from Respondents' purported indifference to various notices or inquiries by television networks and government agencies regarding some of POM's advertising. (*See* CCPTB at 29, citing *Kraft, Inc. v. FTC*, 970 F.2d 311, 323 (7th Cir. 1992)). Specifically, Complaint Counsel cite to a New York Attorney General inquiry, NAD findings, an email from NBC, a question from Comcast, correspondence from researchers and research institutions, the FTC inquiry, and a FDA warning letter for support for their position. (CCFF 662-93). However, materiality of the Challenged Claims cannot be inferred based on these irrelevant materials.

Complaint Counsel's tortured inference of materiality argument hinges entirely on the *Kraft* opinion, which is inapposite and provides no support for inferring materiality in this action. In *Kraft*, the court inferred materiality only after a "high-level Kraft executive" admitted the materiality of the challenged ads by flatly rejecting suggested changes to the ad copy precisely because the "Singles' business is growing for the first time in four years due in large part to the copy." *Kraft*, 970 F.2d at 323 (emphasis added). Thus, Kraft admitted that it was the ad copy

itself that induced consumers to purchase Singles and hence that the claim was material to consumers.[72] Unlike the narrow circumstances in *Kraft*, where a single fact was indicative of materiality (*e.g.*, the ad copy remained unaltered by Kraft because the ad increased sales), ample record evidence exists that reasons other than sales were responsible for Respondents' continued, but altered use of health benefit claims in advertisements after allegedly receiving "warnings." These include, as stated more fully below that, the third party letters and alleged "warnings" referred to did not necessarily contain the "notice" implied by Complaint Counsel, the desire for RCTs is not scientifically supported, the materials Complaint Counsel rely on do not refer to substantiation or assert deception – and, the underlying premise relied on by Complaint Counsel, *i.e.*, that Respondents made no changes in its advertising as a result of these letters, etc., is flat-out wrong. *See infra* Sections IV.B.1-2, 4-8).

First, Complaint Counsel presented no evidence suggesting Respondents ran the Challenged Ads after receiving the inquiries and rulings because they believed the ads increased sales. Moreover, unlike in *Kraft* where the company essentially conceded materiality (*see Kraft*, 970 F.2d at 324-25), Respondents have affirmatively and consistently denied the materiality of the Challenged Claims. (RPTB at 82-92; RFF 2623-30; *see supra* Section II.D). Indeed, as shown by the testimony and survey of Professor Reibstein, the Challenged Claims, in fact, are not material. (RFF 2219, 2613-46, 2678, 2696-2701). Complaint Counsel presented no evidence to rebut Professor Reibstein's testimony and survey. (RFF 2680-84). These critical facts negate Complaint Counsel's assertion that *Kraft* offers a basis for inferring materiality.

Second, the letters and inquires do not constitute "notice" because either it was unclear what standard they utilized or they adopted an inappropriate standard. As to the NBC email discussing its internal guidelines for health claims, there is no record evidence describing those guidelines, their scientific validity or appropriateness to application to health claims regarding

[72] Kraft also conceded that the challenged claims, if made, were false. *Kraft*, 970 F.2d at 314 n. 1. Here, Respondents vigorously dispute Complaint Counsel's assertion that the Challenged Ads are false and deceptive.

whole-fruit products like the Challenged Products. (*See* CX0193_0001). Therefore, Respondents would suffer a grave injustice and clear error would result if the Court inferred materiality of the Challenged Claims based on NBC's unidentified, untested guidelines.

Equally problematic is Complaint Counsel's assertion that materiality of the Challenged Claims should be inferred simply because POM continued making health benefit claims even though some of those claims were not supported by science rising to the level required for FDA drug approval, including being substantiated by two RCTs. However, Respondents have consistently and vigorously argued that RCTs are not required to substantiate the health benefits of natural and safe foods such as the Challenged Products. (RPTB at 35-37, 56). Therefore, to the extent the evidence cited by Complaint Counsel would impose a standard on Respondents contrary to mainstream nutritional research, they cannot be used by Complaint Counsel to short-circuit their burden to prove materiality by a preponderance of the evidence.

Third, many of the materials Complaint Counsel rely upon do not constitute "warning" as Complaint Counsel argue. For example, the letter from the New York Attorney General merely asked whether POM had substantiation for certain advertising claims. (CX1419_0002-0003). Nowhere in the letter is it asserted that POM's ads were deceptive or that POM lacked substantiation for its claims. (CX1419_0002-0003). The FDA warning letter is equally irrelevant because the FDA neither argued the Challenged Claims were deceptive nor asserted that Respondents' research was lacking in scientific rigor. (CX0344_0001). Similarly, the Comcast inquiry is immaterial to the issue of intent because Complaint Counsel never presented evidence that Comcast ever contended that the Challenged Claims were deceptive. All that Complaint Counsel alleges is POM was getting "pushback" from Comcast on a spot. (CX0242).

Moreover, Complaint Counsel's reliance on statements from Dr. Pantuck and Institutional Review Boards is also misplaced. Complaint Counsel uses Dr. Pantuck's emails to falsely argue that he had "concerns" about POM's "misuse" of his prostate cancer study. (CCFF 402, 691). That is a blatant misrepresentation of Dr. Pantuck's emails. As discussed more fully below, POM intended to use certain quotes made by Dr. Pantuck and describe his study in a

press release. *See infra* Section IV.B.5. However, Dr. Pantuck was worried that he might be perceived as a spokesman for POM and, thus, undermine his credibility as an objective researcher. *See id.* Nowhere did Dr. Pantuck express concern about the accuracy of his quotes or description of his study. *See id.* Likewise, statements from Institutional Review Boards ("IRB") do not constitute "notice" that the Challenged Ads conveyed deceptive "disease treatment and prevention claims" because, among other reasons, IRB's do not review advertising and the communications between POM and the IRBs did not concern ads. *See infra* Section IV.B.6.

Fourth, Respondents responded responsibly and appropriately to the letters and inquires and change conduct in regard to POM's advertising when warranted. *See infra* Section IV.B.2. For example, beginning in 2006, largely as a result of the two NAD decisions, POM stopped making generalized statements in advertisements about the science it had done. (RFF 479). Since 2006, when discussing the benefits of its products, POM's policy has been to discuss and describe what research was done, where it was done and to summary the results of the specific scientific studies described in its ads. (RFF 480). Also, as a result of the NAD's decisions, in some of their ads, POM would direct people back to their website to read the full scientific study. (RFF 482). Importantly, since 2007 POM has implemented a more formalized and well-defined vetting process for advertisements relating to the health benefits of its products. (RFF 483).

Fifth, permitting an inference of materiality based on the FTC's own inquiry letter as advocated by Complaint Counsel (*see* CCFF 678) would impermissibly place America's advertisers in a Catch-22. On the one hand, advertisers can acquiesce to the FTC's demands no matter how untenable, unscientific or unconstitutional the FTC's positions might be. Or on the other hand, advertisers could continue making the challenged claims for legitimate, non-sales reasons and suffer the legal and financial consequences as the FTC proceeds to obtain an unfair advantage in litigation because the FTC would be relieved of its burden of proving materiality. Adoption of Complaint Counsel's position would therefore give the FTC carte blanche to run

rough-shot over advertisers violating reason, fairness and the Constitution. Complaint Counsel's effort to avoid affirmatively proving materiality should be rejected.

In sum, Complaint Counsel's criticisms of the Reibstein Survey are baseless and the non-expert consumer research and other evidence they rely upon are irrelevant to the materiality of the Challenged Claims. Moreover, because Complaint Counsel presented no evidence that the Challenged Claims were material, such as a reliable consumer survey or expert opinion, they have failed to meet their burden of proof on the issue. This total absence of evidence on materiality is fatal to Complaint Counsel's ability to prove deception under the FTC Act.

E. Respondents' Claims Do Not Constitute Broad "Treat," "Prevent," or "Reduce the Risk" Establishment Claims That Excuse Complaint Counsel From Meeting Their Burden Under *Pfizer* And Evaluating POM's Significant Body Of Research

At this late stage in the case, in post-trial briefing, Complaint Counsel for the first time are attempting to slip in a radically new theory of the case based on a misstatement of long-standing Commission advertising law. Once again Complaint Counsel seek to have this Court endorse "short cuts" and "bright lines" that although would certainly greatly simplify enforcement actions, but would drastically curtail commercial speech on topics of genuine public interest. This result would be unfortunate as well as unlawful.

Based on a single sentence of dicta from *Removatron*, Complaint Counsel advocate a rule requiring that all establishment claims (as broadly interpreted to capture any claim that mentions "science" or "research") be supported by "well-controlled studies" *Removatron Int'l Corp. v. FTC*, 884 F.2d 1489 n.3 (1st Cir. 1989). Well-controlled studies are interpreted by Complaint Counsel as randomized, placebo controlled clinical trials reaching .95 statistical significance.

This is not the law.

As Complaint Counsel acknowledged in their earlier briefs, the substantiation standard for establishment claims tracks the standard for all claims: if a specific level or type of substantiation is expressly claimed, the advertiser must produce that substantiation. Otherwise, the specific claim and corresponding substantiation must be evaluated to determine whether

experts in the relevant field would find the substantiation appropriate. This is a flexible, case specific inquiry. The Commission has never specified a particular formula for this inquiry (and did not do so in *Removatron*[73]). See *Thompson Med. Co.*, 104 F.T.C. at 821, n.59 (The FTC states that "[t]here is no conceptual or practical reason to single out such [establishment] claims for special treatment. They are but one example of an express or implied claim that an advertiser possesses a particular level of substantiation."); *see also Bristol-Myers*, 102 F.T.C. 21, 1983 WL 486271, *210 ("[T]he establishment/substantial question theory . . . is essentially anchored in the reasonable basis doctrine. What constitutes a reasonable basis for an advertising claim is a question of fact to be determined on a case-by-case basis.").

Even if there were to be such a formula, it would not be Complaint Counsel's randomized, placebo-controlled clinical trial standard: the Commission and the courts have held that this "gold standard" is not appropriate for every case and cannot be applied inflexibly across-the-board. However, Complaint Counsel argue that because POM alludes to or references either POM's large body of science in some of POM's advertisements or refers to "science" in any way, then Respondents' ads are by default "establishment claims" that POM's products are "proven" to "treat," "prevent," or "reduce the risk" of disease. Based on such faulty reasoning, Complaint Counsel seek to be excused from both: 1) any obligation to weigh Respondents' scientific evidence under *Pfizer* for the vast majority of the ads; and 2) their burden to show by a preponderance of the evidence that there is no reasonable basis for Respondents' claims. In doing so, Complaint Counsel ask the Commission to commit clear legal error.

In arguing to be released from their obligations under *Pfizer*, Complaint Counsel first state broadly that the vast majority of Respondents' advertisements "make express and implied representations that their health efficacy claims are 'proven' through clinical research, tests, and

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[73] *See* Respondents Reponses to Conclusions of Law 65 and 66. In *Removatron*, the evidence on substantiation consisted solely of the testimony of Complaint Counsel's expert, who testified that based on the nature of the product and the claim at issue there, he thought a "well-controlled clinical study" would be appropriate. It was in that context that the Commission and the reviewing court repeated that standard.

studies." (CCPTB at. 30). Complaint Counsel, then cite to *Removatron Int'l Corp.*, 111 F.T.C. 206 (1988) for the proposition that "[i]f an advertisement represents that a particular claim has been scientifically established, the advertiser must possess a level of proof sufficient to satisfy the relevant scientific community of the claim's truth." *Id.* at 297. Based solely on the aforementioned two assertions, Complaint Counsel take the extreme position that any reference implied or explicit to something scientific in an advertisement is the equivalent of a broad "clinically proven" establishment claim that releases them from their burden of proving there is no reasonable basis or competent and reliable evidence for POM's claims. Conspicuously absent from CCPTB, however, is legal support for the proposition that the mere mention of scientific evidence renders or converts an advertisement into an establishment claim. More than this, Complaint Counsel also ask the Commission to take the extra step of interpreting the scope of the establishment claim broad enough to mean "clinically proven" to "treat," "prevent" and "reduce the risk" of disease. Complaint Counsel's request to be excused from having to delve into the science is completely meritless.

Complaint Counsel grossly mischaracterize the nature of an establishment claim. An advertisement that contains "express representations about the level of support for a particular claim" is often considered an establishment claim. *Thompson Med. Co., v. FTC*, 791 F.2d 189, 194 (D.C. Cir. 1986) (emphasis added). Mere inclusion of a scientific reference is not sufficient to make a claim an establishment claim. Instead, an establishment claim is a statement "to the effect that scientific tests establish that a product works." *Removatron Int'l Corp. v. FTC*, 884 F.2d 1489, 1492 n.3 (1st Cir. 1989) (emphasis added). Specifically an establishment claim "is one that says in substance, that 'tests or studies prove' a certain fact." *Gillette Co. v. Norelco Consumer Prods. Co.,* 946 F. Supp. 115, 121 (D. Mass. 1996) (emphasis added). Establishment claims are almost never found unless the advertiser used specific and unqualified language such as "medically proven," "doctors recommend," "tests prove" or "based on lab tests." *Sterling Drug, Inc. v. FTC,* 741 F. 2d 1146, 1150 (9th Cir. 1084); *FTC v. Direct Mktg. Concepts, Inc.*, 569

F. Supp. 2d 285, 299 (D. Mass. 2008); *United Indus. Corp. v. The Clorox Co.*, 140 F.3d 1175, 1182 (8th Cir. 1998); *Castrol, Inc. v. Quaker State*, 977 F.2d 57, 62 (2nd Cir. 1992).

Respondents have not made unqualified "proven" health claims in any of their advertisements. Complaint Counsel cannot point to any advertisement in which Respondents expressly state that the Challenged Products are "clinically proven" to prevent, treat or reduce the risk of erectile dysfunction, prostate cancer or heart disease. Nor has Complaint Counsel offered any credible evidence or reasoned analysis to support their claim that Respondents' advertising conveyed implied "clinically proven" efficacy claims.

In short, Respondents' advertisements do not make the health claims that Complaint Counsel say they do. In addition to the face of the advertisements themselves, wherein it is apparent that the advertisements do not make or imply "clinically proven" to "treat," "prevent" or "reduce the risk" claims, Respondents' experts Professor Reibstein and Professor Butters have offered testimony and evidence that shows that "clinically proven" health claims were not made and consumers did not infer such claims.[74] (RFF 33, 2203, 2204).

Furthermore, to the extent an "establishment claim" is made in an ad, it is only to the narrow claim made. For example, assuming *arguendo* that a statement that reads "a clinical study shows a significant reduction in IMT by up to 30%" was an establishment claim, the scope of the claim would be limited by that specific language, e.g., did a clinical study show a significant reduction in IMT by up to 30%?[75] *See Bristol-Myers*, 102 F.T.C. at 321 ([A]dvertiser must possess the level of proof claimed in the ad.").

Accordingly, Respondents have made general non-establishment health claims about the nutritional and health benefits of the Challenged Products. The mere allusion to science in an advertisement does not equate to a broad "treat," "prevent" or "reduce the risk" establishment

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

[75] Such a claim would be substantiated by a study showing a 30% reduction in IMT. (CX0611) (Aviram Study (2004), which showed a comparative improvement in CIMT of 39%).

claims and it certainly does not relieve Complaint Counsel from weighing Respondents' science under the *Pfizer* factors. Moreover, if establishment claims occurred they were very narrow and supported.

1. The Proper Standard to Review Respondents' Claims Is Under *Pfizer*

Regarding the few ads that Complaint Counsel concede warrant evaluation of POM's science Complaint Counsel applies *Pfizer* incorrectly. The FTC's 1972 decision in *Pfizer*, established the basic requirements for advertising substantiation. There the "Commission conclude[d] that the making of an affirmative product claim in advertising is unfair to consumers unless there is a reasonable basis for making that claim." *In re Pfizer Inc.*, 81 F.T.C. 23, 30 (1972) (emphasis added).

There are a number of factors that are weighed to determine if an advertiser has sufficient substantiation and therefore a reasonable basis to make a particular claim. Those factors include: (1) the type of claim made; (2) the type of product; (3) the possible consequences of a false claim; (4) the cost of developing substantiation for the claim; (5) the degree of reliance by consumers on the claims; and (6) the level of substantiation experts would agree is reasonable. *See Id*. at 30; *FTC Policy Statement Regarding Advertising Substantiation,* appended to, *Thompson Medical Co.*, 104 F.T.C. 648, 839 (1984), *aff'd*, 791 F.2d 189 (D.C. Cir. 1986), *cert. denied*, 470 U.S. 1086 (1987).

Complaint Counsel purport to apply these factors to the few Challenged Ads they claim make non-establishment claims. However, Complaint Counsel merely lists, in a half hearted fashion, the factors without any attempt to apply them to the facts of this case – *clearly because all of these factors weigh against requiring RCTs to substantiate health claims made for a 100% natural fruit product*.

Complaint Counsel also completely ignore the considerations and cost benefit analysis required by *Pfizer*, 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. Complaint Counsel, for example, would

provide absolutely no health information to the public that is not backed by large RCT studies, no matter how great the cost of those studies, the value of the information in those studies and the harm done by suppressing the health information from the public, or regardless how slight the risk of harm is from the disclosure of the health information. Based on Complaint Counsel's complete avoidance of the required cost benefit analysis under *Pfizer*, their claims against Respondents should be rejected.

This tribunal should prefer "disclosure over outright suppression." *Pearson I, supra*, 164 F.3d at 657. Where there is doubt as to the completeness or accuracy of an advertisement, the courts should 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; s*ee also Whitaker I*, 248 F. Supp. 2d at 9 ("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."). This preference is of great relevance here, where Complaint Counsel's proposed order, requiring prior FDA for a safe food product like pomegranate juice, would in effect constitute a complete and prior ban on speech.

2. Complaint Counsel's Proposition That Only RCTs are Sufficient to Substantiate Health Claims Is Baseless Both Legally and Scientifically

Although POM has utilized RCT's, "*Nothing in the Federal Trade Commission Act, the foundation of this litigation, 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. *The burden is on the Commission to prove that the statements are false*." *FTC v. QT, Inc.*, 512 F.3d 858, 861 (1st Cir. 2008) (emphasis added). Even the FTC's own policies and guidelines do not require such a narrow and exclusionary interpretation of competent and reliable science. "[B]oth the Commission and the

FDA look to well-designed studies, including clinical research and other forms of reliable and probative scientific evidence, in evaluating health claims for foods." *FTC Enforcement Policy Statement of Food Advertising* at CX0002_006 (emphasis added). "Results obtained in animal and *in vitro* studies will also be examined, particularly where . . . human research is infeasible." *Dietary Supplements: An Advertising Guide for Industry*, CX1014_0015.

Ignoring this, Complaint Counsel continue to advocate the legally and scientifically invalid position that RCTs are the only type of competent and reliable evidence by which health claims may be substantiated.[76] Complaint Counsel's citations to case authority for this proposition are misplaced and/or inaccurate. The cases are readily distinguishable with respect to the types of products at issue as well as the type of evidence (or lack thereof) proffered by the defendants in those other cases. For example, Complaint Counsel persists in citing the district court opinion in the QT litigation even though the Court of Appeals in the same case explicitly disclaimed any proposition that the FTC Act requires randomized, placebo-controlled clinical tests.

[76] Notably, Complaint Counsel's own case authority does not establish that there is one defined standard of "substantiation," and certainly not that such a standard is RCTs. *CCPTB* contains at least three different definitions of substantiation for establishment claims: 1) "a level of proof sufficient to satisfy the relevant scientific community of the claims' truth." 2) "competent scientific proof"; or 3) "well-controlled scientific studies." (CCPTB at 30). Complaint Counsel's summary of the required standard for *non*-establishment claims also identifies no less than two varying definitions of "substantiation": 1) "a high level of substantiation, such as scientific tests"; or 2) "valid clinical trials." (CCPTB at 31). Complaint Counsel then offers at least six different definitions of substantiation for what it refers to simply as "health-related claims": 1) "double-blind, randomized, placebo-controlled trials ('RCTs') (CCPTB at 32); 2) "a double-blind study" (CCPTB at 32); 3) "placebo-controlled study" (CCPTB at 32-33); 4) "two well-controlled clinical trials" (CCPTB at 33); 5) "the level of scientific evidence experts in the field find necessary to substantiate the claims." (CCPTB at 33); or 6) "competent and reliable scientific evidence" (CCPTB at 34).Complaint Counsel then assumes, and asks this tribunal to assume, that all of the above definitions – despite their clear differences in language and subjective interpretation – refer to the exact same thing: RCTs. Complaint Counsel has failed to prove that that is the case, however. Indeed, Complaint Counsel's experts were significantly impeached on this issue. In addition, Complaint Counsel's expert in *Daniel Chapter One*, Dr. Miller, opined that when, as is the case here, the product is derived from a whole food and not a drug, and is not being advertised as a substitute for medical treatment, RCTs are not the only form of reliable scientific evidence. (RFF 701-744) Rather, basic, non-RCT science is also competent scientific proof of the products' health benefits. (RFF 701-744).

a. There Is No Legal Requirement of RCTs to Substantiate a Safe Whole Food Product and "RCTs" Are Not Required to Show a Causal Relationship Between a Health Benefit and Product.

A safe, whole fruit, or a product derived from a whole fruit, that is not offered in place of traditional medical treatment does not legally (or scientifically) warrant the use of a large RCT, which might be warranted with a drug, medical device, hair growth formula, or complex dietary supplement with numerous herbal or chemical components that are potentially unsafe or have harmful side effects.

First, 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*. This was true even where the product at issue had serious side effects (including loss of smell). *Id.* Other courts have likewise recognized that Complaint Counsel's 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").

Moreover, repeatedly in the cases cited by Complaint Counsel, the defendants in those cases were marketing products with no historical or scientifically proven basis for safety and failed to refute the FTC's evidence of falsity with evidence of their own. That is certainly not the case here, where Respondents not only proffered considerable expert testimony that RCTs are not required or even preferred for a whole food or nutrient (as distinguished from a drug), but also submitted – in distinct contrast to the cases cited by Complaint Counsel - a vast amount of their own scientific research (over 70 peer-reviewed studies) demonstrating the actual health

benefits of the Challenged Products. (RFF 393). For example, Complaint Counsel cite *FTC v. Direct Mktg. Concepts, Inc.*, 569 F. Supp. 2d 285 (D.Mass. 2008), for the proposition that double-blind, placebo controlled studies are always required for health claims. Here defendants sold two dietary supplements, Coral Calcium Daily (a herbal supplement derived from coral) and Supreme Greens MSM (a herbal supplement composed of a proprietary blend of 29 different ingredients), neither of which, unlike the Challenged Products, had a proven track record of safety and were derived entirely from a single whole food, with the supplement offering naturally occurring antioxidants within the normal nutritional range of the natural fruit. *Id.* at 303. *See* (RFF 991-1020). Also, unlike the Challenged Products, no studies were conducted on either product and no scientific evidence was offered regarding their safety. *Id.* at 303-304. Additionally, the First Circuit, when reviewing the district court's opinion, expressly noted that although the FTC had argued and produced expert testimony that the claims at issue should be substantiated by double-blind, placebo-controlled studies, "there may be other scientific evidence that could be sufficient, and we may assume for these purposes that a double-blind study is not necessarily required." *FTC v. Direct Marketing Concepts, Inc.*, 624 F.3d 1, 9 (1st Cir. 2010) (emphasis added).

In *Daniel Chapter One,* No. 9329, Initial Decision, 2009 WL 2584873, defendant marketed and sold BioShark, 7 Herb Formula, GDU and BioMixx – dietary supplements composed of a conglomeration of different herbal and other materials including shark cartilage. *Id* at *16-17. The products had side effects that were unsafe, and *Daniel Chapter One* made claims that their products could be taken in the place of conventional therapies. (Miller Tr. 2193-94). In that case, this Court specifically noted that Respondents "did not possess or rely upon any adequate substantiation for their claims that the Challenged Products prevent, treat, or cure cancer." *Id.* at *93. Indeed, the Court noted, in requiring RCTs, that "Respondents had no studies whatsoever of the effects of the Challenged Products themselves." *Id.* (emphasis added). The facts of *Daniel Chapter One* are in stark contrast to the situation here, where Respondents

have a vast body of scientific research and literature supporting their advertising claims, including published peer-reviewed clinical studies.

FTC v. Nat'l Urological Grp., 645 F. Supp. 2d 1167 (N.D. Ga. 2008), also cited by Complaint Counsel is equally unavailing. In this case, defendants had sold dietary supplements for weight loss and erectile dysfunction, under the names Thermalean, Lipodrene and Spontane-Es, all of which were formulated from multiple unspecified ingredients referred to only as proprietary and thermogenic components. *Id.* at 1194-1195. The products themselves were not clinically or scientifically tested and were not shown to be safe, but nevertheless were offered as over the counter substitutes for prescription drugs. *Id.* at 1203-1204. Even there, the court did not hold that claims for erectile dysfunction "required" double-blind placebo-controlled studies, as Complaint Counsel suggests. Rather, the court noted that the defendants had not countered the FTC's expert evidence that such studies were required and granted summary judgment on that basis. *Id.* at 1202.[77] (emphasis added). Had defendants relied on other competent and reliable evidence, as Respondents do here, the court may well have rejected Complaint Counsel's insistence on well-controlled human studies.

The same is true for *FTC v. Braswell*, 2005 WL 4227194 (C.D. Cal., September 27, 2005), in which the defendants sold the dietary supplements Lung Support Formula, AntiBetic Pancreas Tonic and Gero Vita GH3. *Id.* at *1. The products were offered in place of conventional medical treatment for asthma, bronchitis, emphysema, diabetes (in place of insulin) and as a clinically proven method to reverse dementia and Alzheimer's disease. *Id.* at *5-7. (emphasis added) The FTC offered unrefuted evidence that the standard should be double-blind, placebo-controlled tests. *Id.* at *11. (emphasis added). In contrast here, Respondents' expert Dr. Denis Miller, among several other experts who testified similarly, did refute Complaint

[77] The court expressly noted that it would rely on FTC's expert testimony because the "defendants have not countered the testimonies of the FTC's expert regarding what level of substantiation is required for the claims made in this case." *Id.*

Counsel's evidence that RCTs are required for any type of health claim. Moreover, Dr. Miller, testified specifically that when dealing with a whole food product, not offered in place of conventional medical treatment, health benefit claims may be substantiated by basic science. (RFF 744).

Complaint Counsel cite additional cases where courts adopted RCTs based on the record evidence in those particular cases. However, none of these cases dealt with a safe whole fruit product, and none of the defendants had a fraction of the competent and reliable science that Respondents submitted as part of their evidence. Complaint Counsel cite two cases involving complex, multiple component dietary supplements where the defendants, unlike Respondents, had absolutely no competent and reliable science to support their claims. First, *FTC v. SlimAmerica*, 77 F. Supp. 2d 1263 (S.D. Fla. 1999) was an action against *SlimAmerica* and its founder, the latter of whom had a long record of assorted fraudulent schemes for the marketing and sale of weight loss products. *Id.* at 1265. *SlimAmerica* sold three weight loss pills, Slim-Again (containing chromium and HCA), Absorbit-ALL (containing chitin) and Absorbit-ALL Plus (containing glucomanna). *Id.* at 1266. Consumers complained the products were totally ineffective and resulted in unwanted side-effects. *Id*. at 1268. The court found that studies relied on by defendants were not sufficient because they involved only individual components and did not test the actual products. *Id.* Here, however, Respondents have conducted tests on their actual products. (RFF 22).

Second, in *Schering Corp.*, 118 F.T.C. 1030 (1994), cited by Complaint Counsel, the defendant sold Fibre Trim, a pill containing a mixture of various citrus fruit and grain fiber extracts. *Id.* at 1050. Defendant advertised Fibre Trim as a weight loss product. *Id.* at 1057. However, the Fibre Trim studies relied on were done to examine the relationship between a low calorie diet and Fibre Trim, and not weight loss. *Id.* at 1083-85. The court found that those studies on their face could not support defendant's claims because the studies were not designed, and could not by their very nature, show weight loss efficacy. *Id.* at 1116. The Challenged Products, however, are safe food products, and Respondents have offered competent and reliable

evidence that support health claims more strongly than those purportedly made in their advertisements. (RFF 991-1020; *see infra* Section II.F-H).

Complaint Counsel also point to *In re Removatron,* 111 F.T.C. 206 (1988) and *Thompson Med. Co.*, 104 F.T.C. 648 (1984), for the proposition that Respondents made health claims that consumers would find difficult or impossible to evaluate themselves and that Respondents referred to specific facts and figures about the capabilities of the Challenged products and therefore Respondents need RCTs to substantiate their claims. These cases have little application here as both *Removatron* and *Thompson Med. Co.* sold complex, manufacturing intensive, unnatural products completely opposite to a whole food product.

Removatron sold a radio frequency energy hair removal device (*Id.* at 209) that required Federal Communications Commission approval for its operation. *Removatron* at 227. *Removatron* claimed the device would permanently remove hair. *Id.* at 216. However, the doctor who conducted the one study *Removatron* relied on testified that his experiment did not actually demonstrate "permanent" hair removal. *Id.* at 303. Thus, as the Court of Appeal later noted, the defendants in *Removatron* did not have even one well-controlled scientific study to back up their claims. *Removatron Int'l Corp. v. FTC*, 884 F.2d 1489, 1498 (1st Cir. 1989). In contrast, Respondents have hundred of studies including more than seventy published peer-reviewed studies that support their claims as well as RCTs. (RFF 269, 451).

Additionally, *In re Thompson Med. Co.*, 104 F.T.C. 648 (1984), did not even involve a food product but an arthritis medication, Aspercreme. *Id.* Moreover, despite reasoning that the "proper level of substantiation for *Aspercreme efficacy claims* is two well-controlled clinical [80] tests," the F.T.C. in *Thompson* noted that "<u>we do not preclude ourselves from also permitting advertisers to use other types of evidence to comply with our substantiation requirement</u>." *Id.* at *79-80 (<u>emphasis added</u>). Thus, Complaint Counsel's own authority makes clear that substantiation is not the only type of evidence that will substantiate a health claim.

Complaint Counsel also inexplicably cite to the district court opinion for the exact proposition rejected by the Court of Appeal - - that RCTs are required when advertisements tout

medical studies regarding specific benefits. *FTC v. QT, Inc.*, 448 F. Supp. 2d 908. *QT* sold an "ionized" bracelet they claimed was proven, by scientific tests, to provide immediate pain relief. *Id*. The court found that RCT studies were required to substantiate those claims because: 1) both the FTC's expert and defendants' own expert found that all of the studies relied on by QT were flawed (*Id.* at 940-944), unreliable and in some cases purely anecdotal (*Id.* at 943), 2) QT's "materials" expert had no idea how the QT Bracelet was manufactured (*Id.* at 946) while the FTC's expert opined that there was no plausible means of "ionizing" the QT Bracelet – the claimed mechanism of action (*Id.* at 945), 3) QT's other experts were either unfamiliar with the Q-Ray Bracelet and/or had never read the studies upon which QT relied (*Id.* at 947-948). The Court of Appeal noted specifically that a placebo controlled study was not required, but in any event the "tests" on which [QT] relied were bunk." *FTC v. QT, Inc.*, 512 F. 3d 858, 862 (7th Cir. 2008) (emphasis added). It is undisputed that Respondents' science is not "bunk".

Further, in *FTC v. Pantron I*, 33 F.3d 1088 (9th Cir. 1994), *FTC v. California Pacific Research, Inc.*, 1991 WL 208470 (D. Nev. 1991), and *FTC v. Sabal*,32 F. Supp. 2d 2004 (N.D. Ill. 1998) defendants claimed their various polysorbate-based topical hair products would both prevent hair loss and promote new hair growth. The FTC had produced affirmative and un-rebutted clinical evidence showing that polysorbate-based products are ineffective. Again, in this proceeding no such scientific evidence has been offered by Complaint Counsel. The court in *Pantron* found that the defendants had relied on science (not their own) that showed only a placebo effect. *FTC v. Pantron I,* at 1097. The court in *California Pacific* found defendant's own RCT study showed their products were not effective in re-growing new hair. *FTC v. California Pacific Research* at *4. The court in *Sabal* found that the studies offered for substantiation were not peer-review or published, had no adequate summary of the study results or the research methodology underlying them, and in one egregious case, the lead researcher admitted he may have simply mistaken old hairs for new hair growth when he evaluated the treatment. *FTC v. Sabal* at 1008. Therefore, none of the defendants in *Pantron*, *California*

Pacific or *Sabal* had presented sufficient evidence to refute the FTC's affirmative showing of falsity.

In this action, Respondents presented sufficient evidence – indeed a substantial amount of scientific evidence – to support their claims regarding the health benefits of the Challenged Products. (RFF 269, 393). Having no choice but to deal with a respondent who, in complete contrast to the defendants cited by Complaint Counsel, has conducted and sponsored an extensive amount of scientific research, Complaint Counsel props up a false standard for substantiation – RCTs – insisting that nothing less than RCTs is legally and sufficient. In fact, the opposite is true. Courts have explicitly stated that RCTs are not required. *Matrixx*, 131 S.Ct. at 1320.

b. There Is No Scientific Basis Requiring RCTs to Substantiate a Safe Whole Food Product.

Ironically, the rigid two RCT standard Complaint Counsel advocate here is more stringent than that applied by the FDA in the drug context. In many instances, even the FDA approves pharmaceutical products without requiring the type of rigorous clinical trials that Complaint Counsel now demands for a safe food product. (RFF 757-761). The following table provides a few examples of new anticancer agents and their Phase III pivotal study design that led to regulatory approval in the US (FDA) and in Europe (EMEA) which were done without a placebo control arm. (PX0206-0008)

Indication [subtype, line]	Agent (class of agent)	Randomized Study Design
NHL, [diffuse large B-cell, 1st]	Rituximab (anti-CD20 monoclonal antibody)	R-CHOP vs. CHOP
NHL, [follicular, 1st]	Rituximab	R-CVP vs. CVP
NHL [indolent, relapsed]	Rituximab	Monotherapy
CLL [1st]	Rituximab	FCR vs. FC
Pancreatic cancer [1st]	Gemcitabine	Gemcitabine vs. 5-FU
Prostate cancer [stage 4, HRPC, 1st line]	Docetaxel	Docetaxel + prednisone vs. mitoxantrone + prednisone
Renal cell carcinoma [stage 4, 2nd line)	Sunitinib	Sunitinib vs. IL-2

NSCLC [2nd line, IIIb-IV]	Pemetrexed	Pemetrexed vs. docetaxel
CRC [stage IV, 1st line]	Bevacizumab	Bevacizumab + FOLFOX vs. FOLFOX

In addition, from 1973 through 2006, the FDA approved 31 oncology drugs without a randomized trial using the Accelerated Approval and Priority Review Program ("Fast Track Program").[78]

Complaint Counsel's own experts do not support an RCT only standard and were significantly impeached on that very issue. This is especially true of Complaint Counsel's experts Professor Stamper, Dr. Sacks and Dr. Melman.

Complaint Counsel's designated expert on this matter, Professor Stampfer[79], testified that RCTs are not required to conclude a causal link regarding a nutrient and disease. (RFF 624-644; Stampfer, Tr. 830; PX0362 (Stampfer, Dep. at 73-79, 98)). Professor Stampfer further testified that in a nutritional context, a hypothesis about disease causation can, rarely, if ever, be directly tested in humans using the RCT design. (RFF 640; Stampfer, Tr. 832-33; PX0362 (Stampfer, Dep. at 73, 98); RX5007 to Appendix A). In fact, it is openly accepted and discussed, within the scientific community, that there are major problems in using RCTs to study the effects of foods and nutrients on specific health issues.[80]

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[78] See http://jco.ascopubs.org/content/27/36/6243.abstract (last visited, May 11, 2011); *see also* http://www.fda.gov/drugs/resourcesforyou/consumers/ucm143534.htm (last visited, May 11, 2011) (FDA guidance explaining the Fast Track Program); http://www.fda.gov/forconsumers/byaudience/forpatientadvocates/speedingaccesstoimportantnewtherapies/ucm128291.htm (last visited, May 11, 2011) (explaining that "Fast Track" drugs may receive approval based on "an effect on a surrogate, or substitute endpoint reasonably likely to predict clinical benefit"); 21 CFR § 314.510 (allowing approval based on a surrogate endpoint or on an effect on a clinical endpoint other than survival or irreversible morbidity).

[79] Dr. Stampfer is not a practicing physician who treats patients.

[80] *See* Robert Heaney, Connie Weaver, Jeffery Blumberg, *EBN (Evidence-Based Nutrition) Ver. 2.0*, Nutrition Today, Vol. 46, No. 1, (Jan/Feb. 2011); Roger Clemens, *Dietary Guidelines May Produce Unintended Health Consequences*, Food Technology, (Feb. 2011); and Joanne Slovin, *Dissecting the Dietary Guidelines*, Food Technology, (Mar. 2011), *attached to* Petition for Rulemaking to Adopt Statutory and First Amendment Limits on FTC Orders Concerning Health Benefit Claims and Enact Regulations to Implement *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999) *found at* http://www.ftc. gov/os/2011/05/110503alliancenaturalhealth.pdf.

In his expert report, Complaint Counsel's nutrition expert Professor Stampfer, conceded that he "believe[s] that it may be appropriate to use evidence short of randomized clinical trials for crafting public health recommendations regarding nutrient guidelines even when causality cannot be established, because everyone eats and the public should be given advice based on the best evidence available." (CX1293_0029-0030). Indeed, in a recently published article entitled *Evidence-based Criteria in the Nutritional Context*, Professor Stampfer opined that the general principles of evidence-based nutrition "can provide a sufficient foundation for establishing nutrient requirements and dietary guidelines in the absence of RCTs for every nutrient and food group." (RX5007; Stamper, Tr. 831).

According to Professor Stampfer, RCTs are not the best source of valid and reliable information on nutrition for a number of reasons. First, ethical principles do not permit randomizing individuals to diets that may have negative health effects. (RFF 634, 636; RX5007). Second, it is very difficult to ensure that large numbers of participants adhere to an altered diet over long-term periods. (RFF 634, 636; RX5007). Third, the cost of such studies forms an almost insurmountable barrier, given that no exclusive intellectual property rights (like a pharmaceutical patent) will result from a nutritional trial. (RFF 635). Fourth, in a nutritional context, a hypothesis about disease causation can, rarely if ever, be directly tested in humans using the RCT design. (RFF 640). Finally, 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," (PX0362 (Stampfer Dep. at 73), and that a randomized, double blind, and placebo-controlled clinical trial is not required to conclude a causal link regarding a nutrient and disease. (PX0362 (Stamper Dep. at 98). 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. (RFF 639-40, 642, 740). Professor Stampfer testified that when there is little risk and little cost involved and a potential benefit, that we should "definitely" make that information available to the public rather than withhold it. (Stamper, Tr. 838).

Complaint Counsel's expert, Dr. Sacks, concedes that a casual influence can be demonstrated between and agent and its effects on humans without the use of RCTs. (RFF 647; PX0361 (Sacks, Dep. at 134-135)). Dr. Sacks testified that in vitro studies can be competent and reliable evidence of an agent's effect on a particular mechanism and that he considers all levels of science in issuing national guidelines for the prevention or treatment of cardiovascular disease. (RFF 567, 579). Dr. Sacks also testified that you don't need RCT trials to test the benefits of food categories that are included in a diet already tested, like the DASH diet, which includes pomegranates. (RFF 648). Dr. Sacks went so far as to concede that a causal influence can be demonstrated between an agent and its effect in humans without the use of RCTs. Dr. Ornish, Respondents' expert, noted that most of Dr. Sacks' published studies have been epidemiological and observational in nature, rather than RCTs, and include relatively small numbers of patients. (RFF 1186; PX0025-0007).

Finally, Complaint Counsel's expert, Dr. Melman took the extreme position that "pomegranate juice is a drug." (Melman, Tr. 1141) He went so far as to suggest that water is a drug because it is composed of hydrogen and oxygen molecules. (Melman, Tr. 1141). In the alternative, Respondents' expert Dr. Goldstein more reasonably defines pomegranate juice as a whole food nutraceutical (a naturally occurring botanical) (from a plant) product with health-promoting characteristics) – and not a drug. (RFF 2164).

Respondents' experts agree that RCTs are not necessary to evaluate the health benefits of a food or nutrient, and sometimes not even the best evidence.

Dr. Heber testified that most experts in the field of nutrition consider competent and reliable science to support health claims for pomegranate juice based upon the totality of evidence, which does not necessarily include RCTs. (RFF 652; Heber, Tr. 1948-49, 2166, 2182). Dr. deKernion, testified that in the case of fruit juice such as POM Juice, that has low or no toxicity, it is not necessary to have a RCT, placebo-controlled test. (RFF 1784; deKernion, Tr. 3060).

Respondents' erectile and nitric oxide experts, Drs. Goldstein and Burnett, also testified that urologist who treat men with erectile health concerns would not require that pomegranate juice be subjected to RCTs before concluding that pomegranate juice has a beneficial effect on preserving erectile function and erectile dysfunction. (RFF 650-651; 2122, 2123, 2164; PX0149-0006-0007; Burnett, Tr. 2272-74, 2303 (testifying RCTs are not necessary to deal with studies of drinking pomegranate juice); PX0189-0003, 0014; PX0352 (Goldstein, Dep. at 50-52, 61) (testifying that pharmaceutical type trials should not be applied to nutraceuticals—natural, safe, food products from a plant, with health promoting characteristics); Goldstein, Tr. 2600-02, 2620).

Furthermore, Respondents cardio expert, Dr. Ornish, opined in his expert report that "it is an extreme position to state that the therapeutic efficacy of a fruit juice or extract of pomegranate juice should be held to the same standard of evidence as a new drug." (RFF 1192; PX0025-0008). Dr. Ornish believes that the study of pomegranates or pomegranate juice is different than studying a new drug, in which harmful side-effects, both short-term and long-term, are the rule rather than the exception. (RFF 1195; PX0025-0008). Additionally, Dr. Ornish opined that he is "not aware of any studies showing any harmful effects of consuming pomegranates or pomegranate juice." (RFF 1194; PX0025-0008). Dr. Ornish testified that a new drug needs to be held to a higher standard than a juice that has been around for thousands of years. (RFF 1196; Ornish, Tr. 2340).

In contrast to Complaint Counsel's proposition, but in line with Complaint Counsel's experts like Dr. Sacks and Professor Stampfer and Respondents' own experts, Dr. Denis Miller testified that the consensus among competent and reliable scientists is that if you are talking about a (1) safe pure food product or its derivative, and (2) the product is not offered as a substitute for conventional medical care or treatment, then it is appropriate to favor disclosure, and you may rely on basic science for substantiation and RCTs are not required. (Miller, Tr. 2194; PX0206-007, 0015). Dr. Miller believes that this is a flexible standard that must include input by practicing clinicians in the specific areas of health at issue. "It is preferred, for example,

that to accurately examine the desirability of getting information to the public, that input is given by practicing physicians in the relevant affected fields, who have firsthand knowledge regarding the needs and risks faced by their patients and options (or lack thereof) that are available to their patients." (PX0206-0008) (Miller Expert Report). Dr. Miller offers this expert opinion based on his 50 years of practicing medicine and being involved in clinical research on both the academic and industry side.[81] (RFF 660-700). Notably, Dr. Miller previously testified as an expert for the FTC in the *Daniel Chapter One* case, where the respondent urged consumers to use its product to treat cancer in place of recommended medical treatment. However, Dr. Miller recognizes that this case—involving pure fruit juice or pomegranate derived products, threatening no material risk of harm—is eminently distinguishable. In Dr. Miller's opinion there are essentially no risks in consuming the Challenged Products. (RFF 713). By contrast virtually every anticancer agent cause adverse events, some of which are serious and life-threatening, requiring dose reduction or interruption that may cause disease recurrence or induce resistance to therapy. (RFF 713).

Dr. Miller firmly believes that the public should be aware of potentially beneficial foods that have a salutary effect on health and cause no harm. (RFF 727) Informing the public empowers them to add a potentially beneficial, harmless food to their diet that may prevent prostate cancer (and other disorders). (RFF 728). Even Complaint Counsel's experts Professor Stampfer and Dr. Sacks admitted that they have made public health recommendations that were not supported by RCTs. (RFF 751; Stampfer, Tr. at 810, 813-14; PX0300 (Stampfer, Dep. at 173); PX0361 (Sacks, Dep. at 35-38, 130-131)). Dr. Miller reasoned further that, at least with respect to the areas within his clinical expertise, POM's claims regarding its products were supported by competent and reliable scientific evidence. (RFF 723, 731, 736, 741). Dr. Miller

[81] Dr. Denis Miller is the Global Therapeutic Area Leader of Oncology/Hematology at PAREXEL International, one of the world's leading contract research organizations, and Clinical Professor of Pediatrics) at Robert Wood Johnson School of Medicine (New Brunswick, NJ). (RFF 660, 671).

believes in circumstances such as POM's where the product is so obviously safe, even sound basic science could be enough to support a health benefit claim. (RFF 716).

This is clearly the fundamental position of the federal government as well. (RFF 755). (The Agricultural Research Service, which is the U.S. Department of Agriculture's chief scientific 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).

In a final overreaching effort Complaint Counsel make absurd leaps of inference by arguing that because Respondents did in fact conduct some RCTs, Respondents have effectively acknowledged that only RCTs are a reasonable basis for substantiation. This argument is just as defective as it sounds. Respondents commissioned studies because of their sincere desire to discover the truth about the health benefits of the pomegranate. (S. Resnick, Tr. 1859-60). RCTs may be a useful piece, but they are not the entire scope of valid scientific inquiry. Moreover, Respondents have never disputed the validity or importance of RCTs, and certainly utilize them. Rather, Respondents dispute Complaint Counsel's contention that RCTs are the sole and only means by which competent and reliable scientific support must be measured.

c. The Challenged Products Are Safe 100% Whole Food Products That Are Not Offered In Place of Conventional Medical Treatment

The Challenged Products are perfectly safe. Humans have safely consumed pomegranates as nutritious food for thousands of years. (PX0192-0013, 0018, 0042). Pomegranate extract is a food-based dietary supplement which has substances found in pomegranate juice at levels within the nutritional range. (PX0192-0011). Unlike many drugs, pomegranate juice has no adverse side effects. (PX0192-0042). The FDA maintains a list of substances that are identified by the FDA as safe ("GRAS"). (Heber, Tr. 2008-2009). Before a substance can be GRAS identified, the FDA reviews the scientific literature and the traditional intake of the substance. (Heber, Tr. 2009). Both pomegranate juice and pomegranate extract are GRAS identified. (Heber, Tr. 2009; 32; 21 C.F.R. § 182.20). There have been no reported cases

of persons being harmed by eating a pomegranate or drinking pomegranate juice. (Heber, Tr. 1947-1948). There have been no reported cases of toxicity where pomegranates or pomegranate juice have been consumed in nutritional amounts. (Heber, Tr. 1948). In all the studies that have been conducted on pomegranate juice and pomegranate extract, there have never been any reports of any material harm caused to the subjects by consuming the products. (Heber, Tr. 2007-2008; PX0353 (Heber, Dep. at 115)). Nor have any of the clinical studies conducted on pomegranate juice and pomegranate extract found any serious risk to human health from consuming the products.

The Challenged Products have not been offered to consumers in place of traditional medical care or treatment. Indeed, Respondents' have policy and procedures in place to ensure that no such message is conveyed to consumers. (RFF 524-530). Because POM consumers understand that the Challenged Products are wholly derived from the pomegranate fruit (which is heavily emphasized in POM's advertising), no reasonable consumer would interpret Respondents' advertising as claiming they should disregard conventional medical treatment if they were to consume the Challenged Products. (RFF 2204). Instead, POM consumers view the Challenged Products the way they perceive many other whole foods, like broccoli or blueberries, which may help improve your odds against disease, but which are not drugs. (RFF 2204).

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. (RFF 647, 744). Basic science, *in vivo* and *in vitro* laboratory tests and clinical studies, even if not costly RCT studies, are sufficient. (RFF 346, 618, 622, 630, 633-34, 637-42, 645-47, 648-52, 740, 744, 751, 1184-86, 1191, 1204, 1286, 2121, 2784). That view is supported by the expert testimony of distinguished scientists in each medical field at issue. (RFF 346, 618, 622, 630, 633-34, 637-42, 645-47, 648-52, 740, 744, 751, 1184-86, 1191, 1204, 1286, 2121, 2784).

F. POM's Heart Health Claims Are True and Substantiated by Competent and Reliable Scientific Evidence

In their Post-Trial Brief filed on January 11, 2012, wherein Complaint Counsel finally revealed the purported false and misleading advertising and claims made by Respondents, Complaint Counsel alleged that 31 of 43 of Respondents' ads "contain false or unsubstantiated heart disease efficacy claims" and 28 of 43 of Respondents' ads "represent, either expressly or implicitly, that clinical studies prove that the POM Products treat, prevent, or reduce the risk of heart disease." (CCPTB at 43). In their Complaint, Complaint Counsel alleged also that Respondents have falsely misrepresented that the Challenged Products prevent, reduce the risk of, or treat heart disease, by (1) decreasing arterial plaque; (2) lowering blood pressure; and/or (3) improving blood flow to the heart; and that Respondents' studies purportedly prove the same. (Compl., CX 1426_0017-0019).

Respondents dispute Complaint Counsel's allegations that the advertisements at issue suggest the Challenged Products (or "POM Products") can prevent, reduce the risk of, or treat heart disease. As discussed *supra* Sections II.A-C, Respondents' advertising simply does not convey the messages Complaint Counsel contend they say. Instead, Respondents' advertising contains language mostly reporting the scientific results of POM Juice or POMx on cardiovascular health. When the advertisements did cite or quote to Respondents' scientific studies, such statements were qualified with the words "*encouraging*" or "*promising.*" Other of Respondents' ads employed puffery or whimsical humor, using creative images and terms like "amaze your cardiologist," "decompress," or "what gets your heart pumping" to convey a healthy heart message. In short, Respondents have never advertised, expressly or implicitly, that the Challenged Products can somehow treat, prevent or otherwise reduce the risk of cardiovascular disease, like a pharmaceutical drug.

1. The Appropriate Evidentiary and Scientific Standard for Evaluating the Effect of a Fruit or Fruit Juice, Such As Pomegranate Juice (and Its Derivatives), on Cardiovascular Health Is Not RCTs

Contrary to Complaint Counsel's assertions, and those of its experts, Dr. Sacks and Professor Stampfer, RCTs are not required to substantiate the efficacy of a fruit juice or nutrient,

although Respondents certainly do employ the use of RCTs. First, as a matter of law, "[n]othing in the Federal Trade Commission Act…. requires placebo-controlled, double-blind studies. The Act forbids false and misleading statements, and a statement that is plausible but has not been tested in the most reliable way cannot be condemned out of hand." *FTC v. QT, Inc.*, 512 F.3d 858, 861 (7th Cir. 2008); *see also FTC v. Direct Mktg. Concepts, Inc.*, 624 F.3d 1, 9 (1st Cir. 2010) ("a double-blind study is not necessarily required" to satisfy a reasonable basis claim).

Second, as explained by Respondents' experts, Dr. Miller, *infra*, Dr. Ornish and Dr. Heber, the totality of scientific evidence should be examined, not just RCTs, given that: (1) pomegranate juice and its extracts are safe; (2) no one suggests that pomegranate juice or its extracts should be offered in lieu of conventional medical treatment or surgery; (3) the expense associated for conducting a FDA drug study for a non-patentable, natural food is exorbitant and prohibitive; and (4) the potential benefit or information to be gained by the public outweighs any plausible harm. (RFF 1184-1205).

As discussed in Respondents' Post-Trial Brief, Dr. Sacks conceded at trial and in deposition that: (1) in evaluating a natural food, RCTs are simply not necessary in all cases; (2) a lesser standard of evidence is appropriate for fruits and fruit juices as evidenced by his own DASH diet; (3) he has recommended (or would recommend) fish oil (Omega-3) or a reduction in sodium to patients with coronary heart disease even though no RCTs have been conducted; (4) RCTs are not feasible because of logistical, financial, and ethical considerations; and (5) he nevertheless concedes that we should weigh the risk that the product will do harm against the potential of keeping information from the public. (RFF 1214; 1221-22; 1227-48). Dr. Sacks' opinion on the appropriate standard of evidence for evaluating cardiovascular science, therefore, should be disregarded.

Similarly, Professor Stampfer undermines Complaint Counsel's assertion that RCTs are required to demonstrate the efficacy of a whole fruit or juice. In his expert report, for instance, Dr. Stampfer agrees that it may be appropriate to communicate health recommendations in the absence of RCTs:

> I believe that it may be appropriate to use evidence short of randomized clinical trials for crafting public health recommendations regarding nutrient guidelines even when causality cannot be established, because everyone eats and the public should be given advice based on *the best evidence available*…*Long term trials of diet and disease outcomes are often unfeasible due to the financial and participant burden required to perform such studies*, but it is indisputable that the randomized clinical trial is the best study design that permits strong causal inference concerning the relationship between an administered agent (whether drug or nutrient) and any specific outcome.

(CX1293_0029-0030)(emphasis added).

Thus, based on these statements alone, Professor Stampfer concedes that the "*best evidence available*" should be considered, not just RCTs as argued by Complaint Counsel, even when "causality cannot be established" because in his words, "everyone eats." (CX1293_0029-0030). Moreover, Professor Stampfer acknowledges that RCTs "are often infeasible" with respect to diet and disease outcomes. (CX1293_0030). At trial, Professor Stampfer disclosed that he has made public statements or recommendations that food and beverage products lower the risk of certain diseases, in the absence of RCTs and even when the product is not completely safe. (RFF 208-209). Based on the foregoing, neither Professor Stampfer nor Dr. Sacks can faithfully support Complaint Counsel's evidentiary drug standard requiring RCTs to evaluate the effect of a fruit or fruit juice on cardiovascular health.

Complaint Counsel's suggestion that study results must be "statistically significant" with "strong 'p' values" (*i.e.*, $p \leq 0.05$ or a 5 percent or less chance that the change is due to chance) is refuted by Dr. Ornish, and others, who testified that: (1) in evaluating scientific research related to a whole food, it is not necessary to reach statistical significance as opposed to a prescription drug with potential side effects; and (2) the convention that there be a five percent or less finding due to chance is an arbitrary number. (RFF 1252-1254). In addition, as courts have recognized, medical professionals and researchers do not limit the data they consider, even for the purposes of assessing causation, to "statistically significant" data. *Matrix*, 131 S.Ct. at 1320.

In addition, in framing what he considers to be the appropriate "valid surrogate markers" for evaluating scientific research on cardiovascular health, Dr. Sacks improperly adopts a FDA-

drug standard. (CCPTB at 37). In any event, as discussed by Respondents' experts, myocardial perfusion (or blood flow to the heart) and carotid intima-media thickness ("CIMT") are more closely related to, and predictive of, cardiovascular disease then blood pressure or LDL cholesterol. (RFF 1305-1327; 1328-1338).

2. Respondents Possess Competent and Reliable Evidence to Substantiate the Health Benefit Claims Made Regarding the Challenged Products

In their Post-Trial Brief, Complaint Counsel identify and challenge 11 human studies sponsored by Respondents and published in leading peer-reviewed journals. The purported criticisms raised by Dr. Sacks or Professor Stampfer, however, do nothing to detract from the validity of these published findings demonstrating the beneficial effects of pomegranate juice (and its derivatives) on cardiovascular health. Indeed, if any of these so-called flaws were so fatal, no peer-reviewed journal would have published the results.

a. Respondents' Scientific Research Demonstrates a Benefit in Lowering Blood Pressure

Dr. Sacks and Professor Stampfer complain that Dr. Aviram's ACE/BP Study (2001) (PX0005) and CIMT/BP Study (2004) (PX0611) cannot be relied upon because the studies "evaluated a small sample of patients" and were "unblinded and uncontrolled." (CCPTB at 37). Dr. Aviram's studies, demonstrating a 5 percent and 12 percent reduction in systolic blood pressure, however, cannot be rejected in their entirety because of these groundless observations.

The record is replete with evidence confirming that it is entirely appropriate for each patient to serve as his or her own control (RFF 1283) and a study conducted without a placebo does not weaken its importance. (RFF 1285). Indeed, Dr. Sacks concedes that a group taking nothing can serve as a control. (RFF 1298). Dr. Davidson also stated that non-RCTs are accurate, reliable studies generally considered by other scientists and clinicians in the scientific community to be valid. (RFF 1287).

In addition, as Dr. Ornish testified, there is a common misconception that a larger study is a better study, but the opposite can be argued. (RFF 1249). In fact, with a smaller number of patients, the treatment has to be more powerful and consistent in order to show a statistically

significant effect. (RFF 1250). If his study designs were not sufficient, no peer-reviewed journal would have published Dr. Aviram studies. (RFF 1302).

Complaint Counsel point to selected studies sponsored by Respondents in which allegedly no statistically significant differences in blood pressure were observed to show the Challenged Products are not effective. First, none of Respondents' subsequent studies examined blood pressure as a primary endpoint and, as a result, one cannot conclude that there was no effect of POM Juice or POMx on blood pressure. (RFF 1572-1573). In any clinical study, it is routine measure a blood pressure, pulse, body temperature, among other measurements, to make sure patients are healthy. (RFF 1570). Although blood pressure is measured in many studies, a specific claim on blood pressure requires a very specific study involving special equipment and personnel. (RFF 1571). Second, even as Dr. Sacks concedes, subsequent studies showing no statistically significant changes in systolic blood pressure cannot be construed to prove the opposite. (RFF 610-617, 1455, 1513, 1555). Indeed, as courts have observed, "[t]he mere absence of significant affirmative evidence in support of a particular claim . . .does not translate into a negative against it." *Pearson II*, 130 F. Supp 2d at 115. Finally, Complaint Counsel's assertion that Mr. Resnick "has admitted that Respondents do not have enough evidence to support a blood pressure claim" is unavailing. (CCPTB at 38). Mr. Resnick's personal views on substantiation certainly do not amount to expert opinion on what constitutes competent and reliable scientific evidence for the purposes of the FTC Act. For these reasons, Complaint Counsel's suggestion that Dr. Aviram's blood pressure studies are contradicted by subsequent research should be dismissed.

b. Respondents' Scientific Research Demonstrates a Benefit in Reducing Arterial Plaque

Complaint Counsel attempts, but fails, to discredit Dr. Aviram's CIMT/BP Study (2004) (PX 0611), which found a 30% reduction in arterial plaque of individuals who consumed pomegranate juice daily for one year (RFF 1118), and Dr. Davidson's CIMT Study (PX0014), which found a statistically significant reduction in composite measurements in CIMT in subjects

who consumed pomegranate juice for 12 months and a statistically significant reduction in the anterior and/or composite CIMT measurements in a subgroup of individuals with increased oxidative stress at 18 months. (RFF 1139-1146).

With respect to Dr. Aviram's CIMT/BP Study (2004), as discussed *infra*, the fact that the study is considered "unblinded and controlled" by Complaint Counsel does not invalidate the results. (RFF 1289-1302). With respect to Dr. Davidson's CIMT Study, the composite CIMT measurement was listed as a secondary outcome measure, thereby increasing credibility in the result and reducing the likelihood that the finding was "due to chance." (RFF 1431-1440). In any event, Dr. Davidson testified that he believed the primary outcome was modified to be the composite of the anterior and posterior measurements. (RFF 1430). Finally, a strong argument could be made that the composite rate should have been listed initially as the primary end point because it includes all measurements of CIMT, not just the posterior wall. (RFF 1429).

The fact that differences in the composite measurement of CIMT were not statistically significant at 18 months does not change the fact that these differences were statistically significant after 12 months. (RFF 1442). A likely explanation, noted by Dr. Ornish and Dr. Davidson, is that compliance for drinking pomegranate juice declined after a period of one year. (RFF 1444-1448). In any event, an indeterminate result at 18 months is not proof of the negative; it does not mean that POM Juice or POMx does not reduce arterial plaque. (RFF 1449-1450). *See Pearson II*, 130 F. Supp 2d at 115.

Finally, Complaint Counsel cannot ignore Dr. Davidson's findings related to the subgroup merely because it was a "post hoc" analysis. In scientific research, post hoc analysis is routine and even Dr. Sacks admits to having done these in his own studies. (RFF 1460-66). The post hoc analysis has clinical relevance because it is consistent with the potential benefits of antioxidant treatment with pomegranate juice and *could help tens of millions of people in the United States* (RFF 1470, 1472).

Dr. Davidson, who has conducted over 700 clinical studies over the past 25 years and who Dr. Sacks regards as "one of the foremost clinical researchers in the cardiovascular field

with a superb reputation," *has recommended pomegranate juice or POMx to patients* who fit the high-risk profile identified in his study. (RFF 1095, 1097, 1497). Indeed, *Dr. Davidson, who has a very low HDL and high triglyceride levels has been consuming POMx since his study came out*. (RFF 1144).

Complaint Counsel's argument that Dr. Davidson's CIMT Study (2009) contradicts Dr. Aviram's CIMT/BP (2004) study lacks merit. Dr. Aviram's and Dr. Davidson's studies are apples and oranges: both used the same surrogate (CIMT) in a different group of patients. (RFF 1565; Heber, Tr. 1975-76). In Dr. Aviram's study, the subjects had thickened plaque, whereas, in Dr. Davidson's study, his patients had less plaque to the point where it was not significant. (RFF 1561; Heber, Tr. 1975-76; 1983-84). Dr. Davidson's protocol actually excluded people with significant stenosis or plaque from his study. (RFF 1564; Heber, Tr. 1819). As a result, Dr. Aviram's and Dr. Davidson's studies are two different studies, with one group of patients who have very significant disease and the other group where it was just at risk. (RFF 1565; Heber, Tr. 1983-84). The finding of a smaller result in the at-risk group than in the carotid artery stenosis group therefore, is not that surprising. (RFF 1567; Heber, Tr. 1983-84).

In deposition, Dr. Davidson testified that his findings do not contradict and are consistent with previous studies conducted by Dr. Aviram, Dr. Ornish, and other researchers:

> Q. *Is there anything in your study that you conducted that, in your view, contradicts the results of those [Dr. Aviram's and Dr. Ornish's] studies*?
>
> A. No.
>
> * * *
>
> A. *I think the findings are consistent*.
>
> Q. How so?
>
> A. That -- to see an effect of an antioxidant therapy like pomegranate, you need to use it in the population that has high oxidative stress, and *the more oxidative stress that you have, the more likely you're going to see a benefit with the treatment. That's the general theme of our findings, and it's consistent with other research*.

(RFF 1569; CX1336 (Davidson, Dep. at 227-229)) (emphasis added).

Similarly, Complaint Counsel's reliance on Dr. Ornish's unpublished CIMT Study to prove that POM Juice has no effect on CIMT is misplaced. Dr. Ornish's unpublished CIMT study, initially sponsored by Respondents, was designed to evaluate the effects of pomegranate juice in 200 patients for one year. The study, however, only enrolled 73 subjects because funding was cut short. Although the study was "underpowered," Dr. Ornish testified a statistically significant result would have been achieved with 200 patients as originally contemplated. (RFF 1416-1424). In any event, Dr. Sacks concedes that the lack of statistical significance in this study does not prove a negative and does not mean that pomegranate juice is not beneficial. (RFF 1426). *See Pearson II*, 130 F. Supp 2d at 115.

Complaint Counsel's citation to Mrs. Resnick's testimony in a previous deposition does not show that Respondents lacked a reasonable basis in their advertising regarding arterial plaque. Of course, Mrs. Resnick is not an expert on substantiation requirements under the FTC Act and, in any event, she testified at trial that "I have newer information today than I did then, and so I don't know legally what we're allowed or not allowed to say, but I've been led to believe that our basic science is very valid…and especially for a natural food, so I'm not sure, quite frankly." (L. Resnick, Tr. 169).

c. Respondents' Scientific Research Demonstrates a Benefit in Improving Blood Flow

Complaint Counsel raises a number of purported criticisms of Dr. Ornish's myocardial perfusion study, none of which are dispositive to the overall credibility or validity of his study. Complaint Counsel's manufactured critiques of Dr. Ornish's study, which observed a 35% comparative benefit in subjects who consumed POM Juice daily for three months, should be dismissed for the following reasons:

- Myocardial perfusion (blood flow to the heart) is the "bottom line" in coronary heart disease; a better risk factor or surrogate than LDL cholesterol since it is more closely connected to how much blood the heart is getting; and superior than coronary angiography as a predictive test of cardiac events. (RFF 1305-1327; 1328-1338);

- Dr. Ornish's finding of statistically significant changes in the summed difference score (SD) confirmed what the researchers were hoping to find (an improvement in blood flow to the heard when compared to rest and stress) and not in the summed rest score (SRS) or summed stress score (SSS) which measured infarcted or dead heart tissue. (RFF 1339-1358);
- There were no statistically significant differences at baseline in SRS and SDS, only SRS, which would have been accounted for by employing an analysis of variance and statistically by regression to the mean; i.e. if someone were sicker, all other things equal, if there were no effective intervention, it would be expected that the subsequent measures to show the subjects were a little better, not worse. (RFF 1359-1371);
- The study was terminated after three months only because the Resnicks did not provide the funding previously committed, not because the p-value was statistically significant, and this does not undermine the confidence in the three-month findings, which stand on their own. (RFF 1402-1407); and
- The lack of statistically significant changes in blood pressure, cholesterol, inflammatory markers, and oxidative stress cannot be seen to prove the opposite, as Dr. Sacks admits, especially since these biomarkers are not primary endpoints. (RFF 1411-1412; RFF 1572).

Contrary to Complaint Counsel's suggestion, and Dr. Sacks' conclusion, an unbiased doctor could not throw out Dr Ornish's positive myocardial perfusion study based on the criticisms purportedly identified. (RFF 1414). Finally, again, Respondents' subjective beliefs about Dr. Ornish's study do not detract from the study's significance or validity.

Complaint Counsel's assertion that the Dr. Heber/Hill Study (consisting of the "Denver Study" and "San Diego Study") (PX 0139) and Dr. Rock Diabetes Study (PX0127) "showed no improvements" is a gross misstatement of the facts and the record. (CCPTB at 40). The Dr. Heber/Hill Study confirmed the safety of POMx ("no serious adverse events reported") and demonstrated a statistically significant reduction is "TBARS" (thiobarbituric acid reactive substances), which is an important biomarker of oxidative stress and strongly predictive of cardiovascular events. (RFF 1514-1541; CX0934). Likewise, Dr. Rock's study demonstrated a 30% improvement in HDL paraoxonase 1 ("PON 1") and an overall lowering of oxidative stress. (PX0127). In addition, Complaint Counsel's assertion that "there were no changes in antioxidant and inflammation markers in the Davidson CIMT Study" (2009) is without merit given that none of these measurements were primary endpoints of the study and, further, based on Dr. Sack's

repeated concessions, the absence of positive results does not prove the negative. (CCPTB at 40; RFF 1453-1455). *See also Pearson II*, 130 F. Supp 2d at 115.

In reviewing Respondents' cardiovascular research, Dr. Sacks is hardly objective: when any of Respondents' studies do not reach statistical significance, he calls it a good, well-designed study. When Respondents' studies do show a positive result, however, Dr. Sacks calls the research flawed. As discussed *infra*, Dr. Sacks ignores the statistically significant and published results of Dr. Davidson's study, which demonstrate POM Juice's *potential benefit to millions of Americans*. By his own admission, Dr. Sacks cannot rely upon the indeterminate results from the unpublished Ornish CIMT Study or Davidson BART/FMD Study to prove the opposite. (RFF 1426, 1513). *See also Pearson II*, 130 F. Supp 2d at 115.

In reaching his ultimate conclusions, Dr. Sacks fails to consider the totality of scientific evidence, including Respondents' significant basic science, demonstrating the beneficial effects of POM Juice or POMx on cardiovascular health. (*See* RFF 1064-1088). Instead, Dr. Sacks erroneously isolates individual studies, fabricates perceived "flaws," and then claims that the study, standing alone, cannot prove Respondents' health claims. In doing so, Dr. Sacks adopts an improper drug standard in evaluating Respondents' cardiovascular research, rather than examining the totality of the evidence or, as suggested by Professor Stampfer, the "best available evidence." Accordingly, Respondents' scientific research on cardiovascular health represents the "best available evidence" in support of the health benefits of pomegranate juice (and its extracts) on cardiovascular health and provides a reasonable basis for the claims, if any, made in the challenged advertising.

3. Respondents' Competent and Reliable Scientific Evidence Supports "Treat," "Prevent," and "Reduce the Risk of" Claims

Respondents possess competent and reliable scientific evidence supporting heart health claims much stronger than those actually made in their advertisements. Thus, even assuming Respondents did make "reduce the risk," "prevent" or "treat" claims in their advertising (which

they did not), competent and reliable scientific evidence nevertheless exists to support such claims.

Respondents have sponsored approximately 15 published studies in cellular and animal models and approximately 10 published studies on humans demonstrating the beneficial effects of pomegranate juice and/or its extracts on cardiovascular health. (RFF 1064-1100). Together, the totality of this scientific research constitutes competent and reliable scientific evidence supporting Respondents' health claims (RFF 1206-1211), which is "based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results." *See*, *e.g.*, *Brake Guard Prods., Inc.*, 125 F.T.C. 138, 217 (1998). (RFF 1064-1100; 1206-1211; PX0025; PX0192). Indeed, as Dr. Heber testified: "*Competent and reliable science is based on peer-reviewed publications* and generally studies that have been performed that are scientifically valid, whether they're done in cell culture, in animals, in humans, not necessarily a randomized trial." (Heber, Tr. 2058) (emphasis added). *See also Daubert v. Merrell Dow Pharms.*, 43 F.3d 1311, 1318 (9th Cir. 1995)("That the research is accepted for publication in a reputable scientific journal after being subjected to the usual rigors of peer review is a significant indication that it is taken seriously by other scientists, i.e., that it meets at least the minimal criteria of good science.").

a. "Reduce the Risk" of Cardiovascular Disease

To the extent the Commission finds that Respondents' advertisements convey the message that the Challenged Products can "reduce the risk" of heart disease, the totality of Respondents' scientific evidence supports the conclusion that the Challenged Products can "reduce the risk" of heart disease. Dr. Ornish stated in his expert report:

> Taken as a whole, the preponderance of the scientific evidence from basic scientific studies, animal research, and clinical trials in humans reveals that the pomegranate in its various forms (including POM Wonderful 100% Pomegranate Juice, POMx Pills, or POMx Liquid) is likely to be beneficial in maintaining cardiovascular health and is likely to *help reduce the risk of cardiovascular disease*.

(RFF 1206; PX0025-0005) (emphasis added). In addition, both Dr. Ornish and Dr. Heber have testified that the Challenged Products are likely to help prevent or *reduce the risk of heart disease* by (1) decreasing arterial plaque; (2) lowering blood pressure; and/or (3) improving blood flow to the heart. (RFF 1210; PX0025-0005; Ornish, Tr. 2374-75; PX0355 (Ornish, Dep. at 42); PX0192-0045; PX0353 (Heber, Dep. at 76-80)).

b. "Prevent" Cardiovascular Disease

Should Respondents' ads be construed by the Commission to suggest that the Challenged Products can "prevent" heart disease, then the totality of the scientific evidence also supports the conclusion that the Challenged Products "help prevent" heart disease. In this sense, the Challenged Products do not "absolutely prevent" heart disease in all cases (and no product does), but rather help lower the overall incidence. Indeed, Dr. Ornish stated that pomegranate juice "actually improves the blood flow in people who already had heart disease" and if you can "begin to reverse a disease, it would only make sense that it would work even better to help *prevent it in the first place*." (RFF 1211; Ornish, Tr. 2354-55) (emphasis added).

c. "Treat" Cardiovascular Disease

Finally, to the extent the Commission believes that the Respondents' advertisements convey the message that the Challenged Products can "treat" heart disease, then the totality of the scientific evidence supports the conclusion that the Challenged Products can "help treat" or ameliorate symptoms of an existing condition, but not to the extent that it can serve as substitute or replacement for conventional medical care. Dr. Ornish explicitly stated "it is my expert opinion that clinical studies, research and trials, provide significant evidence that pomegranate juice is likely to *reduce blood pressure, improve blood flow, and reduce arterial plaque, period*." (RFF 1210; PX0025-0005; Ornish, Tr. 2374-75; PX0355 (Ornish, Dep. at 42)) (emphasis added). Dr. Ornish, again, if you can "begin to reverse a disease, it would only make sense that it would work even better to help prevent it in the first place." (RFF 1211; Ornish, Tr. 2354-55). Similarly, Dr. Heber also concluded that "[t]here is credible scientific evidence that pomegranate juice and pomegranate extracts have significant health benefits for human cardiovascular

systems, including: (1) *decreases in arterial plaque*; (2) *lowering of blood pressure*; and (3) *improvement of cardiac blood flow*…" (RFF 1209; PX0192-00045; PX0353 (Heber, Dep. at 76-80)) (emphasis added). Complaint Counsel's own expert, Dr. Sacks, acknowledges the role that diet or nutrition can play in "treating" or "preventing" heart disease. In counseling patients on cardiovascular health or disease, for instance, Dr. Sacks explains "my initial emphasis would be nutritional and other nondrug treatment like exercise, weight loss, improving the quality of the diet…" (RFF 1259; PX0361 (Sacks, Dep. at 23-24)) (emphasis added). According to Dr. Sacks, a nutritional emphasis is "the accepted sequence of treatment for prevention of cardiovascular disease…and prevention of recurrent disease." (RFF 1260; PX0361 (Sacks, Dep. at 25)) (emphasis added).[82]

4. Competent and Reliable Scientific Evidence Supports Each of the Challenged Heart Advertisements

Complaint Counsel attack 31 "ads and promotional pieces" as representing "either expressly, or implicitly, that clinical studies prove that the Challenged Products treat, prevent, or reduce the risk of heart disease." (CCPTB at 43). As explained earlier, Complaint Counsel's support for this assertion is erroneous because they ignore, among other things, the overt puffery and humor in the headlines, sub-headlines and imagery and the fact that the Challenged Products are 100% fruit juice or derived from 100% fruit. (*See supra* Sections II.A-C). Indeed, as evidenced by the ads themselves, it is impossible for Complaint Counsel to "conclude with confidence" that the Challenged Ads convey the broad establishment or efficacy claims asserted by Complaint Counsel based on the face of the ads themselves.

Of these 31 ads, 9 ads stated that "our juice showed promising results for heart health. 'Stress-induced ischemia (restricted blood flow to the heart) decreased in the pomegranate group.' Dr. Dean Ornish reported in the *American Journal of Cardiology*, 2005." These challenged pieces are: CX0348/CX0350 ("24 Scientific Studies" Ads); CX0342/CX0353 (Take

[82] Dr. Sacks also concedes that "prevention" means to "lower the incidence of a cardiovascular event, like myocardial infarction or stroke, in proportion to the cases in the population." (PX0361 (Sacks, Dep. at 64-65)).

Out A Life Insurance" Ads); CX0331/1426 Ex. J ("Healthy Wealthy" Ad); CX0280 ("Live Long Enough" Ad); CX0328 ("Your New Health Care Plan" Ad); CX0337 ("The First Bottle You Should Open" Ad); CX0279 ("Science Not Fiction" Ad); CX0180/1426 Ex. K ("Antioxidant Superpill" Ad); CX0351/CX0355 ("Only Antioxidant Supplement Rated X" Ads). One ad described the results of the Ornish MP Study (2005) as follows: "Pomegranate juice improves myocardial perfusion in coronary heart patients." (CX0169/1426 Ex. L ("The Power of POM" Ad). And in some instances the Ornish MP Study (2005) and its results were described with more detail. (CX1426 Ex. I ("Antioxidant Superpill" brochure); CX1426 Ex. M (POMx Heart Newsletter)). These frequent references to the Ornish MP Study (2005) are not and cannot be support for Complaint Counsel's broad establishment or efficacy claims because the science was accurately described in these ads. *See also Edwards v. District of Columbia*, 765 F. Supp. 2d 3, 13 (D.D.C. 2011)(posting and/or citation to scientific articles is constitutionally protected speech against government suppression).

Of the 31 challenged ads, 11 ads referenced the results of the Aviram CIMT/BP (2004) Study which in fact showed a 30% reduction of arterial plaque. These challenged pieces are: CX0034 ("Amaze your cardiologist" Ad); CX1426 Ex. I ("Antioxidant Superpill" brochure); CX0031 ("Floss your arteries. Daily" Ad"); CX0331/1426 Ex. J ("Healthy Wealthy" Ad); CX0280 ("Live Long Enough" Ad); CX0328 ("Your New Health Care Plan" Ad); CX0337 ("The First Bottle You Should Open" Ad); CX0279 ("Science Not Fiction" Ad); CX0029 ("10 out of 10 People" Ad); CX0180/1426 Ex. K ("Antioxidant Superpill" Ad); CX1426 Ex. M (POMx Heart Newsletter). Also, one ad described the results of the Aviram CIMT/BP (2004) Study as follows: "Pomegranate juice pilot research suggests anti-atherosclerosis benefits." (CX0169/1426 Ex. L ("The Power of POM" Ad). And in the Antioxidant Superpill brochure, the body copy described the study with such text: "In two groundbreaking preliminary studies, patients who drank POM Wonderful 100% Pomegranate Juice experienced impressive cardiovascular results. A pilot study at the Rambam Medical Center in Israel included 19 patients with atherosclerosis (clogged arteries). After a year, arterial plaque decreased 30% for

those patients who consumed 8 oz of POM Wonderful 100% Pomegranate Juice daily." (CX1426 Ex. I ("Antioxidant Superpill" brochure). Each of these statements are supported by the results of Aviram CMIT/BP Study (2004).

Also, of the 31 challenged ads, 6 ads made a general reference to encouraging results in cardiovascular health without referencing a specific study. These ads include: CX0188/CX0036 ("Cheat Death" Ads); CX0103 ("Decompress" Ad); CX0109 ("Heart Therapy" Ad); CX0033 ("Life Support" Print Ad); CX0475/1426 Ex/ A (Juice Bottle Hang Tag); CX0192 ("What gets your heart pumping" Ad). Similarly, the Drink and Be Healthy ad described the benefits of the pomegranate juice as being able to minimize factors that would lead to atherosclerosis without describing or referring to a specific study. (CX0016 ("Drink and Be Healthy" Ad)). Notably, with the exception of the older, 2005, Cheat Death outlier ad, these ads make no reference to POM helping to address specific cardiovascular diseases. Moreover, even the older ads emphasize the 100% juice and 100% fruit derived aspect of the product, and at most, convey benefits only in the sense that some fruits or vegetables are healthy for you and may help reduce the risk of disease. Indeed, none of these ads expressly state that POM Juice prevents or treats heart disease or that POM Juice is clinically proven to prevent, treat or reduce the risk of heart disease. Moreover, there is nothing in any of these ads that could lead anyone to believe that drinking POM Juice would treat, prevent or cure any disease.

Lastly, some of the challenged ads make no health benefit claim whatsoever. For example, the Heart Therapy banner ad featured a POM Juice bottle reclining on a chaise lounge with limited body copy about the amount of money spent on medical research. (CX0463 ("Heart Therapy" Banner Ad)). An evaluation of all the elements in this ad as a whole, does not and cannot support a conclusion that POM Juice prevents or reduces the risk of heart disease.

Although Respondents have not made "clinically proven" establishment claims with respect to cardiovascular health in their advertising, Respondents have shown, and the record reflects, that they nevertheless have overwhelming competent and reliable scientific evidence to support such claims. Respondents' 15 published basic science studies constitute competent and

reliable scientific evidence that the Challenged Products are beneficial to cardiovascular health by resulting in, among other things:

- reducing oxidation of LDL cholesterol;
- lessening the uptake of oxidized and native LDL cholesterol by macrophage foam cells;
- diminishing the size of atherosclerotic lesions and foam cells;
- inhibiting macrophage cholesterol biosynthesis;
- decreasing macrophage oxidative stress;
- protecting against cellular lipid peroxidation;
- reducing serum lipids and glucose levels;
- improving PON1;
- lessening of platelet aggregation;
- increasing and preserving levels of nitric oxide and decreasing expression of genes associated with stress and progression of atherosclerosis;
- reducing LDL oxidation, size of atherosclerotic plaques, and formation of foam cells;
- reversing effects of shear stress, which can damage the endothelial cells or thin layer of cells that line the interior of blood vessels;
- decreasing cellular production and release of oxygen radicals in the vascular wall; inhibiting activation of oxidation-sensitive genes; and
- improving biological activity of nitric oxide.

(RFF 1064-1088; PX0025; PX0192; PX0002, PX0007, PX0008, PX0009, PX0010, PX0015, CX0543, PX0017, PX0022, CX0053, PX0055, PX0056, PX0057, PX0058, PX0059).

Respondents' 10 published human clinical studies confirm and support the benefits found in the basic research and together, the totality of the evidence constitutes competent and reliable scientific evidence that pomegranate juice and/or its extracts promote cardiovascular health by, among other things, having the following beneficial benefits:

- decrease of LDL susceptibility to aggregation and retention;
- increase in PON1;
- protection against oxidation of LDL;
- reduction in the activity of angio-tensin converting enzyme ("ACE"), an enzyme which produces "angiotensin II", a protein that causes blood vessels to constrict;
- lowering of systolic blood pressure;
- reduction in CIMT; and
- increase blood flow or myocardial perfusion.

(RFF 1089-1099; PX0025; PX0192; PX0004, PX0005, CX0611, PX0014, PX0020, PX0021, PX0023, PX0038, PX0127, CX0934).

The Aviram CIMT/BP Study (2004) and Davidson CIMT Study (2009) constitute competent and reliable scientific evidence that the consumption of the Challenged Products are beneficial to cardiovascular health by, among other things, reducing arterial plaque. (RFF 1111-1126; 1139-1146; 1288-1302; 1427-1504; PX0014; PX0611; PX0025-0009-0010; 0019-0022; PX0192-0036-0037, 0039; 0048, 005; Heber Tr. 1979-86; PX0014).

The Ornish MP Study (2005) constitutes competent and reliable scientific evidence that the consumption of the Challenged Products are beneficial to cardiovascular health by, among other things, improving blood flow. (RFF 1127-1138; 1303-1414; PX0023; PX0025-0011-0018; PX0192-0037-0038; 0053, Ornish, Tr. 2354-55).

The Aviram ACE/BP Study (2001) and Aviram CIMT/BP Study (2004) constitute competent and reliable scientific evidence that the consumption of the Challenged Products are beneficial to cardiovascular health by, among other things, improving blood pressure. (RFF 1107-1126; 1280-1302; CX0542; CX0611; PX0025-0009-0011; PX0192-0035-0037; 0052).

The following chart summarizes Respondents' scientific research in support of the challenged heart advertisements identified by Complaint Counsel in Appendix A to their Post-Trial Brief.

	Dissemination Date	**Appendix[83]/ RFF[84]/ RRFF[85]**	**Overall Net Impression of Advertisements**	**Scientific Support**
CX0348/CX0350 ("24 Scientific Studies" Ads)	4/1/2010 4/26/2010	Appendix 762-785 RRFF 419-424	• Contains naturally occurring antioxidants that help fight free radicals.	Ornish MP Study (2005) Heart Human Science[86]

[83] "Appendix" refers to Respondents' Supplemental Appendix of Advertisements.

[84] "RFF" refers to Respondents' Finding of Fact.

[85] "RRFF" refers to Respondents' Reply Finding of Fact.

	Dissemination Date	Appendix[83]/ RFF[84]/ RRFF[85]	Overall Net Impression of Advertisements	Scientific Support
			• Good for heart health. • May help increase blood flow.	Heart Basic Science[87] Antioxidant and POM Juice/POMx equivalency studies[88]
CX0034 (Amaze your cardiologist" Ad)	2/1/2005	Appendix 66-93 RFF 2374-2399 RRFF 344-348	• Contains naturally occurring antioxidants that help fight free radicals. • May help reduce plaque by up to 30%.	Aviram CIMT/BP Study (2004) Heart Human Science Heart Basic Science Antioxidant and POM Juice/POMx equivalency studies
CX1426, Ex. I ("Antioxidant Superpill" brochure)	Not Established	Appendix 809-826 RRFF 430-434	• Contains naturally occurring antioxidants that help fight free radicals. • POMx is loaded with antioxidants. • Good for heart health. • May help increase	Aviram CIMT/BP Study (2004) Ornish MP Study (2005) Heart Human Science Heart Basic

[86] All cardiovascular health claims in the challenged advertisements are supported by, in part or by whole, Respondents' Heart Human Science. Respondents' Heart Human Science constitutes competent and reliable scientific evidence that pomegranate juice and/or its extracts promote cardiovascular health by, among other things, decreasing LDL susceptibility to aggregation and retention; increasing PON 1; protecting against oxidation of LDL; reducing ACE, lowering systolic blood pressure, reducing CIMT, and increasing blood flow (or myocardial perfusion). (RFF 1089-1099; PX0025; PX0192; PX0004; PX0005; CX0611; PX0014; PX0020; PX0021; PX0023; PX0038; PX0127; CX0934).

[87] All cardiovascular health claims made in the challenged advertisements are supported by, in part or by whole, Respondents' considerable Heart Basic Science. Respondents' Heart Basic Science constitutes competent and reliable scientific evidence that pomegranate juice and/or its extract are beneficial toward cardiovascular health by, among other things, reducing the oxidation of LDL cholesterol and its uptake, diminishing the size and scope of atherosclerotic legions, macrophages, and foam cells, lessening platelet aggregation, and enhancing the presence of nitric oxide. (RFF 1064-1088; PX0025; PX0192; PX0002, PX0007, PX0008, PX0009, PX0010, PX0015, CX0543, PX0017, PX0022, CX0053, PX0055, PX0056, PX0057, PX0058, PX0059).

[88] Peer-reviewed and published studies and independent websites about the effects of antioxidants, the bioavailability of pomegranate based antioxidants and equivalency of POM Juice and POMx. (RFF 745-958).

	Dissemination Date	Appendix[83]/ RFF[84]/ RRFF[85]	Overall Net Impression of Advertisements	Scientific Support
			blood flow. • May help reduce plaque by up to 30%.	Science Antioxidant and POM Juice/POMx equivalency studies
CX0180/CX1426 Ex. K ("Antioxidant Superpill" Ad)	2/3/2008	Appendix 619-636 RRFF 406-414	• Contains naturally occurring antioxidants that help fight free radicals. • POMx is loaded with antioxidants. • Good for heart health. • May help increase blood flow. • May help reduce plaque by up to 30%.	Aviram CIMT/BP Study (2004) Ornish MP Study (2005) Hear Human Science Heart Basic Science Antioxidant and POM Juice/POMx equivalency studies
CX0188 ("Cheat Death" Ad)	4/1/2008	Appendix 502-523	• Contains naturally occurring antioxidants that help fight free radicals. • POM Juice is loaded with antioxidants. • Good for heart health.	Heart Human Science Heart Basic Science Antioxidant and POM Juice/POMx equivalency studies
CX0036 ("Cheat Death" Ad)	3/10/2005	Appendix 470-501 RFF 2264-2290 RRFF 349-356	• Contains naturally occurring antioxidants that help fight free radicals. • POM Juice is loaded with antioxidants. • Good for heart health.	Heart Human Science Heart Basic Science Antioxidant and POM Juice/POMx equivalency studies
CX0103 ("Decompress" Ad)	3/1/2007	Appendix 94-131 RFF 2315-2348 RRFF 357-362	• Contains naturally occurring antioxidants and helps fight free radicals. • Good for heart health.	Heart Human Science Heart Basic Science Antioxidant and POM Juice/POMx equivalency

	Dissemination Date	Appendix[83]/ RFF[84]/ RRFF[85]	Overall Net Impression of Advertisements	Scientific Support
				studies
CX0016 ("Drink and be healthy" Ad)	10/12/2003	Appendix 1-17 RFF 2291-2314 RRFF 325-328	• Contains naturally occurring antioxidants and helps fight free radicals. • POM Juice is loaded with antioxidants. • Good for heart health. • May help reduce the risk of atherosclerosis.	Heart Human Science Heart Basic Science Antioxidant and POM Juice/POMx equivalency studies
CX0031 ("Floss your arteries. Daily" Ad)	12/1/2004	Appendix 37-65 RFF 2349-2373 RRFF 336-340	• Contains naturally occurring antioxidants that help fight free radicals. • POMx is loaded with antioxidants. • Good for heart health. • May help reduce plaque by up to 30%.	Aviram CIMT/BP Study (2004) Heart Human Science Heart Basic Science Antioxidant and POM Juice/POMx equivalency studies
CX0331/CX1426 Ex. J ("Healthy, Wealthy, and Wise" Ad)	9/27/2009	Appendix 699-718 RRFF 415-418	• Contains naturally occurring antioxidants that help fight free radicals. • Good for heart health. • May help increase blood flow. • May help reduce plaque by up to 30%.	Aviram CIMT/BP Study (2004) Ornish MP Study (2005) Heart Human Science Heart Basic Science Antioxidant and POM Juice/POMx equivalency studies
CX0109 ("Heart therapy" Ad)	4/1/2007	Appendix 132-149 RRFF 363-367	• Contains naturally occurring antioxidants and helps fight free radicals. • Good for heart health.	Heart Human Science Heart Basic Science Antioxidant and POM Juice/POMx equivalency studies

	Dissemination Date	Appendix[83]/ RFF[84]/ RRFF[85]	Overall Net Impression of Advertisements	Scientific Support
CX0463 ("Heart Therapy" Banner Ad)	Not Established	Appendix 524-540 RRFF 536-538	No Health Claim.	N/A
CX0033 ("Life support" Ad)	12/30/2004	Appendix 450-469 RRFF 341-343	• Contains naturally occurring antioxidants that help fight free radicals. • POM Juice is loaded with antioxidants. • Good for heart health.	Heart Human Science Heart Basic Science Antioxidant and POM Juice/POMx equivalency studies
CX0280 ("Live Long Enough" Ad)	3/12/2009	Appendix 656-676 RRFF 415-418	• Contains naturally occurring antioxidants that help fight free radicals. • Good for heart health. • May help increase blood flow. • May help reduce plaque by up to 30%.	Aviram CIMT/BP Study (2004) Ornish MP Study (2005) Heart Human Science Heart Basic Science Antioxidant and POM Juice/POMx equivalency studies
CX0279 ("Science, Not Fiction" Ad)	3/1/2009	Appendix 637-655 RRFF 397-405	• Contains naturally occurring antioxidants that help fight free radicals. • Good for heart health. • May help decrease stress-induced ischemia. • May help reduce plaque by up to 30%.	Aviram CIMT/BP Study (2004) Ornish MP Study (2005) Heart Human Science Heart Basic Science Antioxidant and POM Juice/POMx equivalency studies
CX0029 ("10 out of 10 People" Ad)	11/1/2004	Appendix 18-36 RRFF 325-328	• Contains naturally occurring antioxidants that help fight free radicals. • POM Juice is loaded	Aviram CIMT/BP Study (2004) Heart Human

	Dissemination Date	Appendix[83]/ RFF[84]/ RRFF[85]	Overall Net Impression of Advertisements	Scientific Support
			with antioxidants. • Good for heart health. • May help prevent formation of oxidized LDL. • May help reduce plaque by up to 30%.	Science Heart Basic Science Antioxidant and POM Juice/POMx equivalency studies
CX0475/1426 Ex. A ("Super Health Powers" Juice Bottle Hang Tag)	No date available	Appendix 426-449 RRFF 385-388	• POMx is loaded with antioxidants. • Good for heart health.	Heart Human Science Heart Basic Science Antioxidant and POM Juice/POMx equivalency studies
CX0342/CX0353 ("Take Out A Life Ins" Ads)	2/22/2010	Appendix 740-761 RRFF 419-424	• Contains naturally occurring antioxidants that help fight free radicals. • Good for heart health. • May help increase blood flow. • May help reduce plaque by up to 30%.	Ornish MP Study (2005) Heart Human Science Heart Basic Science Antioxidant and POM Juice/POMx equivalency studies
CX0337 ("The First Bottle You Should Open" Ad)	1/3/2010	Appendix 719-739 RRFF 415-418	• Contains naturally occurring antioxidants that help fight free radicals. • Good for heart health. • May help decrease stress-induced ischemia. • May help reduce plaque by up to 30%.	Aviram CIMT/BP Study (2004) Ornish MP Study (2005) Heart Human Science Heart Basic Science Antioxidant and POM Juice/POMx equivalency studies

	Dissemination Date	Appendix[83]/ RFF[84]/ RRFF[85]	Overall Net Impression of Advertisements	Scientific Support
CX0351/CX0355 ("Only Antioxidant Supplement Rated X" Ads)	6/1/2010 7/1/2010	Appendix 786-808 RRFF 425-429	• Contains naturally occurring antioxidants that help fight free radicals. • Good for heart health. • May help decrease stress-induced ischemia.	Aviram CIMT/BP Study (2004) Ornish MP Study (2005) Heart Human Science Heart Basic Science Antioxidant and POM Juice/POMx equivalency studies
CX0169/1426, Ex. L ("The power of POM" Ad)	1/6/2008	Appendix 599-618 RRFF 406-414	• Contains naturally occurring antioxidants that help fight free radicals. • POMx Pills are loaded with antioxidants. • Good for heart health. • May help prevent myocardial perfusion in coronary heart patients. • May help reduce the risk of atherosclerosis.	Ornish MP Study (2005) Aviram CIMT/BP Study (2004) Heart Human Science Heart Basic Science Antioxidant and POM Juice/POMx equivalency studies
CX0192 ("What gets your heart pumping" Ad)	5/1/2008	Appendix 150-168 RRFF 363-367	• Contains naturally occurring antioxidants that help fight free radicals. • Good for heart health.	Heart Human Science Heart Basic Science Antioxidant and POM Juice/POMx equivalency studies
CX0328 ("Your New Health Care Plan" Ad)	11/8/2009	Appendix 677-698 RRFF 415-418	• Contains naturally occurring antioxidants that help fight free radicals. • Good for heart health. • May help decrease stress-induced ischemia. • May help reduce	Aviram CIMT/BP Study (2004) Ornish MP Study (2005) Heart Human Science Heart Basic Science

	Dissemination Date	Appendix[83]/ RFF[84]/ RRFF[85]	Overall Net Impression of Advertisements	Scientific Support
			plaque by up to 30%.	Antioxidant and POM Juice/POMx equivalency studies
CX1426, Ex. M (POMx Heart Newsletter)	Summer 2007	Appendix 827-845 RRFF 435-441	• Contains naturally occurring antioxidants that help fight free radicals. • Good for heart health. • May help increase blood flow. • May help reduce plaque by up to 30%.	Aviram CIMT/BP Study (2004) Ornish MP Study (2005) Heart Human Science Heart Basic Science Antioxidant and POM Juice/POMx equivalency studies
CX0013 (Jan. 2003 POM Juice press release)	1/9/2003	Appendix 868-872 RFF 2252 RRFF 541-548	• Contains naturally occurring antioxidants that help disease. • POM Juice is loaded with antioxidants. • Good for heart health. • May help reduce the risk of atherosclerosis. • May help reduce the risk of atherosclerosis. • May help reduce angiotensin converting enzymes ("ACE").	Aviram 2002 Aviram ACE/BP Study (2001) Heart Human Science Heart Basic Science Antioxidant and POM Juice/POMx equivalency studies Aviram, et al., Pomegranate juice flavonoids inhibit low-density lipoprotein and cardiovascular diseases; studies in atherosclerotic mice and humans, Drugs Under Experimental and Clinical Research, 2002, 28 (2/3): 49-62

	Dissemination Date	Appendix[83]/ RFF[84]/ RRFF[85]	Overall Net Impression of Advertisements	Scientific Support
CX0044 (Sept. 2005 POM Juice press release)	9/16/2005	Appendix 873-876 RFF 2252, 2295, 2506 RRFF 549-555	• Contains naturally occurring antioxidants that help fight free radicals. • POM Juice is loaded with antioxidants. • Good for heart health. • May help increase blood flow.	Ornish MP Study (2005) Heart Human Science Heart Basic Science Antioxidant and POM Juice/POMx equivalency studies
CX0065_002 (July 2006 POMx press release)	7/10/2006	Appendix 877-881 RFF 2252, 2285, 2499, 2506 RRFF 556-562	• Contains naturally occurring antioxidants that help protect against disease. • POM Juice is loaded with antioxidants. • Good for heart health.	Aviram Study (2006) (CX0053) Heart Human Science Heart Basic Science Antioxidant and POM Juice/POMx equivalency studies
CX0473 (June 2008, Tupper on Fox Business show)	6/17/2008	Appendix 886 RFF 2610-2621 RRFF 572-573	• Good for heart health. • May help increase blood flow. • May help reduce the risk of atherosclerosis.	Ornish MP Study (2005) Heart Human Science Heart Basic Science Antioxidant and POM Juice/POMx equivalency studies
Web Promo (4)		RRFF 442-535	• Contains naturally occurring antioxidants that help fight free radicals. • POMx is loaded with antioxidants. • Good for heart health. • May help increase blood flow. • May help reduce plaque by up to 30%.	Aviram CIMT/BP Study (2004) Ornish MP Study (2005) Heart Human Science Heart Basic Science Antioxidant and POM Juice/POMx equivalency

	Dissemination Date	Appendix[83]/ RFF[84]/ RRFF[85]	Overall Net Impression of Advertisements	Scientific Support
				studies

For the foregoing reasons, Respondents' possessed a reasonable basis for substantiating the heart health claims alleged by Complaint Counsel in the Complaint.

G. POM's Erectile Claims Are True and Substantiated by Competent and Reliable Scientific Evidence

Based on an unsupported and extreme view, Complaint Counsel accuse POM, through its eight challenged advertisements, of making false and unsubstantiated claims that the Challenged Products can "treat," "prevent," and "reduce the risk of" erectile dysfunction ("ED"). (CX1426_0019; CCPTB at fn. 14). Respondents vehemently deny ever making such claims and a review of the eight ads at issue show that POM never did so. Instead, POM's highly qualified advertising highlighted the healthiness of POM as a 100% authentic and pure fruit juice containing potent antioxidants that "fight for . . . erectile health," or promote "better erectile function"— never that POM somehow can treat, prevent or otherwise reduce the risk of ED, like a pharmaceutical drug. To the extent POM's ads even mentioned "erectile dysfunction," as when quoting from the published *Forest/Padma-Nathan RCT Study*, the statements were highly qualified with language like, "emerging science suggests," "help protect," and "in a preliminary study on erectile function," all of which contradict any impression that the ads showed pomegranate juice as being clinically proven to treat, prevent or reduce the risk of erectile dysfunction. Moreover, the fact that the product is fruit juice or 100% derived from the pomegranate, which is emphasized in the advertising, contradicts any impression that the product can prevent or treat disease like a drug. (*See In re Thompson Med. Co.*, 104 F.T.C. 648, 789 (1984), *aff'd,* 791 F.2d 189 (D.C. Cir. 1986)). The net impression of such ads mentioning "erectile dysfunction," if any, is that the product "could" or "may help" reduce the risk of erectile dysfunction, just like a healthy diet of fruits and vegetables and exercise reduce the risk of disease, and not like a pharmaceutical drug that reduces the risk of disease.

POM's erectile claims are true, and supported by competent and reliable scientific evidence (*i.e.*, "tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results." *See*, *e.g.*, *Brake Guard Prods., Inc.*, 125 F.T.C. 138, 217 (1998)). Moreover, as further discussed below, POM's competent and reliable scientific evidence can support claims much stronger than those actually made in its ads. In fact, contrary to Complaint Counsel's assertions, the testimony of Dr. Arthur Burnett and Dr. Irwin Goldstein, Respondents' world-renowned erectile and nitric oxide experts, confirms that drinking pomegranate juice can indeed support "treat," "prevent," and "reduce the risk of" ED claims in some categories of men. (RRFF 1088).

1. RCTs Are Not Required to Substantiate POM's Erectile Claims

The linchpin of Complaint Counsel's entire case rests on their belief that RCTs are required to support claims that pomegranate juice prevents, reduces the risk of, or treats erectile dysfunction. (CCPTB at 51, 53). Complaint Counsel's erectile expert, Dr. Arnold Melman, states in his report that "experts in the field of erectile dysfunction would require at least one clinical trial, involving several investigatory sites, in order to conclude that competent and reliable scientific evidence exists to support such claims [that pomegranate juice prevents, reduces the risk of or treats erectile dysfunction.]" (CX1289_0008). Dr. Melman testified that, in requiring such RCTs, he was applying the FDA standard for drugs because he insisted that pomegranate juice "is a drug." (RFF 2159, 2161-63). Complaint Counsel and Dr. Melman, however, apply a legally and scientifically incorrect standard.

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." *FTC v. QT, Inc.*, 512 F.3d 858, 861 (7th Cir. 2008); *see also FTC v. Direct Mktg.*

Concepts, Inc., 624 F.3d 1, 9 (1st Cir. 2010) ("a double-blind study is not necessarily required" to satisfy a reasonable basis claim).

Second, POM categorically denies making advertising claims that its products would "treat," "prevent," or "reduce the risk" of ED, and a review of the eight challenged ads show that POM never did. Therefore, because disease claims are not being conveyed, POM should not be subject to a RCT requirement before communicating that a safe and natural fruit juice, such as pomegranate juice, has beneficial effects on erectile health and erectile function. (RFF 2123).

Third, even assuming *arguendo* POM made ED claims, pomegranate juice is not a drug, contrary to Dr. Melman's extreme assertion, but a safe 100% pure fruit juice, and therefore does need not to be subject to FDA scrutiny for approval of a pharmaceutical before concluding that the whole food product has beneficial effects. (RFF 2122, 2123, 2151-63). Respondents' experts wholeheartedly agree that RCTs are not necessary to evaluate the beneficial effects of pomegranate juice. Specifically, Dr. Goldstein testified that *pharmaceutical* type trials should not be applied to nutraceuticals (a naturally occurring botanical product (*i.e.*, from a plant) with health-promoting characteristics), like pomegranate juice. (RFF 2122, 2164; PX0352 (Goldstein, Dep. at 50-52)). Dr. Burnett echoed Dr. Goldstein's opinion, testifying that he does "not think [RCTs] apply" to pomegranate juice studies. (RFF 2122; RRFF 771, 1055). Moreover, as discussed *supra/infra*, this view is supported not only by Respondents' experts, but also by Complaint Counsel's experts, including Dr. Stampfer, as well as by federal agencies and internationally recognized academic institutions. (RFF 624-630, 744, 754-761; RPPTB at Sections II.F-2 and II.H-1).

Dr. Melman's extreme and uninformed opinions in this case did not end with his testimony that pomegranate juice is a "drug." (RRFF 1055). Dr. Melman, Complaint Counsel's purported expert in the design and conduct of erectile clinical trials, testified that he did not know the meaning of the term "RCT." (RFF 2174; RRFF 718). On cross-examination, Dr. Melman admitted that he made public claims about his "fountain of youth" gene-transfer therapy for ED although they were not supported by the kind of elaborate clinical studies he

testified were essential to making such claims. (RFF 2143, 2151-2160, 2191). On the contrary, even though he acknowledged there are severe health risks with gene-transfer therapy, and that people have died and/or become very sick from it, Dr. Melman's public claim was based only on the results of a single animal study. (RFF 2143-2146, 2191). Notwithstanding this hypocrisy, Dr. Melman contends that "the standards . . . for substantiating a claim for fruit juice are the same as for substantiating a claim for gene transfer therapy." (RFF 2147).

Dr. Melman further testified that he had never heard of the GAQ (global assessment questionnaire) and had no experience with the measure prior to his involvement in this case, even though the GAQ is widely used and commonly accepted as a standardized instrument among those conducting erectile dysfunction research —including in virtually every published study of Viagra, Cialis, and Levitra. (RFF 1996-2001, 2167-71; RRFF 1060). Also, Dr. Melman concedes that he has never conducted any clinical work on a food product, including pomegranate juice. (RFF 2177-80; RRFF 718). Finally, most telling, on cross-examination, Dr. Melman was read the Supreme Court's recent opinion in *Matrixx Initiatives, Inc. v. Siracusano*, 131 S.Ct. 1309, 1320 (2011) that "medical professionals and researchers do not limit the data they consider to statistically significant evidence." (RFF 2176; RRFF 718). Not realizing that the quote was from the opinion of the United States Supreme Court, Dr. Melman said he completely disagreed with it. (RFF 2176; RRFF 718).

Thus, for these reasons and those set forth in Respondents' Post Trial Brief (RFF 2134-96), Complaint Counsel and Dr. Melman's extreme position that RCTs are always required in evaluating the health benefits of a food product should be disregarded. Rather, as Respondents' expert opined, the Challenged Products are not drugs and therefore should not be governed by a FDA drug standard.

2. Respondents Possess Competent and Reliable Scientific Evidence Demonstrating that the Challenged Products are "Without a Question" Beneficial to Erectile Health and Function

a. "Excellent" Basic Science Demonstrates the Beneficial Effects of Pomegranate Juice on the Erectile Mechanism

In addition to proclaiming the necessity of RCTs for a safe natural fruit, not surprisingly, Complaint Counsel also ignore wholesale the significant body of POM's *in vitro* and *in vivo* studies in reaching the conclusion that POM's scientific research is allegedly not sufficient to demonstrate the likely beneficial effects of pomegranate juice in humans. (CCPTB at 52-54). Given POM's "excellent" basic science, which includes significant scientific findings by Nobel Laureate Dr. Louis Ignarro, Complaint Counsel's attempt to sweep such science under the rug is not surprising. (RRFF 764, 1083, 1085; PX0352 (Goldstein, Dep. at 51)) (Dr. Goldstein testified that "pomegranate juice has excellent basic science both in animal tissue and human tissue and excellent animal model data.") (emphasis added). Indeed, Complaint Counsel's reliance on Dr. Melman in support of this conclusion is misplaced as Dr. Melman has been significantly impeached on this very issue. Specifically, Dr. Melman testified that based on the results of his single animal study for his gene therapy ED product, he was "personally satisfied" that his ED product would work in humans. (RRFF 769, 1085). Similarly, Respondents' experts, however, have testified that POM's compelling basic science suggests a probable benefit of pomegranate juice on erectile health at the human level.[89] (RFF 2096-2107).

Specifically, as explained by Respondents' world renowned nitric oxide ("NO") expert, Dr. Burnett, POM's basic science alone "support[s] the potential benefit at the human level to improve the physiology of erectile tissue preserving erect tissue health." (RRFF 764, 1081, 1085; RFF 2019, 2020, 2103-07). Dr. Burnett, whose lab was also instrumental in describing NO as a physiologic mediator of penile erection and the mechanism of NO-dependent penile

[89] The mechanism by which pomegranate juice in its various forms promotes erectile health and function is via its potent antioxidant components and its impact on nitric oxide ("NO"), which is of "paramount importance" to good erectile health and function and is the key molecule that governs penile erections. (RFF 1924, 1936-91, 2065-79; RRFF 1087). Such strategies that encourage the integrity, structure, function and endothelial health of the erectile tissue systems promotes erectile health. (RFF 2047, 2048, 2058-60).

erection, (RFF 2020), stated in his expert report that "basic scientific evidence exists that establishes that pomegranate juice possesses potent anti-oxidative molecular effects and these effects operate by activating endothelial NO mechanisms in vasculature [structures involved in human penile erection]." (RRFF 764, 1083, 1085; RFF 2089, 2093). Moreover, Dr. Burnett testified compellingly that POM's basic science alone:

> provide powerful support for pomegranate juice. . . as antioxidants; that they work with very potent effects on the nitric oxide regulatory mechanism; that there's evidence that they do demonstrate antioxidant effects on genes that have to do with the oxidative stress mechanisms and the nitric oxide release mechanisms; that there is evidence that these agents do reduce some of the pathophysiologic effects at the tissue level including structural changes on the tissue in terms of atherosclerosis, that is, hardening of vessels that leads to the functional changes where the tissue is not able to properly relax and is consistent with how the blood vessels have to dilate and allow blood flow to occur within target organs.

(RRFF 764, 1083, 1085; RFF 2106)

Finally, Dr. Burnett testified that he believes pomegranate juice has "potential benefit on the basis of animal studies or *in vitro* studies to likely improve one's erection physiology," not just maintain it. (RRFF 764, 1083, 1085) (emphasis added).

This testimony supporting POM's basic science claims were also validated by Respondents' erectile/sexual medicine expert, Dr. Goldstein, who stated that POM's "strong *in vitro* and *in vivo* studies . . . suggest a probable benefit of pomegranate juice on erectile health," and that "in and of itself has shown huge pieces of information that will be helpful in understanding how it works in humans . . . ." (RRFF 764, 1083, 1085; PX0189-0013). Moreover, Dr. Goldstein opined that the large body of basic science supports the mechanism by which consuming pomegranate juice promotes erectile health—*i.e.*, "through the data that pomegranate juice possesses antioxidant properties, antioxidants help maintain endothelial health, endothelial health is strongly associated with erectile health, and therefore, pomegranate juice helps to maintain erectile health." (RFF 2096).

For example, Dr. Louis Ignarro, a Nobel Prize winner for his work on nitric oxide, conducted an *in vitro* study on vascular endothelial cells, entitled *Pomegranate juice protects nitric oxide against oxidative destruction and enhances the biological actions of nitric oxide*, and found that pomegranate juice possesses more antioxidant activity than grape juice, blueberry juice, red wine and ascorbic acid, and was in fact around 5,000 times more potent than these other beverages. (RFF 1965-68; 2086-87). Dr. Ignarro further found that pomegranate juice's potent antioxidant activity results in marked protection of nitric oxide against oxidative destruction, which thereby augments the biologic actions of nitric oxide. (RFF 1967, 2089). Dr. Ignarro concluded that "pomegranate juice was 20 times better than any other fruit juice at increasing nitric oxide." (PX484; Burnett, Tr. 2254-55; PX0484). Not surprisingly, Dr. Goldstein testified that the

> Ignarro study is another part of the sequence of evidence that supports that a nutraceutical, specifically pomegranate juice, has incredible vascular-sparing properties that ultimately, when you follow this path leads to the improvement of erectile function in men with erectile health issues.

(RFF 1968).

In another study entitled *Oxidative stress in arteriogenic erectile dysfunction: Prophylactic role of antioxidants*, Dr. Azadzoi[90] and colleagues also found that pomegranate juice possessed the highest free radical scavenging capacity among known antioxidant beverages. (RFF 1945-53). Dr. Azadzoi also found that long term pomegranate juice intake increased intracavernosal blood flow, improved erectile responses, improved smooth muscle relaxation, and decreased erectile tissue fibrosis in arteriogenic ED in rabbits. (RFF 1949-51). Dr. Azadzoi concluded antioxidant therapy may be useful as a prophylactic for preventing smooth muscle dysfunction and fibrosis in erectile dysfunction. (RFF 1949-52).

[90] Dr. Azadzoi is a distinguished research professor of urology and pathology at the Boston University School of Medicine and Director of Urology Research at the Veterans Affairs Boston Healthcare System. (RFF 1945).

Similarly, a study by Dr. Aviram, entitled *Pomegranate juice consumption reduces oxidative stress, atherogenic modifications to LDL and platelet aggregation: Studies in humans and in atherosclerotic apolipoprotein e-deficient mice*, reported that pomegranate juice was associated with inhibition of atherosclerosis in humans and atherosclerotic mice that may be attributable to the pomegranates antioxidative properties. (RFF 1936-43). Dr. Goldstein noted that Dr. Aviram's study is "a very fascinating and very important piece of information." (RFF 1944).

Additionally, three studies by Dr. de Nigris and colleagues found that, in human endothelial cells, pomegranate juice reduced the activation of oxidation-sensitive genes and increased endothelial NO synthase expression, and increased cyclic GMP levels. (RFF 1954-64; RRFF 1081). Also, Dr. de Nigris observed that, in hypercholesterolemic mice, the administration of pomegranate juice reduced the progression of atherosclerosis. (RFF 1954-64; RRFF 1081). As such, the researchers concluded that the pro-atherogenic efforts of perturbed shear stress can be reversed with chronic administration of pomegranate juice and extract. (RFF 1954-64, RRFF 1081).

In sum, Complaint Counsel cannot ignore POM's basic science which provides compelling evidence that pomegranate juice is likely to benefit erectile health and function in humans.

b. The *Forest/Padma-Nathan RCT Study* Has Major Clinical Significance in Showing a Benefit on Erectile Health and Function

Complaint Counsel, and their expert Dr. Melman, argue that the results of the *Forest/Padma-Nathan RCT Study* should be disregarded in their entirety because its findings (1) relied on the GAQ questionnaire, and (2) did not achieve statistical significance. Both of Complaint Counsel's and Dr. Melman's criticisms fail even basic scrutiny.

The *Forest/Padma-Nathan RCT Study*, studied 53 subjects with mild-to-moderate erectile dysfunction who underwent two four-week treatment periods separated by a two-week washout. (RFF 1974-78). Using a GAQ, Dr. Padma-Nathan found that participants rated pomegranate

juice 50% more effective than placebo at improving erections. (RFF 1979-85). 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." (RFF 1983-85). Complaint Counsel's erectile expert, however, argues that because this "p-value" was a few thousandths of a percentage point shy of an arbitrary 95% threshold, the study is not entitled to any weight.

First, Complaint Counsel's criticism of the GAQ questionnaire is baseless as both of Respondents' experts testified that it is "extremely widely used" and very "informative and . . . valuable to use in clinical studies." (RFF 1992-2002, 2171; RRFF 1056-57, 1060-61) (emphasis added). Moreover, Respondents' experts testified that the GAQ is commonly accepted as a standardized instrument among those conducting erectile dysfunction research, and was used in every published sildenafil (Viagra), vardenafil (Levitra) and tadalafil (Cialis) trial. (RFF 1997-2002; RRFF 1056-57, 1060-61). Indeed, Dr. Goldstein testified that "in the development of pharmaceutical products for sexual medicine the [FDA] widely approves of nonvalidated PROs [patient-reported outcomes, such as the GAQ]. (RRFF 1056-57, 1060-61). To that end, Dr. Goldstein testified "it has to be strongly suspicious that an unvalidated questionnaire constantly gets repeated." (RRFF 1056-57, 1960-61). Thus, Complaint Counsel's assertion lacks merit.

Second, Complaint Counsel's and Dr. Melman's criticism of the *Forest/Padma-Nathan RCT Study* because it did not reach statistical significance[91] is inconsistent with the holding in *Matrixx Initiatives, Inc. v. Siracusano*, 131 S.Ct. 1309 (2011), where the United States Supreme Court held that "[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." *Matrixx*, 131

[91] "Statistical significance" occurs when the results of a study have a p-value of .05 or less, meaning that the results would occur by chance less than 5 times out of a hundred or that there is a 95 percent probability of validity as opposed to chance. (RFF 600).

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).

Consistent with the Supreme Court's holding in *Matrixx*, Respondents' expert in the clinical aspects of erectile health, Dr. Goldstein, testified that, while the p-value was a few thousandths of a percentage point shy of an arbitrary[92] 95% threshold, the *Forest/Padma-Nathan RCT Study* "provides very valuable information" regarding erectile health and function and is absolutely "clinically significant because 'it supports the conclusion that the positive results in the basic science are borne out in human function.'"[93] (RFF 1986, 2098-99; RRFF 1077). Dr. Goldstein further testified that the study is clinically significant because it proved pomegranate juice was safe, unlike pharmaceutical ED drugs. (RRFF 1077). Dr. Goldstein also testified that the *Forest/Padma-Nathan RCT Study* "is of extreme relevance to the clinician and consumer" and is "suggestive evidence that use of pomegranate juice would benefit [a] patient with erectile dysfunction." (RFF 2098-99; RRFF 1077). Overall, Dr. Goldstein opined that he would take the results of the *Forest/Padma-Nathan RCT Study* "to the bank." (RRFF 1077).

Similarly, Dr. Burnett also opines that the *Forest/Padma-Nathan RCT Study* supports the conclusion that pomegranate juice has a beneficial effect on erectile tissue physiology, health, and function, and is "a potential treatment for ED." (RFF 1986-87, 2100-2106; RRFF 1088). Dr. Burnett further testified compellingly that he "[m]ost certainly" believes that if a man has

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[92] Dr. Goldstein testified that choosing a significance level is technically an arbitrary task, and although a p-value of 0.050 was agreed upon in the *Forest/Padma-Nathan RCT Study*, "in specific situations a different value could be utilized." (RFF 1984).

[93] Although the authors of the *Forest/Padma-Nathan RCT Study* concluded that "[f]urther studies are warranted to clarify the efficacy and clinical role of POM on male ED," that does not imply the study is a "negative study." Dr. Goldstein testified that "[t]hat sentence [regarding further studies] is a part of every end of every manuscript in the Journal of Sexual Medicine, virtually." (RRFF 1074). Dr. Goldstein testified that "[w]e always need more studies," and that "there isn't any aspect of sexual medicine where further studies are not warranted." (RRFF 1074). In fact, Dr. Goldstein testified that "further studies are warranted for Viagra and Levitra and Cialis despite more than 10 years of studies." (RRFF 1074).

erectile dysfunction and does something that improves his erectile function, he has thereby helped his erectile dysfunction. (RRFF 1088). Moreover, Dr. Burnett testified that unlike clinical treatments by way of pharmaceutical drugs, a study evaluating pomegranate juice does not need to reach statistical significance before important results are given to the public. (RRFF 1077).

In addition, Dr. Heber also testified that the *Forest/Padma-Nathan RCT Study* "could [not] be disregarded" and that "it is a positive in providing important scientific information consistent with the basic science that pomegranate juice may be helpful for men with erectile dysfunction." (Heber, Tr. 2001). Dr. Heber also testified that POM's competent and reliable science shows that pomegranate juice is likely to lessen the risk of erectile disease and enhance erectile function. (RFF 2107; RRFF 1086). Dr. Padma-Nathan, the principal researcher of the *Forest/Padma-Nathan RCT Study*, testified that the "study concluded that [pomegranate juice has] a potential benefit" on erectile dysfunction. (RRFF 1086; CX1338 (Padma-Nathan, Dep. at 184)).

Finally, in addition to the *Forest/Padma-Nathan RCT Study*, a significant body of scientific literature also supports the validity of the mechanisms of action by which pomegranate juice promotes erectile function. (RFF 1988-1991). For example, Dr. Esposito's clinical study entitled "*Dietary Factors, Mediterranean Diet and Erectile Dysfunction*" showed that the adoption of the Mediterranean diet (which pomegranate juice is consistent with) for two years by obese men with erectile dysfunction had statistically significant improvement in their erectile dysfunction score compared to men in the control group. (RFF 1990; RRFF 1084, 1087; PX0190; Goldstein, Tr. 2641-42; PX0352 (Goldstein, Dep. at 134-135); PX0189-0013).

In sum, Respondents have presented significant, contrary testimony and evidence demonstrating that the *Forest/Padma-Nathan RCT Study* provides clinically significant results despite the fact that statistical significance was not reached. Thus, Complaint Counsel and Dr. Melman's criticisms of the *Forest/Padma-Nathan RCT Study* should be rejected. (RFF 603-607).

3. The Competent and Reliable Scientific Erectile Evidence Support "Treat," "Prevent," and "Reduce the Risk of" Claims

Respondents dispute Complaint Counsel's allegations that the eight advertisements at issue suggest that the Challenged Products can "treat," "prevent," or "reduce the risk of" erectile dysfunction. Instead, as discussed *infra*, Respondents' advertisements only promote the message of erectile health and function like a whole food can. (RFF 2047-50). To the extent POM's ads even mentioned "erectile dysfunction," as when quoting from the published *Forest/Padma-Nathan RCT Study*, the statements were highly qualified with language like, "emerging science suggests," "help protect," and "in a preliminary study on erectile function," all of which contradict any impression that these ads are clinically proven to treat, prevent or reduce the risk of erectile dysfunction. In any event, POM possesses competent and reliable scientific evidence, confirmed by Respondents' erectile experts, that support erectile claims much stronger than those actually made in POM's advertisements, *i.e.*, claims that drinking pomegranate juice can improve one's erection, as well as "treat," "prevent," and "reduce the risk of" ED in certain men. (RRFF 764, 1085, 1088).

a. "Treat" Erectile Dysfunction

Respondents vehemently deny ever making any claims or suggesting that drinking eight ounces of POM Juice daily "treats" erectile dysfunction. Moreover, Respondents never suggested that POM Juice or its derivatives can serve as a replacement or substitute for conventional medical treatment. To the extent the Commission believes that the Respondents' advertisements convey the message that the Challenged Products can "treat" erectile dysfunction, the totality of the scientifically valid and peer-reviewed evidence supports the conclusion that the Challenged Products may help or ameliorate symptoms of an existing condition and improve erectile function—and not serve as substitute or replacement for conventional medical treatment. (RRFF 1085, 1088).

If the Commission, however, finds that Respondents' advertisements somehow suggest something stronger, Respondents' erectile expert, Dr. Goldstein, testified that with respect to the treatment and improvement of erectile dysfunction, he would strongly recommend and

encourage the use of pomegranate juice for men with endothelial related erectile dysfunction who have had an insufficient response to PDE5 inhibitors (*i.e.*, Viagra, Levitra and Cialis) and who are unwilling to consider invasive or mechanical therapies. (RRFF 1088). Dr. Goldstein testified that "pomegranate juice has evidence for dealing with the underlying pathophysiology [of endothelial-related erectile dysfunction], and antioxidants like pomegranate juice have shown [statistically significant] benefit in treating men who have similar situations." (emphasis added). (RRFF 1088). Therefore, Dr. Goldstein testified that he "personally recommends" pomegranate juice in his own clinical practice. (RRFF 1088).

Dr. Burnett also testified that, based on the basic science and Dr. Padma-Nathan's human clinical RCT study, he "believe[s] that [pomegranate juice] has a likely beneficial effect on erectile function." (RRFF 1088; Burnett, Tr. 2255-56; PX0349 (Burnett, Dep. at 60)). Dr. Burnett further stated that if a man has erectile dysfunction and does something that improves his erectile function, he has thereby helped his erectile dysfunction. (RRFF 1088; Burnett, Tr. 2303). To that end, Dr. Burnett testified that even POM's basic science suggested a "potential benefit . . . to likely improve one['s] erection physiology." (RRFF 764, 1085). Dr. Burnett also testified that pomegranate juice "could be a treatment [to erectile dysfunction] in the sense that it offers some potential health benefits." (RRFF 1088; Burnett, Tr. 2312) (Dr. Burnett noted that "'treatment' can have different meanings behind it, and 'treatment' in the context of a pharmaceutical drug that is approved by the FDA as an intervention for a disease state, that may have a different meaning for 'treatment' than the broad term of treatment, which is to intervene for a condition.")

Even though Respondents never made claims to consumers beyond erectile health maintenance, competent and reliable scientific evidence, however, supports "treat" claims.

b. "Prevent" Erectile Dysfunction

Respondents also deny ever making any claims or suggesting that drinking eight ounces of POM Juice daily "prevents" erectile dysfunction like the pharmaceutical drug Lipitor prevents disease. However, should Respondents' advertisements be construed by the Commission to

suggest that the Challenged Products can "prevent" erectile dysfunction, the advertisement could only convey this in the same fashion as exercise and good diet can "help prevent" future problems.

If the Commission, however, finds that Respondents' advertisements somehow suggest something stronger, Respondents' expert, Dr. Burnett, testified that if prevention means "something that potentially has a risk modification benefit that may help preserve erectile function" then, there is competent and reliable scientific evidence "that pomegranate juice has that potential role" of preventive intervention capacity, albeit not as a primary intervention. (RRFF 1088; Burnett, Tr. 2301; 2272-73) ("I don't think there's a therapy out there in the world of sexual medicine that we've established as of yet to be a true preventative intervention for erectile dysfunction. We do think there are various sorts of interventions that we believe likely have some potential benefit, anything from dietary changes to weight loss and perhaps things that we're still evaluating, but we're not sure really have a role, but because they seem to be potentially beneficial and do not necessarily have harms and likely have benefits, that we feel comfortable in promoting.")

In addition, Dr. Goldstein testified that he would recommend the use of pomegranate juice as a preventative intervention in men who would appear to have early signs of endothelial related erectile dysfunction.[94] (RRFF 1088). Dr. Goldstein testified that in this context, pomegranate juice has "substantial scientific data that it can counter the inflammatory endothelial [related erectile dysfunction] problems. . . ." (RRFF 1088; PX0352; Goldstein, Dep.

[94] Complaint Counsel have mischaracterized Dr. Goldstein's testimony regarding the context in which he would recommend a dialogue with a healthcare provider. Dr. Goldstein testified a dialogue with a healthcare provider would be recommended under two selected clinical ED settings: 1) where a patient has experienced a loss in erectile health, but does not have erectile dysfunction yet, and wants to know what they can do safely to keep their erectile health, especially where they have a family history of erectile dysfunction; (PX0352 (Goldstein, Dep. at 157-158)), and 2) where a patient has erectile dysfunction and first line therapies have not worked for him, and they do not want more invasive therapies as they are risk aversive and want a more positive risk-benefit ratio. (PX0352 (Goldstein, Dep. at 159; RRFF 1094)). Dr. Goldstein never testified that one should consult with a physician prior to drinking a harmless pure fruit juice.

at 44, 157) ("So exposure of your body to antioxidants would, if you had erectile health, arguably, hypothetically, prophylax the development of an erectile problem.") Thus, although POM never made "prevent" claims to consumers, competent and reliable scientific evidence, however, exists to support such claims in some categories of men.

c. "Reduce the Risk of" Erectile Dysfunction

Finally, Respondents deny ever making any claims or suggesting that drinking eight ounces of POM Juice daily "reduces the risk of" erectile dysfunction. However, to the extent the Commission finds that Respondents' advertisements convey the message that the Challenged Products can "reduce the risk" of erectile dysfunction, then it could only be in the same fashion as consumers perceive many other especially healthy whole foods, like broccoli and blueberries, or like a healthy diet of fruits and vegetables helps improve your odds or "reduce the risk" of disease— and not how a drug with a single target of action "reduces the risk of" disease. Indeed, consuming the Challenged Products, which are harmless and 100% derived from a natural pomegranate fruit, is no different than eating especially healthy fruits or vegetables like broccoli or blueberries to "reduce the risk of" any disease.

If the Commission, however, finds that Respondents' advertisements somehow suggest something stronger, Dr. Goldstein testified that reasonable and competent science shows that pomegranate juice "reduces the risk" of erectile dysfunction caused by endothelial dysfunction or blood flow impairment or oxidative stress. (RRFF 1088; PX0352 (Goldstein, Dep. at 46-47) (there is substantial evidence that pomegranate juice reduces the risk of endothelial related erectile dysfunction, which is the underlying mechanism of dysfunction for many patients who lose erectile health). Thus, although POM never made "reduce the risk of" claims to consumers, competent and reliable scientific evidence, however, exists to support such claims in some categories of men.

4. The Competent and Reliable Scientific Evidence Supports Each of the Challenged Erectile Advertisements

Based solely on a plainly incorrect facial reading of the ads, Complaint Counsel assert that eight of the Challenged Ads "represent, either expressly or implicitly, that clinical studies

prove that POM Juice[95] treat[s], prevent[s], or reduce[s] the risk of erectile dysfunction" (hereinafter, "Challenged Erectile Ads").[96] (CCPTB at 54). Indeed as discussed as below, POM never states, expressly or by implication, conspicuously on the face of any of the Challenged Advertisements that scientific tests prove that the Challenged Products "treat, prevent, or reduce the risk of erectile dysfunction." (*See supra/infra* at II.A, G-4). Rather, as demonstrated in the chart below, Respondents' scientific research supports each of the qualified claims actually conveyed in each of the Challenged Erectile Ads.

	Dissemination Date[97]	**Appendix[98]/ RFF/RRFF**	**Overall Net Impression of the Advertisement**	**Scientific Support**
CX0475/1426 Ex. A ("Super HEALTH Powers!" Hang Tag)	Not established	Appendix 396 – 414 RRFF 385-388	• POM Juice contains lots of antioxidants. • POM Juice is good for you and fights for erectile health.	Antioxidant and POM Juice/POMx Equivalency Studies[99] *Forest/Padma-Nathan RCT Study*[100] Erectile Basic Science[101]
CX0351/CX0355 ("Only Antioxidant Supplement Rated X" Ads)	6/1/2010, 7/1/2010	Appendix 494-529 RRFF 425-429	• Contains antioxidants that help fight free radicals.	Antioxidants and POM Juice and POMx Equivalency

[95] Complaint Counsel also apparently mistakenly limit their claims regarding erectile dysfunction to "POM Juice" in their post-trial brief (at pp. 54) when Appendix A, attached thereto and Complaint Counsel's respective findings of fact on the Challenged Erectile Ads, indicate that POMx is included in their claims. (See Appendix A to CCPTB and CCFF 429, 535).

[96] Complaint Counsel also erroneously assert that the Challenged Erectile Ads make false and unsubstantiated ED efficacy claims. (CCPTB at 54).

[97] Dissemination data per evidentiary record.

[98] "Appendix" refers to Respondents' Reply Ad Appendix.

[99] Peer-reviewed and published studies and independent websites about the effects of antioxidants, the bioavailability of pomegranate-based antioxidants and equivalent of POM Juice and POMx. (RFF 745-954).

[100] *The Forest/Padma-Nathan RCT Study* (CX0908).

[101] Respondents' "Erectile Basic Science" includes the Aviram Study (2000) (PX00004), Azadzoi Study (2005) (PX0051), deNigris Study (2007) (PX0057), deNigris Study (2005) (PX0059), deNigris Study (2007) (PX0056) and Ignarro Study (2006), and it constitutes competent and reliable scientific evidence that pomegranate juice and/or its extract are beneficial toward erectile health. (RRFF 1063-1085).

	Dissemination Date[97]	Appendix[98]/ RFF/RRFF	Overall Net Impression of the Advertisement	Scientific Support
			• Research has revealed promising results for erectile health. • A preliminary study on POM Juice reported a 50% greater likelihood of improved erections as compared to placebo. • POM Juice and POMx Pills have potential in the management of erectile dysfunction though further studies are warranted.	Studies *Forest/Padma-Nathan RCT Study* Erectile Basic Science
CX0473[102] (POMWonderful.com)	4/2009	RFF 1930, 1932-1935 RRFF 443-471	• A pilot study reported that POM Juice may help to improve erections.	*Forest/Padma-Nathan RCT Study* Erectile Basic Science
CX0473/CX0336_001[103] (POMWonderful.com Community site)	10/2009, 12/2009	RRFF 472-495	• A pilot study reported that POM Juice was good for erectile health. • POM could fund additional research on POM Juice in connection with erectile function.	*Forest/Padma-Nathan RCT Study* Erectile Basic Science
CX0473[104] (Pomegranatetruth.com)	4/28/2009	RFF 1928, 1933-1935	• Numerous published clinical studies have reported that POM Juice is good for erectile function.	*Forest/Padma-Nathan RCT Study* Erectile Basic Science

[102] Complaint Counsel's expert, Professor Mazis, testified that Complaint Counsel is not challenging POM's ads for POM Juice that ran after December 2008. (Mazis, Tr. 2753-59). Accordingly, based on these representations, Complaint Counsel cannot now challenge this ad.

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	Dissemination Date[97]	Appendix[98]/ RFF/RRFF	Overall Net Impression of the Advertisement	Scientific Support
CX0473 (POMPills.com)	Not Established	RRFF ¶¶ 526, 530	• Initial study results linking POM Juice and erectile performance are promising. • A soon to be published clinical study reported that POM Juice may help erectile performance.	*Forest/Padma-Nathan RCT Study* Erectile Basic Science
CX0128_0002 (June 2007 POM Juice press release)	6/2007	RFF 2503-2505	• A pilot study reports POM Juice may beneficial for erectile dysfunction and may help the management of erectile dysfunction. • Drinking POM Juice may be an important addition to the diet as a non-invasive, non-drug way to potentially manage or alleviate ED.	*Forest/Padma-Nathan RCT Study* Erectile Basic Science
CX0473 (Mar. 2009, Lynda Resnick interview in Newsweek.com)[105]	3/2009	RFF 2583-2595	• This is not advertising. RRFF 576-578. It is Mrs. Resnick expressing her personal belief. To the extent it is viewed as advertising, the research to date would substantiate such claims. RRFF 576-578. • Lynda Resnick personally believes that Pomegranate Juice is 40% as effective as Viagra.	*Forest/Padma-Nathan RCT Study* Erectile Basic Science

[105] Respondents contend that the Newsweek.com interview by Mrs. Resnick is not actionable advertisement under the FTCA because it: (1) does not constitute "advertising"; (2) represents constitutionally protected speech of Mrs. Resnick and (3) in any event, cannot be considered as material to the purchasing decision of any consumers. (CC's Post-Trial Br. at 92-96; RFF 2252 at 268, 2545-51, 2581-95).

As explained below, there is no question that Complaint Counsel's facial analysis of each the above purported advertisements is flawed, as the net impression of such purported advertisements is not that clinical studies prove that POM Juice treats prevents or reduces the risk of erectile dysfunction.

1. "Super HEALTH Powers!" Hang Tag (CX0475/1426 Ex. A) [106]

Complaint Counsel's facial analysis of the "Super HEALTH Powers!" Hang Tag is flawed. The hang tag, seen by the consumer at the point-of-sale (*i.e.*, in the fresh produce section of the supermarket),[107] resembled the shape of a fresh pomegranate, and contained the headline "SUPER HEALTH POWERS!" on the outside and contained the following body copy inside the hang tag:

> 100% PURE POMEGRANATE JUICE.
>
> It's 100% Pure! It's heroically healthy! It's The Antioxidant Superpower, P♥M Wonderful 100% authentic pomegranate juice.
>
> Backed by $25 million in medical research. Proven to fight for cardiovascular, prostate and erectile health. Committed to keeping you healthy for a good, long time!

(CX0475/1426 Ex. A). Complaint Counsel assert that:

> the mere references to "[p]roven to fight for…erectile health' and that the juice is '[b]acked by $25 million in medical research…convey the net impression that POM Juice treats, prevents, or reduces the risk of…erectile dysfunction, and that these health benefits are clinically proven."

(CCFF 388).

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[106] Respondents contend that this hang tag ad is not at issue because Complaint Counsel presented no specific dissemination information. (RFF 2252 at 267). In their proposed findings of fact, Complaint Counsel contend that this ad was disseminated on September 2009 and cite to CX0475 and CX1426_00027 as evidence of this contention. Those citations, however, do not prove this contention because no dissemination is included on the face of those exhibits. (*See* CX0475 and CX1426_00027).

[107] (See Butters, Tr. 2869).

Viewing the hang tag as a whole, including the interaction of headlines, body copy and visual imagery, reveals that Complaint Counsel's facial analysis is patently incorrect. First, it is illogical to infer that the mere investment of a specific amount of money in scientific research equates to the conclusion that POM Juice treats, prevents, or reduces the risk of erectile dysfunction, or that it is clinically proven to do so. (RRFF 385-388; Reply Ad Appendix.) Second, this "logical leap" is even less credible, here, where the advertisement solely claims that POM Juice is proven to "fight for…erectile health"— not erectile dysfunction—and the advertisement emphasizes the fact that the product is a whole-fruit 100% juice that is good for your health. (RRFF 385-388; Reply Ad Appendix). Third, the statement that POM Juice is "proven to fight for erectile health" emphasizes the qualifier "fight for"[108] and is immediately paired with the statement that POM Juice is "committed to keeping you healthy for a good, long time" which certainly contradicts Complaint Counsel's purported facial analysis alleging that the product can treat, prevent or reduce the risk of erectile dysfunction like a drug with a single target of action would be able to. (*See* Reply Ad Appendix, ¶¶ 407-411; RRFF 385-388; Reply Ad Appendix). If anything, the advertisement, at most, reads that it is "proven" to be good for erectile health, which credible, competent and reliable evidence supports. (RFF 2094-2118). Regardless, to the extent that the advertisement conveyed the claims alleged by Complaint Counsel (which it does not), Respondents science support those claims. (RRFF 385-388; Reply Ad Appendix).

2. "Only Antioxidant Supplement Rated X" Ads (CX0351/CX0355)

Complaint Counsel's facial analysis of the "Rated X" Only Antioxidant Supplement Ad is similarly flawed. The humorous ad, run in both *Playboy* and the Advocate magazines, contains images of red, ripe pomegranates and focuses on the pomegranate-like shape of the POMx bottle. (RRFF 425-429; Reply Ad Appendix). It contained the following body copy:

[108] "Fight for" hardly means that one will win the battle or the fight; it means "to strive vigorously" or "to contend with." For example, politicians "fight for" various rights, but it does not mean that they successfully obtain these rights for their constituents. (Butters, Tr. 2887).

> Emerging science suggests that antioxidants are critically important to maintaining good health…
>
> ***
>
> POMx is made from the only pomegranates backed by $32 million in medical research at the world's leading universities. Not only has this research documented the unique and superior antioxidant power of pomegranates, it has revealed promising results for erectile…health.
>
> ***
>
> Our P♥Mx pills are made from the same pomegranates we use to make our P♥M Wonderful 100% Juice, on which each of the following medical studies was conducted.
>
> In a preliminary study on erectile function, men who consumed POM Juice reported a 50% greater likelihood of improved erections as compared to placebo. "As a powerful antioxidant, enhancing the actions of nitric oxide in vascular endothelial cells, POM has the potential in the management of ED…further studies are warranted." *International Journal of Impotence* Research, '07.

(CX0351, *see also* CX0355). Complaint Counsel assert that:

> The advertisements…convey the net impression that taking one POMx Pill [or drinking eight ounces of POM Juice] daily treats, prevents, or reduces the risk of…erectile dysfunction, and that those health benefits are clinically proven.

(CCFF 388).

Viewing the ad as a whole again establishes that Complaint Counsel's facial analysis is erroneous. First, the advertisement, which appeared both in *Playboy* and the *Advocate*[109] magazines, was meant to be humorous and to give the reader a "chuckle" as evidenced by the overt puffery and outrageous sub-headlines in the ad. (*E.g.*, "Always Use Protection," "POMx Super-potent. Like you," and "Is that POMx in your pocket?")." (Appendix of Advertisements ¶ 505; RRFF 425-429; Reply Ad Appendix). Second, the ad emphasizes from the very

[109] Complaint Counsel erroneously assert that the *Advocate* is a "male-oriented" magazine. (*See* CCFF 425). On the contrary, it is the leading national gay and lesbian news magazine, which by definition includes a large percentage of women. http://www. advocate.com

beginning that "emerging science" suggests antioxidants are "important to maintaining health." (CX0351; CX0355). The ad emphasizes, heavily, the connections between POM Juice and POMx Pills, noting that POMx Pills are made from the same pomegranates as the juice, and that therefore, this is a 100% derived pomegranate product. (CX0351; CX0355; RRFF 425-429; Reply Ad Appendix). Third, when the advertisement addresses erectile health, it does so by solely accurately describing, summarizing and even quoting the qualified results or outcomes of the specific scientific research contained in the journal-published Forest/Padma-Nathan RCT Study. Indeed, the advertisement explicitly qualifies the findings of the Forest/Padma-Nathan RCT Study as "preliminary," "promising," "emerging science," "has potential" and specifically highlights that "further studies are warranted." (CX0351; CX0355; RRFF 425-429; Reply Ad Appendix).[110] Indeed, the only phrasing referring to "erectile dysfunction" relates to a direct quote from the Forest/Padma-Nathan RCT Study which stated verbatim that "POM has potential in the management of ED…further studies are warranted." (*Id.*) Accurately summarizing and quoting the highly qualified results of a published scientific study about preliminary and potential benefits cannot logically convey, as Complaint Counsel argue, the net impression that the Challenged Products treat, prevent, or reduce the risk of erectile dysfunction, or that they are clinically proven to do so without qualification. (RRFF 425-429; Reply Ad Appendix). The net impression of the ads mentioning "erectile dysfunction," if any, is that the product "could" or "may help" reduce the risk of erectile dysfunction, like a healthy diet of fruits and vegetables and exercise reduce the risk of disease, and not like a drug reduces the risk of disease. However, while such claims are not conveyed by the advertisement, Respondents' science supports the stronger claims alleged by Complaint Counsel**.** (RRFF 425-429; Reply Ad Appendix).

[110] Respondents' ad also explicitly advised that none of the health claims described therein had been evaluated by the FDA. (CX0351/CX0355)

3. Website Content and Press Release (CX0473, POMWonderful.com); (CX0473, POMWonderful.com Community site); (CX0473, Pomegranatetruth.com); CX0473, POMPills.com); (CX0128_0002, June 2007 POM Juice press release)

Likewise, Complaint Counsel's facial analysis of Respondents' website content and a press release are inherently flawed. On their websites (POMWonderful.com, POMWonderful.com Community site, Pomegranatetruth.com, and POMPills.com), Respondents cited to, and provided consumers accurate summaries of, the qualified results and outcomes of the journal-published *Forest/Padma-Nathan RCT Study* in connection with disclosing to the public the research conducted on the Challenged Products in association with erectile health, function and dysfunction. (*See* RRFF 447, 469, 489, 496, 498, 530, 563, 565). Similarly, a June 2007 press release accurately summarized the results of that study as well as quoting the accurate summary of the study's qualified findings from one of its authors: Dr. Padma-Nathan. (RRFF 563-567).

Complaint Counsel, however, argue that with respect to the website content and press release, such accurate summaries convey, on the basis of their facial analysis, the net impression that, without qualification, drinking eight ounces of POM Juice daily, taking one POMx Pill or taking one teaspoon of POMx Liquid, daily, "treats, prevents, or reduces the risk of…erectile dysfunction, and that these health benefits are clinically proven." (CCFF 471, 494, 500, 535, 567).

First, Complaint Counsel's expert, Professor Mazis, testified that Complaint Counsel is not challenging this ad, and other POM ads for POM Juice that ran after December 2008. (Mazis, Tr. 2753-59; Ad Appendix at 497).

Second, viewing the ad as a whole confirms that Complaint Counsel's facial analysis is incorrect. The vast majority of such web content discuss the results of the *Forest/Padma-Nathan RCT Study* in the context of "erectile function" rather than "erectile dysfunction." (RRFF 447, 481, 489, 496). Further, those references, which merely accurately summarized the study, explicitly qualified the results. (*See e.g.*, CCFF 498 (characterizing results of *Forest/Padma-Nathan RCT Study* as "promising")). To the extent the web content and press release discussed

erectile dysfunction, it was in direct reference to the results of the *Forest/Padma-Nathan RCT Study* and were couched in appropriately qualified terms. (*See* CCFF 530 ("initial results…are promising"; CCFF 563 ("may help the management of erectile dysfunction")). Indeed, the press release actually quotes verbatim Dr. Padma-Nathan's own accurate analysis of the qualified results of his own study: (*See* CCFF 565 ("findings are very encouraging as they suggest a non-invasive, non-drug way to potentially alleviate [ED]…Drinking pomegranate juice daily could be an important addition to the diet in the management of this condition.")

Again, the accurate summary of the qualified results of a published scientific study about preliminary and potential benefits cannot convey, as Complaint Counsel argues, the net impression that using the Challenged Products treats, prevents, or reduces the risk of ED, or that they are clinically proven to do so without qualification. (Reply Ad Appendix). Moreover, while such claims are not conveyed by the advertisement, Respondents believe their science supports the stronger claims alleged by Complaint Counsel. (RRFF 442-567); RFF 2116; CX1363 (S. Resnick, Coke Depo at 77-78 (Dr. Ignarro informed Mr. Resnick that POM Juice was "about 40% as effective" as Viagra)).

4. Lynda Resnick Newsweek.com Interview (CX0473)

Finally, Complaint Counsel argue that a Newsweek.com interview of Ms. Resnick, in which she stated her own personal belief that POM Juice was "40 percent as effective as Viagra" is an advertisement which conveys the net impression that drinking "POM Juice treats, prevents, or reduces the risk of erectile dysfunction, and that this effect is clinically proven. (CCFF 576-577). First, the assertion that the interview is an "advertisement" under the FCTA is incorrect. (CCPTB at 92-96; RFF 2252 at 268, 2545-51, 2581-95). Indeed, Ms. Resnick's main purpose in agreeing to the interview was to provide the viewer or reader with a wide-ranging discussion of the economy, politics and her business policy. (CCPTB at 92-96; RFF 1929, 2252 at 268, 2545-51, 2581-95). Further, Ms. Resnick's statements regarding the health properties of pomegranates were reactive to an unsolicited question and solely constituted her genuinely-held personal belief which is constitutionally protected speech. (RFF 2581-2595.) Regardless, while the interview

could not convey any advertising message (because it was not an advertisement), Respondents believe their science, including the *Forest/Padma-Nathan RCT* Study supports the claims alleged by Complaint Counsel. (RRFF 576-578).

H. POM's Prostate Health Claims Are True and Substantiated by Competent and Reliable Scientific Evidence

In its Complaint, during the proceedings, and now in post-trial briefing, Complaint Counsel accuse 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; CCPTB at 44). POM denies making such claims and a review of the Challenged Advertisements, as demonstrated through the proceedings and briefing, show that POM never did.[111] (RFF 2197-2622).

Instead, POM's "prostate" ads used edgy 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*). POM has never claimed in any advertising that the Challenged Products "prevent" or "treat" or "reduces the risk of" prostate cancer. And when POM's "prostate" advertisements did cite 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.*)

POM's "prostate" ads instead convey that (1) POM is a great source of antioxidants which medical research has suggested can combat free radicals, which are unhealthy, and may contribute to diseases of the prostate including prostate cancer; (2) POM consumption has been shown to lengthen PSADT in men with biochemical recurrence of PSA following treatment for prostate cancer; and (3) POM is healthy and likely good for prostate health (CX260_0001;

[111] POM refers the ALJ to the Reply Ad Appendix and associated findings of fact for an overview of the "prostate" ads at issue and POM's position on what claims were actually made with regard to each prostate ad.

CX1426_0028, Exh. B). Again, nowhere does POM claim it "treats" "prevents" or "reduce the risk of" prostate cancer.

Similarly, although POM denies ever making explicit or implicit "establishment" claims, to the extent it is found to have made implied establishment claims with regard to the prostate, those claims are verifiably true and limited to the study results noted in the advertising—namely that "an initial UCLA medical study showed statistically significant prolongation of PSA doubling time" in men following radical prostatectomy due to prostate cancer. (*See* Appendix of Advertisements). At best, that is the "establishment" claim made—POM's advertisements say nothing about the data proving or otherwise suggesting that POM is effective in "treating" or "reducing the risk of" "preventing" prostate cancer.

Even assuming, *arguendo* that POM did make "reduce the risk," "prevents" or "treats" prostate cancer claims in its advertising, a large body of basic and clinical studies underlying POM's prostate advertising demonstrates competent and reliable science exists to support such claims. As stated by Dr. deKernion, there is a "high degree of probability" that POM or POMx "will improve the chances of avoiding or deferring the recurrence of prostate cancer" and "high degree of probability" that POM or POMx can "inhibit[] the clinical development of prostate cancer in men who have not been diagnosed with prostate cancer." (deKernion, Tr. 3059-61).

In sum, the testimony of the parties' experts has shown that Complaint Counsel's criticisms of the science or POM's use of it are not well taken, not appropriate for a safe food product like POM, and instead only serve to underscore and confirm that POM's prostate health claims are substantiated and backed by a broad spectrum of peer-reviewed science.

1. RCTs Are Not Required to Substantiate POM's Prostate Claims

Complaint Counsel again rotely declare in its post-trial briefing that only RCTs on "an appropriate sample population" can support claims that the Challenged Products prevent or treat prostate cancer. (CCPTB at 44-45.) Complaint Counsel's criticism, through Dr. Eastham and Dr. Stampfer, is 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 and therefore, no matter the

broadness or consistent nature of POM's "prostate" evidence, it can never be enough. (RFF 1823).

Such a standard is misplaced in the arena of a wholesome food. Particularly in the context of prostate cancer, which can take decades to clinically affect or ultimately kill the patient, Complaint Counsel's position almost certainly would 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. And 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. (RFF 1824-1827). Rather than recognize this reality, and the fact that a cheap and safe adjunct that may assist with prostate heath or prostate cancer exists in a food like pomegranate juice, and is backed by significant pre-clinical and clinical science, Complaint Counsel mindlessly adopts the mantra of a drug standard.

Tellingly, rather than shying from the extraordinary cost, time and complexity of attempting to definitively prove to a drug standard that pomegranate juice is beneficial, Complaint Counsel embrace without reservation, that a RCT is always required, despite that such a study would involve between 10,000 to 30,000 participants, cost in the range of $600 million, and take decades to complete—all on something that is healthy and safe to consume and likely has significant prostate health benefits. (RFF 1822; CCPTB at 44).

Complaint Counsel's conditionless "requirement" of RCTs is undermined by its own experts, however. During cross-examination, Dr. Eastham 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, he 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. (RFF 1824). 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. (RFF 1825).

Dr. Stampfer similarly undermined Complaint Counsel's assertion that RCTs are always required to demonstrate the efficacy of a whole fruit or juice. In his expert report, Dr. Stampfer concedes that it may be appropriate to communicate health recommendations in the absence of RCTs:

> I believe that it may be appropriate to use evidence short of randomized clinical trials for crafting public health recommendations regarding nutrient guidelines even when causality cannot be established, because everyone eats and the public should be given advice based on the best evidence available…Long term trials of diet and disease outcomes are often unfeasible due to the financial and participant burden required to perform such studies, but it is indisputable that the randomized clinical trial is the best study design that permits strong causal inference concerning the relationship between an administered agent (whether drug or nutrient) and any specific outcome.

(CX1293_0029-0030)(emphasis added).

In other words, Dr. Stampfer admits that in the case of food and nutritional health recommendations, the public should be made aware of the best evidence available, and not just after drug trials have been completed. Further, he admits that conducting RCTs on something like food is financially and practically "unfeasible". (*Id.*) Dr. deKernion, Respondents' prostate expert, mirrored this exact position in his report and in testimony. (RFF 1784). Drs. Eastham and Stampfer's admissions are fatal to Complaint Counsel's extreme position and demonstrate that the purported requirement of RCTs for all substantiation claims is simply not required.

2. Respondents Possess Competent and Reliable Basic and Clinical Scientific Evidence Demonstrating that the Challenged Products Are "Very Likely" Beneficial to Prostate Health

In addition to proclaiming the necessity of RCTs no matter the substance or safety, Complaint Counsel also attack POM's "prostate" science on a number of other meritless grounds: (1) it was not conducted in healthy men, (2) was done without blinding; (3) was done without placebo control in the original clinical studies; and (4) was done using an invalid marker. (CCPTB at 44-46). In addition, Complaint Counsel omit the significant pre-clinical science performed on antioxidants and pomegranate juice in reaching the conclusion that POM's science

is allegedly not sufficient to demonstrate the likely beneficial effects of pomegranate juice on prostate heath and prostate cancer. Each of Complaint Counsel's criticisms fail even basic scrutiny.

a. The Pre-Clinical Basic Science Shows a Robust Effect of POM Products on Prostate Cancer Cells

During the proceedings and now in its briefing, Complaint Counsel ignore wholesale the significant body of *in vitro* and animal studies showing a robust effect of POM Juice on prostate cancer. (RFF 1639-58, 1661, 1676, 1699). Given the amount and strength of this research, Complaint Counsel's actions are not surprising. 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*). As explained by Dr. deKernion in his expert report and during his testimony, "It is well-known that pre-clinical laboratory studies, both *in-vitro* and *in-vivo*, are critical to a preliminary assessment of the value of a new treatment. The pre-clinical laboratory evidence to support an effect of POM on prostate cancer is robust." (PX0161; deKernion Expert Report at 8-9).

For example, in a study by *Seeram, Heber et al.*, in 2007 (RFF 1641, 1869), the researchers evaluated the effects of pomegranate extract on prostate cancer growth in immune deficient mice injected with human prostate cancer cells and on prostate cancer cells *in vitro*. (RFF 1641-1644). The study showed that pomegranate extract significantly inhibited the growth of the human prostate cancer in the mouse as compared to the control and significantly inhibited the growth of human prostate cancer cells *in-vitro.* (*Id.*) Also found was that the bioactive derivatives of the anti-oxidants found in pomegranate extract localized in the mouse prostate tissue. (*Id.*)

In another study, by *Rettig MB*, *Heber et al.*, in 2008 (RFF 1650-53, 1870), the researchers evaluated POMx Pills and POM Juice and found that their consumption in immune deficient mice 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. (RFF 1628-29). 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. (RFF 1650-53, 1870). 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.,* in 2008 (RFF 1654-58; 1871), the researchers found that POMx significantly inhibited angiogenesis (blood vessel growth) both *in-vitro* on human prostate cancer tissue and in immune deficient 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. (*Id.*) Prostate cancer cell growth in turn is directly linked to PSADT. (RFF 1743-55, 1869-1903). 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. (RFF 1654-58, 1871).

In sum, POM's peer reviewed and published pre-clinical science both *in-vitro and in-vivo*, performed using "tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results" provide competent and reliable evidence and support the "very convincing" conclusion that POM Juice has a significant inhibitory effect on prostate cancer. (RFF 1777-83; *see, e.g.*, *Brake Guard Prods., Inc.*, 125 F.T.C. 138 (1998)).

b. Complaint Counsel's Challenge of PSADT as a Marker Is Not Well-Taken

Complaint Counsel also attack in its briefing, primarily through Dr. Eastham, the appropriateness of PSADT as a surrogate marker for prostate cancer clinical recurrence or survival. (RFF 1831-32). But Complaint Counsel does so in an indirect way. Rather than address the science head-on, which would frankly be futile given the volume of peer-reviewed studies and articles, showing PSADT is currently the best marker available for detecting prostate cancer and is used by physicians and researchers across the nation (RFF 1719, 1739, 1743-44, 1869-1903), Complaint Counsel instead cite out-of-context quotes of researchers or Respondent employees or affiliates expressing reservations or otherwise noting that PSADT has not been *absolutely* proven to be predictive of clinical recurrence or death. (CCPTB at 45-46.) But POM has never claimed as such, and its expert Dr. deKernion explained that PSADT has never been definitively proven to be a surrogate for clinical recurrence and/or death.[112] (PX0161). But it is currently the *best* marker available and the one primarily used by prostate cancer researchers and treating physicians alike. (RFF 1743-1759). Complaint Counsel's attack thus is without merit.

First, dozens of published articles over the last 20 years have shown PSADT to be the *best* marker available for prostate cancer clinical recurrence and eventual mortality. (RFF 1841-1851, 1869-1903). 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. (RFF 1889). In another 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. (RFF 1850). In yet another study by *Tollefson, et al.* (Mayo. Clin. Proc. 2007; RFF

[112] As Dr. deKernion explained in his expert report, in deposition and on the stand, the reason for this is at least two-fold: (1) prostate cancer is typically a slow growing cancer that often does not clinically recur or kill the patient and (2) prostate cancer usually occurs in older men that typically die from other age-related causes before the prostate cancer can kill them. Because of this, large, lengthy and extremely expensive studies would be required to prove (if even possible) absolutely that PSADT is surrogate marker for clinical recurrence and death. This has yet to be done. (PX00161).

1844-1846; 1893), 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." (RFF 1844) (emphasis added)). And a recent study by *Teeter, et al.* (Urology 2011; RFF 1841-1843; 1892) 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." (RFF 1841). The multitude of additional peer-reviewed articles cited by Dr. deKernion in his expert report confirm this fact. (RFF 1719, 1739, 1743-1744, 1869-1903).

Second, Dr. Eastham admits 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." (RFF 1838-40) (emphasis added). He further admits in the article that "PSADT is an important prognostic marker in men with biochemical failure after local therapy for prostate cancer, and it predicts the probable response to salvage radiotherapy, progression to metastatic disease and prostate cancer specific death."[113] (RFF 1838-40).

Third, most, if not all treating urologists, including Dr. Eastham and Dr. deKernion, utilize PSADT as a prognostic marker for recurrence of prostate cancer and mortality following radical prostatectomy. (RFF 1666, 1744, 1832). Why it is useful and prognostic in Dr. Eastham's practice, but not otherwise here, is unknown.

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[113] In fact, on the website of Memorial Sloan-Kettering Cancer Center, the hospital where Dr. Eastham practices, information about the pomegranate is included on their Cancer Care Integrative Medicine web page. (Memorial Sloan-Kettering Cancer Center, Pomegranate, *available at* http://www.mskcc.org/cancer-care/herb/pomegranate (last visited Jan. 3, 2012)). The webpage even includes a clinical summary of the research stating that pomegranate juice has been shown to "suppress inflammatory cell signaling, inhibit prostate tumor grown, and lower serum PSA levels." (Memorial Sloan-Kettering Cancer Center, Pomegranate, *available at* http://www.mskcc.org/cancer-care/herb/pomegranate (last visited Jan. 3, 2012)). It also cites many POM sponsored studies including the Pantuck (prostate) study. (Memorial Sloan-Kettering Cancer Center, Pomegranate, *available at* http://www.mskcc.org/cancer-care/herb/pomegranate (last visited Jan. 3, 2012)). (RFF 1807-1810).

In fact, only after being challenged about the obvious contradiction in his testimony and his article above, did Dr. Eastham concede that PSADT following radical prostatectomy was a prognostic marker for clinical progression and death from prostate cancer. (RFF 1832). Dr. Eastham 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. (RFF 1832). As before, he was unable to articulate why PSADT is predictive and useful immediately following treatment but no longer useful after that.

Apparently recognizing this inconsistency, Dr. Eastham later modified his theory: stating that 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. (RFF 1831-34). Dr. Eastham had no explanation for this new theory and Complaint Counsel similarly make no attempt to explain it despite adopting it wholesale in its post-trial briefing. *(Id;* CCPTB 44-50). 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?

Tellingly, Dr. Stampfer takes an opposite view from Dr. Eastham and Complaint Counsel. He testified that PSADT was "a predictor of disease of mortality" and that, if the extension of PSADT time is true, it would substantially prolong lives. (RFF 1835). 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).

Accordingly, PSADT is currently the most widely accepted surrogate for prostate cancer clinical recurrence and death following radical prostatectomy and Complaint Counsel's challenge to it is without merit. (RFF 1743-155, 1869-1903).

c. Study of Healthy Men, Blinding, and Placebo Control Are Not Required for Substantiation and In Any Event These Alleged Deficiencies Were Addressed in Follow-Up Studies

In addition to the above attacks, Complaint Counsel sprinkles throughout its post-trial briefing a variety of other criticisms of POM's prostate science. As before, this shotgun approach fails.

Complaint Counsel first alleges that because the prostate clinical studies on POM were not conducted on healthy men with their prostates, no conclusions as to the effectiveness or likely effectiveness of POM in preventing prostate cancer can be made. As stated before, POM has never made prevention claims, but it possesses sufficient evidence to do so.

As explained by Dr. deKernion, the basic science showing a direct effect of POM 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" conclusion that POM Juice has a significant inhibitory effect on prostate cancer. (RFF 1777-83). He further 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). Dr. Heber mirrored this opinion, testifying that "there's a significant body of scientific evidence to indicate that both pomegranate fruit juice and pomegranate extract can help to prevent or reduce the risk or help to treat prostate cancer." (RFF 1783).[114]

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[114] In fact, the ALJ specifically questioned Dr. deKernion on this very issue. JUDGE CHAPPELL: If you were going to conduct a study with something like POM Juice, would the study be more effective with someone with or without prostate cancer? THE WITNESS: Well, if -- if you want to demonstrate it has an effect on tumor cells, you really -- first of all, you should -- you wouldn't want to substitute it for -- for the legitimately hormone treatment or surgery. You wouldn't substitute even -- you wouldn't do anything except standard treatment if you are positive there is cancer there. JUDGE CHAPPELL: You're not going to ask the control group to do without medicine. THE WITNESS: No. No. No. No. Now, on the other hand, what we've found in the data -- I shouldn't say "we"; I didn't do it -- but what has been shown is that it has effect on tumor, microscopic tumor, so one could then argue that it might be good for people who have their prostates who don't have known cancer. But -- and in that sense it could make -- it is a very good idea perhaps. But in terms of -- if you want to show an effect of POM on cancer, the best way is to do it in a pure form, where the prostate is gone, the presence of a PSA elevation is an absolute (continued…)

Complaint Counsel next attack POM's clinical prostate trials for not being blinded. (CCPTB at 44-46). This is a classic red herring. First, the *Carducci* Phase II Study was a randomized *double-blind* clinical trial. (RFF 1695). It could not have been any more blinded.[115] Ignoring this apparent oversight, Dr. Eastham himself admitted that blinding in the context of a Phase II study, like the *Pantuck* study, is not critical:

> "Q. Again, do you think blinding had anything to do with the results of the Pantuck study, influenced it one way or the other?
>
> A. The Pantuck study was a Phase II study of one dose so you couldn't blind it. There was no placebo arm, so no, I don't think -- it's impossible for his results to have been impacted.
>
> Q. If you look on page 19 [of your report], the top paragraph --
>
> A. In retrospect, that was probably an overstatement.
>
> Q. You would agree now that the blinding doesn't matter essentially?
>
> A. For the Pantuck study, blinding is not that critical. It's still important, but it's not critical, because it wasn't a randomized trial, so as a hypothesis-generating study for the Pantuck study, blinding was not that important."

(Eastham, Dep. at 143-144). Respondents' expert Dr. deKernion mirrored this view, highlighting that in studies where objective results (like blood levels of PSADT) are involved, blinding is particularly not important. (deKernion, Tr. 3059-3060; PX0351 (deKernion, Dep. At 97-99).

Finally, Complaint Counsel criticize the clinical trials on POM on the basis they lacked a placebo control arm. (CCPTB at 45-46.) Dr. deKernion addressed this "issue" during his

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indication as cancer, and it can't be due to anything else, and that PSA that's expressed, any alteration in it could be attributable to what kind of treatment you're doing, so that's where you'd start anyway. (deKernion, Tr. 3056-3057)

[115] Complaint Counsel apparently ignores this study because POMx and not specifically POM Juice was tested. As testified to by Dr. Heber (and verified by several studies) however, the two are functional equivalents in the body. (RFF 915-951).

testimony. First, he noted that placebo control arms, as a rule, are not required in Phase II trials. (RFF 1768). Second, he testified that there is nothing in the literature or his many years of research and practice to suggest that anything other than the POM being tested was responsible for the changes in PSADT that were being observed. (PX0161-0011-0012). Third, he was unaware and has never observed PSADT spontaneously lengthening without intervention (beyond very specific situations not applicable). (PX0161-0008). And finally, he testified that the use of a placebo control is really only needed when you have subjective reporting of results—particularly in situations where there is a real risk of toxicity or side-effects that need to be ferreted out. (deKernion, Tr. 3059-3061). Here, only objective results are being studied—that of blood PSADT levels. Tellingly, Dr. deKernion testified that in many ways, for clinical trials studying PSADT in men following radical prostatectomy, the patient himself makes the best control, as one can then directly study the effect of POM, if any, on that specific person, with all other variables inherently controlled for. (deKernion, Tr. 3056-57).

And as explained by Dr. Miller, and contrary to Complaint Counsel's rote reliance on RCT and placebo control arm, this is often not the standard in the real world. (RFF 744-761). For example, RCTs with placebo control arms are not the standard nor required by the National Cancer Institute or other regulatory agencies. (RFF 752, PX0206-0002). In fact, the success in treating children with cancer at the National Cancer Institute was achieved without RCTs. (RFF 753, PX0206-0002). And in many instances, even the FDA has approved pharmaceutical products without requiring the type of rigorous clinical trials the FTC would require of a safe food product. (RFF 757, PX0206-0008-0009). For example, many cancer agents now used in clinical practice in the U.S. and around the world were approved by the FDA in open-label randomized controlled trials without a placebo control arm. (RFFs 757-759, PX0206-0008). Accordingly, rote reliance on RCTs or placebo control, particularly in the context of a safe and cheap food simply is not only not the standard but would be contrary to common practice and common sense.

3. Competent and Reliable Scientific Evidence Support Prostate Health Claims as Well as "Treat," "Prevent" and "Reduce the Risk" Claims

Respondents dispute Complaint Counsel's allegations that the 29 advertisements at issue suggest that the Challenged Products can "treat," "prevent" or "reduce the risk" of prostate cancer. Instead, as discussed *infra*, Respondents' advertisements convey: (1) POM is a great source of antioxidants which medical research has suggested can combat free radicals, which are unhealthy, and may contribute to diseases of the prostate including prostate cancer; (2) POM consumption has been shown to lengthen PSADT in men with biochemical recurrence of PSA following treatment for prostate cancer; and (3) POM is healthy and likely good for prostate health (CX260_0001; CX1426_0028, Exh. B). Again, nowhere does POM claim it "treats" or "prevents" or "reduces the risk" of prostate cancer.

a. "Treat" Prostate Cancer

Respondents vehemently deny ever making any claims or suggesting that drinking eight ounces of POM Juice or consuming pomegranate extract daily "treats" prostate cancer. Moreover, Respondents never suggested that POM Juice or its derivatives can serve as a replacement or substitute for conventional medical treatment. To the extent the Commission believes that the Respondents' advertisements convey the message that the Challenged Products can "treat" prostate cancer, the totality of the scientifically valid and peer-reviewed evidence support the conclusion that the Challenged Products may help treat prostate cancer by extending PSA doubling time with men with rising PSA following primary therapy for prostate cancer. Dr. deKernion testified that in each of POM's human clinical studies, when the subjects were given POM Juice (Pantuck study) or POMx (Carducci study), the studies showed that it slowed the growth of their prostate tumor cells as expressed by the longer time it took for those tumor cells to double. (RFF 1763; *See also* RFFs 1577, 1919-1922). Further, when Dr. Carducci was asked by Complaint Counsel whether his study showed that POMx was treatment for prostate cancer, Dr. Carducci responded, "It did." (CX1340 (Carducci, Dep. at 87)).

In addition, clinicians currently recommend pomegranate juice consumption as an adjunct to traditional medical care for some categories of patients with prostate cancer.

Dr. deKernion testified that POM products are a reasonable adjunct, meaning in addition to and not a substitute for medical care for prostate cancer patients and recommends POM to some of his patients. (RFF 1793). Dr. deKernion also stated that POM is a reasonable adjunct for a patient who wishes to boost their general health and help avoid a clinical recurrence of prostate cancer. (RFF 1794). He further opined that a food can be used as a treatment for prostate cancer if there is evidence that it might treat it and if there is no toxicity. (RFF 1795). Dr. Pantuck similarly testified that there are categories of patients that he recommends pomegranate juice to. (RFF 1796). Dr. Pantuck also testified that he is aware of doctors who have discussed the findings of his research with their patients. (RFF 1797). Dr. Heber testified that he informs prostate cancer patients about the research on pomegranate juice and pomegranate extract. (RFF 1800). Finally, Dr. Miller opined that, there may be some subcategory of patients, who do not have many or any alternatives, and for them a clinician may reasonably decide to recommend, among other things, the consumption of pomegranate. (RFF 1801).

b. "Prevent" Prostate Cancer

Respondents also deny ever making any claims or suggesting that drinking eight ounces of POM Juice daily or consuming pomegranate extract "prevents" prostate cancer, like the pharmaceutical drug Lipitor prevents disease. However, should Respondents' advertisements be construed by the Commission to suggest that the Challenged Products can "prevent" prostate cancer, it can only be in the same fashion as exercise and a healthy diet can "help prevent" disease. To the extent the Commission believes that the Respondents' advertisements convey the message that the Challenged Products can "prevent" prostate cancer, the totality of the competent and reliable scientific evidence supports the conclusion that the same mechanism shown in the *in vitro* and animal studies and in the Pantuck and Carducci human studies also showed with a "high degree of probability" that the Challenged Products inhibit the clinical development of prostate cancer cells in men who have not been diagnosed. (RFF 1577, 1927).

Dr. deKernion opined that in healthy men, who have never been diagnosed with prostate cancer, the Challenged Products could possibly play a role in preventing them from getting

prostate cancer. (RFF 1778). He stated that the data has shown that the Challenged Products and especially specific polyphenols have an impact on the inflammatory pathways in the prostate and that evidence suggests it could prevent prostate cancer. (RFF 1780). Dr. Heber also testified that there is competent and reliable science showing that POMx and POM are likely to lower the risk of prostate problems for men who have not yet been diagnosed with prostate cancer. (RFF 1779). He further opined that, "there's a significant body of scientific evidence to indicate that both pomegranate fruit juice and pomegranate extract can help to prevent or reduce the risk or help to treat prostate cancer." (RFF 1783). In Dr. Miller's expert opinion, he stated that it is more likely than not, if POM is effective in men with biochemical recurrence, that it may prevent prostate cancer in an otherwise healthy but at risk individual. (RFF 1781).

Dr. Heber attended meetings with Respondents about prostate cancer research attended by Doctors Allan Pantuck, Phil Kantoff, and Michael Carducci. (RFF 1911). He testified that at that meeting there was a discussion that the scientific data and considering the studies done to date, suggested the Challenged Products could help prevent prostate cancer. (RFF 1912). Dr. Heber further testified that there was enthusiasm from everyone including Dr. Kantoff of Harvard Medical School. (RFF 1913). Dr. Heber stated that ultimately there, "was substantial agreement on the body of evidence there that it could help to prevent in the correct setting." (RFF 1914). Dr. Heber further testified that prevent would not mean absolutely prevent nor a substitute for a pharmaceutical prevention. (Heber, Tr. 2157-58). (RFF 1915).

c. "Reduce The Risk" of Prostate Cancer

Respondents deny ever making any claims or suggesting that drinking eight ounces of POM Juice or consuming pomegranate extract daily "reduces the risk" or prostate cancer. However, should Respondents' advertisements be construed by the Commission to suggest that the Challenged Products can "reduce the risk" of prostate cancer, it could only be in the same fashion as exercise and a healthy diet can "reduce the risk" of disease. To the extent the Commission believes that the Respondents' advertisements convey the message that the Challenged Products can "reduce the risk" of prostate cancer, the totality of the competent and

reliable scientific evidence supports the conclusion that the same mechanism shown in the *in vitro* and animal studies and in the Pantuck and Carducci human studies also showed with a "high degree of probability" that the Challenged Products inhibit the clinical development of prostate cancer cells in men who have not been diagnosed. (RFF 1577, 1927).

Dr. Heber testified that there is competent and reliable science showing that POMx and POM are likely to lower the risk of prostate problems for men who have not yet been diagnosed with prostate cancer. (RFF 1779). Dr. Heber further opined that, "there's a significant body of scientific evidence to indicate that both pomegranate fruit juice and pomegranate extract can help to prevent or reduce the risk or help to treat prostate cancer." (RFF 1783).

In conclusion: (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 high degree of probability inhibit the clinical development of prostate cancer or recurrence of it after treatment and the public has a right to have this information. (RFF 1577-1579, 1584-1922).

As specifically summed up by Dr. deKernion during his testimony, there is a "high degree of probability" that POM or POMx "will improve the chances of avoiding or deferring the recurrence of prostate cancer" and "high degree of probability" that POM or POMx can "inhibit[] the clinical development of prostate cancer in men who have not been diagnosed with prostate cancer." (deKernion, Tr. 3059-3061).

4. Competent and Reliable Scientific Evidence Support Each of the Qualified Claims Actually Conveyed in the "Prostate" Advertisements Identified by Complaint Counsel

As discussed below, Respondents deny Complaint Counsel's assertion that "[o]ver sixty-five percent (29 of 43) of the challenged ads and promotional materials contain false or

unsubstantiated prostate cancer efficacy claims" and that "twenty-seven of the 29 pieces making prostate cancer efficacy claims represent, either expressly or implicitly, that clinical studies prove that the POM Products treat, prevent, or reduce the risk of prostate cancer."[116] (CCPTB, at 49-50).

Complaint Counsel attacks 29 "ads and promotional pieces" as representing "either expressly, or implicitly, that clinical studies prove that the Challenged Products treat, prevent, or reduce the risk of prostate cancer." (CCPTB at 43). Complaint Counsel's support for this assertion is erroneous because they ignore, among other things, the overt puffery and humor in the headlines, sub-headlines and imagery, the qualifying body text and the fact that the Challenged Products are 100% fruit juice or derived from 100% fruit and advertised heavily as such. (*See* Appendix of Advertisements; Reply Ad Appendix). Indeed, as evidenced by the ads themselves, it is impossible for Complaint Counsel to "conclude with confidence" that the Challenged Ads convey the establishment or efficacy claims based on the face of the ads themselves. To the contrary, nowhere in the Challenged Ads is it written or suggested that POM is effective in "treating", "preventing" or otherwise "reducing the risk" of prostate cancer.

Instead, of the 29 advertisements, the actual claims made by Respondents can be summarized as follows: an initial study on POM Juice reported hopeful results for prostate health and that study reported significant prolongation of PSA doubling times; *in vitro* studies reported

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[116] CX0260/1426 Ex. B ("Drink to Prostate Health"); CX0274/1426 Ex. C ("I'm off to save prostates" Ad); CX0314 ("Drink to Prostate Health" Magazine Wrap); CX0372/CX0379/CX0380 ("Lucky I have super health powers" Magazine Wrap); CX0475/1426 Ex. A (Juice Bottle Hang Tag); CX0120 ("One Small Pill for Mankind" Ad); CX0122 ("Science, Not Fiction" Ad); CX0169/1426 Ex. L ("The power of POM" Ad); CX0180/1426 Ex. K ("Antioxidant Superpill" Ad); CX0279 ("Science, Not Fiction" Ad); CX0280 ("Live Long Enough" Ad); CX0328 ("Your New Health Care Plan" Ad); CX0331/1426 Ex. J ("Healthy Wealthy" Ad); CX0337 ("The First Bottle You Should Open" Ad); CX0342/CX0353 ("Take Out A Life Ins" Ads); CX0348/CX0350 ("24 Scientific Studies" Ads); CX0351/CX0355 ("Only Antioxidant Supplement Rated X" Ads); CX1426 Ex. I ("Antioxidant Superpill" brochure); CX1426 Ex. N (POMx Prostate Newsletter); CX0473 (POMWonderful.com);CX0473 (POMWonderful.com Community site); CX473 (Pomegranatetruth.com); CX0473 (POMPills.com); CX0065_0002 (July 2006 POMx press release); CX0473 (June 2008, Tupper on Fox Business show); CX0472 (Feb. 2009, Lynda Resnick on CBS Early Show); CX0473 (Mar. 2009, Lynda Resnick interview in Newsweek.com); CX0466/CX1426 Ex. H ("Off to save prostates" Banner Ad); CX0473 (Nov. 2008, Lynda Resnick on Martha Stewart Show).

that POM Juice decreased prostate cancer cell growth and increased cancer cell death; POM Juice has the ability to neutralize free radicals and to inhibit excess inflammation; POM Juice is loaded with antioxidants and is good for prostate health; POMx fights free radicals; POMx helps guard your body against free radicals; an initial study on POM Juice reported hopeful results for men with prostate cancer; and POM Juice fights for prostate health. (*See* Chart Analyzing 29 challenged prostate health advertisements, below).

Each and every claim made in the 29 prostate health Challenged Advertisements are substantiated by competent and reliable science including:

1. The preclinical studies on POM's effect on prostate cancer, including: Agensys (2001) (RFF 1873, PX065); Heber (2007) (RFF 1641, 1869, PX0069); Heber (2008);(RFF 1608-1658; PX0066, PX0067, PX0068, PX0070, PX0071, PX0173, PX0207);

2. The multitude of published and peer-reviewed Studies referenced by Dr. deKernion in his expert report and testimony regarding the significance of PSA doubling time. (RFF 1743-1755, 1869-1903);

3. Peer-reviewed and published studies and independent websites about the effects of antioxidants, the bioavailability of pomegranate based antioxidants and equivalency of POM Juice and POMx. (RFF 745-958);

4. Dr. Pantuck's peer-reviewed published Phase II Study (2006) and Dr. Pantuck's Long Term Follow-Up Study (2008). (RFF 1661-1694, PX0060; RFF 1676, PX0061); and

5. Dr. Carducci's Study (2011) (RFF 1695-1717, PX0175).

As noted herein, Respondents contend that the three interviews by Mrs. Resnick and Mr. Tupper (CX0473/CX1426, Exh. E-7 (Tupper Interview on Fox Business, June 2008); CX0472_0003 (Lynda Resnick Interview on *The Early Show*, February 2009) and CX0473/CX1426, Exh. F (Newsweek Interview with Lynda Resnick, March 2009)) are not actionable under the FTCA because they do not constitute "advertising". To the extent these interviews are viewed as advertising, the research to date as noted above would also substantiate these claims.

Although Respondents have not made "prevent, treat, or reduce the risk" claims with respect to their prostate health advertising, Respondents have shown, and the record reflects, that they nevertheless have overwhelming competent and reliable scientific evidence to support such

claims. Respondents' basic science studies and peer-reviewed published clinical trials constitute competent and reliable scientific evidence that the Challenged Products are beneficial to prostate health, including by prolonging PSA doubling time in men with rising PSA after primary treatment for prostate cancer. (RFF 1577-1578; 1919-1922). Additionally, competent and reliable scientific evidence supports the conclusion that the same mechanism shown in the *in vitro* and animal studies and in the Pantuck and Carducci human studies also showed with a "high degree of probability" that the Challenged Products inhibit the clinical development of prostate cancer cells in men who have not been diagnosed. (RFF 1577-1578; 1919-1922).

The following chart summarizes Respondents' scientific research in support of the Challenged Advertisements identified by Complaint Counsel in Appendix A to their Post-Trial Brief as well as the take away points from each "prostate" ad.

	Dissemination Date	**Appendix[117]/RFF/RRFF**	**Overall Net Impression of the Advertisements**	**Scientific Support**
CX0260/1426 Ex. B ("Drink	12/1/2008	Appendix 169-	• Good for prostate	Prostate Basic

[117] Unless otherwise noted, all prostate health claims made in the challenged advertisements are supported by in part or by whole, Respondents' considerable basic science. Respondents' basic science constitutes competent and reliable scientific evidence that pomegranate juice and/or its extract are beneficial toward prostate health. (See Agensys, Investigation of the Effect of Pomegranate Juice (PJC) on Human Prostate Cancer (Unpublished Study Results, 2001) (PX065). Agensys, Investigation of the Effect of Pomegranate Juice (PJC) on Human Prostate Cancer, Final Power Point Presentation (2003) (PX0066). Agensys, PJC Reduces Subcutaneous Growth of Prostate Tumors (11/20/2001) (PX0067) Hong MY, Seeram NP, and Heber D, Pomegranate polyphenols down-regulate expression of androgen synthesizing genes in human prostate cancer cells over expressing the androgen receptor, Journal of Nutritional Biochemistry 19 (2008) 848-855. (PX0068). Seeram NP, Aronson WJ, Zhang Y, Henning SM, Moro A, Lee R, Sartippour M, Harris DM, Rettig M, Suchard MA, Pantuck AJ, Belldegrun A, and Heber D, Pomegranate Ellagitannin-Derived Metabolites Inhibit Prostate Cancer Growth and Localize to the Mouse Prostate Gland, J. Agric. Food Chem.2007, 55, 7732-7737. (PX0069). Rettig MB, Heber D, An J, Seeram NP, Rao JY, Liu H, Klatt T, Belldegrun A, Moro A, Henning SM, Mo D, Aronson WJ, and Pantuck A, Pomegranate extract inhibits androgen-independent prostate cancer growth through a nuclear factor-κB-dependent mechanism, Molecular Cancer Therapy 7 (9): 2662-2671 (2008). (PX0070). Sartippour MR, Seeram NP, Rao JY, Moro A, Harris DM, Henning SM, Firouzi A, Rettig MB, Aronson WJ, Pantuck AJ, and Heber D, Ellagitannin-rich pomegranate extract inhibits angiogenesis in prostate cancer in vitro and in vivo, International Journal of Oncology 32: 475-480, 2008. (PX0071). Malik, et al., Pomegranate Fruit Juice for Chemoprevention and Chemotherapy of Prostate Cancer, Proc. Natl. Acad. Sci. USA, 2005 Oct 11; 102(41): 14813-8, pomegranate fruit extract was shown to have an effect on prostate cancer cells. (PX0173). Albrecht M, Jiang W, Kumi-Diaka J, et al., *Pomegranate extracts potently suppress proliferation, xenograft growth, and invasion of human prostate cancer cells*. J Med Food 7: 274-283, 2004, pomegranate extract was shown to have anti-tumor activity. (PX0207). (*See also*, RFF 1608-1659; 1855-1868).

	Dissemination Date	Appendix[117]/RFF/RRFF	Overall Net Impression of the Advertisements	Scientific Support
to Prostate Health")		190 RRFF 368-371	health. • May help maintain prostate health. • May help prolong PSA doubling times.	Science Pantuck Study (2006) (RFF 1661, PX0060)[118] Pantuck Study (2008) (RFF 1676, PX0061) PSADT Studies[119] Antioxidant and POM Juice/POMx equivalency studies[120]
CX0274/1426 Ex. C ("I'm off to save prostates" Ad)	2/9/2009	Appendix 191-214 RRFF 372-376	• Good for and fights for prostate health.	Prostate Basic Science Pantuck Study (2006) (RFF 1661, PX0060) Pantuck Study (2008) (RFF 1676, PX0061) Carducci Study (2011) (RFF 1695, PX0175) PSADT Studies Antioxidant and POM Juice/POMx equivalency studies
CX0314 ("Drink to Prostate Health" Magazine Wrap)	9/9/2008	Appendix 215-306 RRFF 377-380	• POM helps to fight free radicals. • POM is loaded with antioxidants. • Good for prostate health.	Prostate Basic Science Pantuck Study (2006) (RFF 1661, PX0060) Pantuck Study

[118] "Appendix" refers to Respondents' Reply Ad Appendix

[119] Multitude of PSADT Studies published and peer-viewed Studies referenced or reviewed by Dr. deKernion in his expert report regarding the importance of PSADT. (RFF 1743-1755, 1841-1851, 1869-1903).

[120] Peer-reviewed and published studies and independent websites about the effects of antioxidants, the bioavailability of pomegranate based antioxidants and equivalency of POM Juice and POMx. (RFF 745-958).

	Dissemination Date	Appendix[117]/RFF/RRFF	Overall Net Impression of the Advertisements	Scientific Support
			• May help maintain prostate health. • May help prolong PSA doubling times.	(2008) (RFF 1676, PX0061) Carducci Study (2011) (RFF 1695, PX0175) PSADT Studies Antioxidant and POM Juice/POMx equivalency studies
CX0372/CX0379/CX0380 ("Lucky I have super health powers" Magazine Wrap)	9/10/2009	Appendix 307-425 RRFF 381	• POM helps to fight free radicals. • POM is loaded with antioxidants. • Good for prostate health. • May help maintain prostate health. • May help prolong PSA doubling times.	Prostate Basic Science Pantuck Study (2006) (RFF 1661, PX0060) Pantuck Study (2008) (RFF 1676, PX0061) Carducci Study (2011) (RFF 1695, PX0175) PSADT Studies Antioxidant and POM Juice/POMx equivalency studies
CX0475/1426 Ex. A (Juice Bottle Hang Tag)	Not Established	Appendix 426-449 RRFF 386-388	• POM Juice contains lots of antioxidants. • POM Juice fights for prostate health.	Prostate Basic Science Pantuck Study (2006) (RFF 1661, PX0060) Pantuck Study (2008) (RFF 1676, PX0061) Carducci Study (2011) (RFF 1695, PX0175) PSADT Studies Antioxidants and equivalency of POM Juice and POMx
CX0120 ("One Small Pill for Mankind" Ad)	5/28/2007	Appendix 560-579	• POMx helps to fight free radicals. • POMx is loaded with	Prostate Basic Science Pantuck Study

	Dissemination Date	Appendix[117]/RFF/RRFF	Overall Net Impression of the Advertisements	Scientific Support
		RRFF 397-401	antioxidants. • Good for prostate health. • May help maintain prostate health.	(2006) (RFF 1661, PX0060) Pantuck Study (2008) (RFF 1676, PX0061) Carducci Study (2011) (RFF 1695, PX0175) PSADT Studies Antioxidant and POM Juice/POMx equivalency studies
CX0122 ("Science, Not Fiction" Ad)	6/1/2007	Appendix 580-589 RRFF 398-401	• POMx helps to fight free radicals. • POMx is loaded with antioxidants. • Good for prostate health. • May help maintain prostate health.	Prostate Basic Science Pantuck Study (2006) (RFF 1661, PX0060) Pantuck Study (2008) (RFF 1676, PX0061) Carducci Study (2011) (RFF 1695, PX0175) PSADT Studies Antioxidant and POM Juice/POMx equivalency studies
CX0169/1426 Ex. L ("The power of POM" Ad)	1/6/2008	Appendix 599-618 RRFF 406-407, 410, 412-414	• POMx helps to fight free radicals. • POMx is loaded with antioxidants. • Good for prostate health. • May help maintain prostate health. • May help prolong PSA doubling times.	Prostate Basic Science Pantuck Study (2006) (RFF 1661, PX0060) Pantuck Study (2008) (RFF 1676, PX0061) Carducci Study (2011) (RFF 1695, PX0175) PSADT Studies Antioxidant and POM Juice/POMx equivalency

	Dissemination Date	Appendix[117]/RFF/RRFF	Overall Net Impression of the Advertisements	Scientific Support
				studies
CX0180/1426 Ex. K ("Antioxidant Superpill" Ad)	2/3/2008	Appendix 619-636 RRFF 408, 411-414	• POMx helps to fight free radicals. • POMx is loaded with antioxidants. • Good for prostate health. • May help maintain prostate health. • May help prolong PSA doubling times.	Prostate Basic Science Pantuck Study (2006) (RFF 1661, PX0060) Pantuck Study (2008) (RFF 1676, PX0061) Carducci Study (2011) (RFF 1695, PX0175) PSADT Studies Antioxidant and POM Juice/POMx equivalency studies
CX0279 ("Science, Not Fiction" Ad)	3/1/2009	Appendix 637-655 RRFF 409-411-414	• POMx helps to fight free radicals. • POMx is loaded with antioxidants. • Good for prostate health. • May help maintain prostate health. • May help prolong PSA doubling times.	Prostate Basic Science Pantuck Study (2006) (RFF 1661, PX0060) Pantuck Study (2008) (RFF 1676, PX0061) Carducci Study (2011) (RFF 1695, PX0175) PSADT Studies Antioxidant and POM Juice/POMx equivalency studies.
CX0280 ("Live Long Enough" Ad)	3/12/2009	Appendix 656-676 RRFF 415-418	• Contains antioxidants that help fight free radicals. • Good for prostate health. • May help maintain prostate health. • May help prolong PSA doubling times.	Prostate Basic Science Pantuck Study (2006) (RFF 1661, PX0060) Prostate Basic Science Pantuck Study (2008) (RFF 1676, PX0061) Carducci Study (2011) (RFF

	Dissemination Date	Appendix[117]/RFF/RRFF	Overall Net Impression of the Advertisements	Scientific Support
				1695, PX0175) PSADT Studies Antioxidant and POM Juice/POMx equivalency studies
CX0328 ("Your New Health Care Plan" Ad)	11/8/2009	Appendix 677-698 RRFF 415-418	• Contains antioxidants that help fight free radicals. • Good for prostate health. • May help maintain prostate health. • May help prolong PSA doubling times.	Prostate Basic Science Pantuck Study (2006) (RFF 1661, PX0060) Pantuck Study (2008) (RFF 1676, PX0061) Carducci Study (2011) (RFF 1695, PX0175) PSADT Studies Antioxidant and POM Juice/POMx equivalency studies
CX0331/1426 Ex. J ("Healthy Wealthy" Ad)	9/27/2009	Appendix 699-718 RRFF 415-418	• Contains antioxidants that help fight free radicals. • Good for prostate health. • May help maintain prostate health. • May help prolong PSA doubling times.	Prostate Basic Science Pantuck Study (2006) (RFF 1661, PX0060) Pantuck Study (2008) (RFF 1676, PX0061) Carducci Study (2011) (RFF 1695, PX0175) PSADT Studies Antioxidant and POM Juice/POMx equivalency studies
CX0337 ("The First Bottle You Should Open" Ad)	1/10/2010	Appendix 719-739 RRFF 415-418	• Contains antioxidants that help fight free radicals. • Good for prostate health. • May help maintain	Prostate Basic Science Pantuck Study (2006) (RFF 1661, PX0060) Pantuck Study

	Dissemination Date	Appendix[117]/RFF/RRFF	Overall Net Impression of the Advertisements	Scientific Support
			prostate health. • May help prolong PSA doubling times.	(2008) (RFF 1676, PX0061) Carducci Study (2011) (RFF 1695, PX0175) PSADT Studies Antioxidant and POM Juice/POMx equivalency studies
CX0342/CX0353 ("Take Out A Life Ins" Ads)	2/22/2010	Appendix 740-761 RRFF 419-424	• Contains antioxidants that help fight free radicals. • Good for prostate health. • May help maintain prostate health. • May help prolong PSA doubling times.	Prostate Basic Science Pantuck Study (2006) (RFF 1661, PX0060) Pantuck Study (2008) (RFF 1676, PX0061) Carducci Study (2011) (RFF 1695, PX0175) PSADT Studies Antioxidant and POM Juice/POMx equivalency studies
CX0348/CX0350 ("24 Scientific Studies" Ads)	4/1/2010	Appendix 762-785 RRFF 419-424	• Contains antioxidants that help fight free radicals. • Good for prostate health. • May help maintain prostate health. • May help prolong PSA doubling times.	Prostate Basic Science Pantuck Study (2006) (RFF 1661, PX0060) Pantuck Study (2008) (RFF 1676, PX0061) Carducci Study (2011) (RFF 1695, PX0175) PSADT Studies Antioxidant and POM Juice/POMx equivalency studies
CX0351/CX0355 ("Only Antioxidant Supplement	6/1/2010	Appendix 786-808	• Contains antioxidants that help fight free	Prostate Basic Science

	Dissemination Date	Appendix[117]/RFF/RRFF	Overall Net Impression of the Advertisements	Scientific Support
Rated X" Ads)		RRFF 425-429	radicals. • Good for prostate health. • May help maintain prostate health. • May help prolong PSA doubling times.	Pantuck Study (2006) (RFF 1661, PX0060) Pantuck Study (2008) (RFF 1676, PX0061) Carducci Study (2011) (RFF 1695, PX0175) PSADT Studies Antioxidant and POM Juice/POMx equivalency studies
CX1426 Ex. I ("Antioxidant Superpill" brochure)	Not Established.	Appendix 809-826 RRFF 430-434	• POMx helps to fight free radicals. • POMx is loaded with antioxidants. • Good for prostate health. • May help maintain prostate health. • May help prolong PSA doubling times.	Prostate Basic Science Pantuck Study (2006) (RFF 1661, PX0060) Pantuck Study (2008) (RFF 1676, PX0061) Carducci Study (2011) (RFF 1695, PX0175) PSADT Studies Antioxidant and POM Juice/POMx equivalency studies
CX1426 Ex. N (POMx Prostate Newsletter)	Fall 2007	Appendix 846-863 RRFF 435-436, 439-441	• Good for prostate health. • May help maintain prostate health. • May kill or slow the growth of prostate cancer. • May help prolong PSA doubling times.	Prostate Basic Science Pantuck Study (2006) (RFF 1661, PX0060) Pantuck Study (2008) (RFF 1676, PX0061) Carducci Study (2011) (RFF 1695, PX0175) PSADT Studies Antioxidant and POM Juice/POMx

	Dissemination Date	Appendix[117]/RFF/RRFF	Overall Net Impression of the Advertisements	Scientific Support
				equivalency studies
CX473 (Pomegranatetruth.com)	4/28/2009	Appendix 864-867 RRFF 496-500	• Good for prostate health. • May help maintain prostate health. • May kill or slow the growth of prostate cancer. • May help prolong PSA doubling times.	Prostate Basic Science Pantuck Study (2006) (RFF 1661, PX0060) Pantuck Study (2008) (RFF 1676, PX0061) Carducci Study (2011) (RFF 1695, PX0175) PSADT Studies Antioxidant and POM Juice/POMx equivalency studies
CX0473 (POMPills.com)		Appendix 864-867 RRFF 501-535	• POMx helps to fight free radicals. • POMx is loaded with antioxidants. • Good for prostate health. • May help maintain prostate health. • May help prolong PSA doubling times.	Prostate Basic Science Pantuck Study (2006) (RFF 1661, PX0060) Pantuck Study (2008) (RFF 1676, PX0061) Carducci Study (2011) (RFF 1695, PX0175) PSADT Studies Antioxidant and POM Juice/POMx equivalency studies
CX0065_0002 (July 2006 POMx press release)	7/10/2006	Appendix 877-881 RRFF 556-562	• POMx is loaded with antioxidants. • Good for prostate health. • May help maintain prostate health. • May help prolong PSA doubling times.	Prostate Basic Science Pantuck Study (2006) (RFF 1661, PX0060) Pantuck Study (2008) (RFF 1676, PX0061) Carducci Study (2011) (RFF 1695, PX0175)

	Dissemination Date	Appendix[117]/RFF/RRFF	Overall Net Impression of the Advertisements	Scientific Support
				PSADT Studies Antioxidant and POM Juice/POMx equivalency studies
CX0473 (June 2008, Tupper on Fox Business show)	6/17/2008	Appendix 886 RFF 2610-2621 RRFF 572-573	• Not advertising; Mr. Tupper expressing his opinion. To the extent it is viewed as advertising, the research to date would substantiate such claims. • ["Progression of prostate cancer slowed drastically."]	Prostate Basic Science Pantuck Study (2006) (RFF 1661, PX0060) Pantuck Study (2008) (RFF 1676, PX0061) Carducci Study (2011) (RFF 1695, PX0175) PSADT Studies Antioxidant and POM Juice/POMx equivalency studies
CX0472 (Feb. 2009, Lynda Resnick on CBS Early Show)	2/19/2009	Appendix 886 RFF 2567-2580 RRFF 574-575	• Not advertising; Mrs. Resnick expressing her opinion. To the extent it is viewed as advertising, the research to date would substantiate such claims. • Julie Chen: And how did you start marketing [POM]? Because, like I see that bottle and I just want to drink it. Mrs. Resnick: I know. I know. . . And we decided to see if that was true. We started doing scientific, peer-reviewed research. And we found out, indeed, that the pomegranate has all these health-giving properties. There isn't a man in America that	Prostate Basic Science Pantuck Study (2006) (RFF 1661, PX0060) Pantuck Study (2008) (RFF 1676, PX0061) Carducci Study (2011) (RFF 1695, PX0175) PSADT Studies Antioxidant and POM Juice/POMx equivalency studies

	Dissemination Date	Appendix[117]/RFF/RRFF	Overall Net Impression of the Advertisements	Scientific Support
			shouldn't drink 8oz. a day. Because it keeps you from getting prostate cancer or your PSA from rising. It's really an, amazing, amazing thing. And good for circulation too.	
CX0473 (Mar. 2009, Lynda Resnick interview in Newsweek.com	3/20/2009	Appendix 886 RFF 2581-2595 RRFF 576-577	Not advertising; Mrs. Resnick expressing her opinion. To the extent it is viewed as advertising, the research to date would substantiate such claims. [Interviewer:] Should I take vitamins? [L. Resnick:] I don't know your family history. How's your father? [Interviewer:] He's in good health. Had a bout of prostate cancer, but that's— [L. Resnick:] You have to be on pomegranate juice. You have a 50 percent chance of getting it. Listen to me. It is the one thing that will keep your PSA normal. You have to drink pomegranate juice. There is nothing else we know of that will keep your PSA in check. Ask any urologist—your father should be on it. Your father should be on it. I'm sorry to do this to you, but I have to tell you. We just did a study at	Prostate Basic Science Pantuck Study (2006) (RFF 1661, PX0060) Pantuck Study (2008) (RFF 1676, PX0061) Carducci Study (2011) (RFF 1695, PX0175) PSADT Studies Antioxidant and POM Juice/POMx equivalency studies

	Dissemination Date	Appendix[117]/RFF/RRFF	Overall Net Impression of the Advertisements	Scientific Support
			UCLA, on 43 men … It arrested their PSA. How old are you, 28?	
CX0466/CX1426 Ex. H ("Off to save prostates" Banner Ad)	No date available	Appendix 541-559 RRFF 539-540	Good for prostate health	
CX0473 (Nov. 2008, Lynda Resnick on Martha Stewart Show)	11/20/2008	Appendix 886 RFF 2552-2566 RRFF 570-571	Not advertising; Mrs. Resnick expressing her opinion. To the extent it is viewed as advertising, the research to date would substantiate such claims. Ms. Stewart: But, the medical benefits even outweigh the mythical benefits? Ms. Resnick: Oh, they do, they do. I mean, it's the magic elixir of our age and of all ages, and we know that it helps circulation, it helps Alzheimer's, it helps all sorts of things in the body— Ms. Stewart: Antioxidants. Ms. Resnick: Antioxidants. Polyphenol antioxidants off the chart. Ms. Stewart: Right. Ms. Resnick: And if you know a man that you care about or you are a man, make him drink eight ounces of pomegranate juice a day because what it does for prostate cancer is amazing.	Prostate Basic Science Pantuck Study (2006) (RFF 1661, PX0060) Pantuck Study (2008) (RFF 1676, PX0061) Carducci Study (2011) (RFF 1695, PX0175) PSADT Studies Antioxidant and POM Juice/POMx equivalency studies

III. COMPLAINT COUNSEL IS NOT ENTITLED TO AN ORDER AGAINST RESPONDENTS

Complaint Counsel describe their requested relief as an "entitlement" ("Complaint Counsel is Entitled To The Proposed Order Against Respondents"). However, the law places the affirmative burden on Complaint Counsel to prove, by a preponderance of the evidence, that (1) the requested relief is warranted; and (2) that it is warranted against each of the Respondents against whom they have asserted their claims. *See e.g.*, *Novartis Corp.*, 127 F.T.C. at 749 n.23 (holding that the government has the burden of proving that a remedy is appropriate because "[i]t is well established that '[t]he party seeking to uphold a restriction on commercial speech carries the burden of justifying it" (quoting *Edenfield v. Fane*, 507 U.S. 761, 770 (1993)). They have not met their burden.

A. The Corporate Respondents POM Wonderful and Roll Global Are Not Liable Under the FTC Act

For all the reasons stated in Respondents' previous and concurrent submissions, liability should not attach to any of the Respondents, as no deceptive or misleading conduct has occurred. Moreover, additional reasons exist to deny liability as to Respondent Roll, whose sole basis for being included in the complaint appears to rest on Complaint Counsel's common enterprise or related participation theories. Roll is not liable under either theory.

By Complaint Counsel's own admission, the common enterprise theory exists solely where corporations are so entwined that a judgment of no liability against one defendant would provide another defendant "with a clear mechanism for avoiding the terms of the order." (CCPB at 55 citing *Nat'l Urological Grp.*, 645 F. Supp. 2d at 1182. A finding of no liability against Roll, whose only alleged involvement in the challenged conduct was to provide advertising services to POM through its separate advertising agency, "Firestation," (RFF 64-71), would not provide POM with a clear mechanism for avoiding the terms of any order. The Firestation advertising agency operates like any other advertising agency. (Perdigao, Tr. 616-17). It takes instructions regarding the advertising from its clients, such as POM. (Leow, Tr. 462-63) POM's marketing department, not Firestation, decides whether to disseminate an ad or PR piece.

(Perdigao, Tr. 637, 38). Firestation operates separately from POM and, in fact, services several other companies owned by Mr. and Mrs. Resnick. (Perdigao, Tr. 593-94). Its marketing services provided to POM (and other Resnick entities) are separately billed out to POM (and the various other Resnick companies) and paid for by the distinct entities. (Perdigao, Tr. 616-17). There is nothing in the record to suggest, and certainly not by a preponderance of the evidence, that without attaching liability to the entity, Roll, the terms of an order against POM can be avoided. They cannot. As part of any order, POM is responsible for the conduct of its advertising department.

In addition to the common enterprise theory, Complaint Counsel also seeks an order against Roll because its in-house advertising, public relations, and consulting departments provided services to POM with regard to its advertising and marketing of the Challenged Products. (CCPTB at 54-55). Such an order is neither necessary nor supported by the law as these various Roll departments merely provided services in the same fashion as outside agencies hired for the same purpose would and lacked any knowledge that the science behind the advertising was allegedly unsubstantiated. (RFF 70-71).

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

Here, the undisputed testimony from employees working at Firestation, the consulting department, and the PR department of Roll, is that the science and research to be integrated into the advertisements, press release and the like, came from and was formulated by POM. (Perdigao, Tr. 659-60). None of the various departments undertook to separately examine whether the science was "substantiated" to levels required by the FDA, FTC or any other government agency. (RFF 70-71). Any why would they? The science was peer-reviewed, often

published in prestigious journals, performed by scientists and medical doctors alike, and provided in a form from persons they had had no reason to doubt as to substantiation. (RFF 378-435; 312-45; 266-69). In other words, Roll, like any other agency servicing a client, had no reason to suspect or to investigate that the advertisements may have been deceptive for any reason, let alone that the science given to them was allegedly unsubstantiated.

Accordingly, under the standard set forth in *Standard Oil*, 84 F.T.C. 1401 and *Bristol-Myers Co.*, 102 F.T.C. 21 (1983), Roll cannot be held liable for POM's conduct.

B. The Individual Respondents Are Not Liable Under the FTC Act

Liability should not attach to any of the Respondents under the FTC Act. However, additional reasons exist to dismiss Matthew Tupper from the case. Matthew Tupper has never belonged in this case, yet Complaint Counsel argue that Mr. Tupper should be held individually liable because he "formulated, directed, and controlled the policies, acts or practices of POM." This is simply not true. Complaint Counsel is well aware, that POM is not a public company where the President is typically in complete command. POM is part of a privately held conglomeration of companies, where ultimate decision making authority lies with the owners of POM, Mr. and Mrs. Resnick. (RFF 68, 69, 80, 92-102). Admittedly, Mr. Tupper was a high-level and loyal employee of POM until his retirement last year. (RFF 106) However, the direction and ultimate control of marketing and advertising was never within his purview. (RFF 92-102).

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. *FTC v. Bay Area Business Council, Inc.*, 423 F.3d 627 (7th Cir. 2005). Assuming this threshold is met, individual liability then requires that the individual (1) directly participated in the challenged advertising or (2) had the ability to control it. *See Rentacolor, Inc.*, 103 F.T.C. 400, 438 (1984); *Thiret v. FTC*, 512 F.2d 176 (10th Cir. 1975).

Although the above test is outlined as an either/or test, in practice, liability focuses almost exclusively on the ability to control or limit the offending advertising not whether the individual

actually reviewed or edited or approved the advertising at issue. *See FTC v. Direct Marketing Concepts, Inc. et al*., 624 F.3d 1 (1st Cir. 2010) (finding 50% owner and officer liable because he had the ability to stop the challenged ads); *FTC v. Freecom Comm., Inc.*, 401 F.3d 1192, 1205 (10th Cir. 2005) (finding principal shareholder and decision maker at closely held corporation liable because he had the authority to control the deceptive acts or practices); *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 employees who participated in the dissemination of false and misleading advertisements lacked sufficient control or responsibility for liability).

The ability to control the offending conduct or advertising (i.e., being the ultimate decision maker) is always the key inquiry. *See In the Matter of Universal Electronics Corp., et al.*, 1971 WL 128754 (F.T.C.) (1971); *FTC v. Swish Marketing et al.*, 2010 WL 653486 (N.D. Cal. Feb. 22, 2010); *FTC v. Transnet Wireless Corporation*, 506 F. Supp. 2d 1247, 1261-65 (S.D. Fla. 2007); *FTC v. Verity International, Ltd.*, 335 F. Supp. 2d 479, 499 (S.D.N.Y. 2004); *FTC v. Amy Travel Service, Inc.*, 875 F. 2d 564, 574-575 (7th Cir. 1997); *FTC v. Think Achievement Corp.*, 144 F. Supp. 2d 993, 998-1002 (N.D. Ind. 2000); *FTC v. J.K. Publications*, 99 F. Supp. 2d 1176, 1181-1185, (C.D. Cal. 2000); *F.T.C. v Direct Mktg. Concepts, Inc. et al.*, 624 F.3d 1, 12-14. (1st Cir. 2010).

This standard was developed under the backdrop of individual liability as originally envisioned by the FTC Act: corporate officers may be held individually liable for violations of the FTC Act, 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. *FTC v. Standard Education Society*, 302 U.S. 112, 120 (1937). As the Supreme Court noted, individual liability was only to be used to stop owners of closely held corporations from dissolving the offending corporation and beginning a new one as a means to avoid a FTC cease and desist order. *Id.* at 119. This principle 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, 563-64 (1994) (finding individual who was vice president, treasurer and director liable for distributing solicitation in violation of the FTC Act because he was in charge of the company.).

Mr. Tupper, before his retirement, was involved in several aspects of POM's operations, science, advertisements, and general POM themes. However, none of these aspects were under his ultimate control. (RFF 77-78, 80, 82, 94, 99-102). Mr. Tupper reported directly to Stewart Resnick and had a "dotted line" to Lynda Resnick. (RFF 91-92). In Mr. Resnick's own words, he alone is the "ultimate and sole decision-maker on everything." (CX1367 (S. Resnick, Welch Dep. at 55). Mr. Resnick made it clear at trial that Mr. Tupper had no more authority at POM than was delegated to him. (S. Resnick, Tr. 1870). Mr. Tupper consulted Mr. or Mrs. Resnick for any major restructuring or personnel decisions. (RFF 98). Mr. Tupper did not, independent of the Resnicks, develop marketing direction or decide how the POM Products would be marketed. (RFF 100-101). Instead, Mr. Tupper only implemented the direction once decided upon by the Resnicks. (RFF 100). Lynda Resnick, for example, had the final authority over advertising content and concepts. (CX1368 (L. Resnick, Welch Dep. at 9); L. Resnick, Tr. 93)). Stewart Resnick had the ultimate ability to decide whether any advertisements would be run. (S. Resnick, Tr. 1870; Tupper, Tr. 2975). By no stretch of the imagination is Mr. Tupper the typical ultimate decision making corporate officer who may be subject to liability in FTC cases. *See e.g. FTC v. Publishing Clearing House*, 104 F.3d 1168, 1171 (9th Cir. 1997) (finding individual liability despite claims that individual lacked the requisite knowledge regarding the alleged deceptive practices because he was the President of the company, was ultimately in charge and had the ability to stop the offending practices); *FTC v. Neovi, Inc. et al.*, 598 F. Supp. 2d 1104 (S.D. Cal. 2008) (finding President and Vice President of company liable under the FTC Act because both men had ability to control the offending practices, participated directly, managed corporate affairs); *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 FTC cease and desist order to ensure compliance with the order as these persons were ultimately in control).

1. Any Order Against Mr. Tupper Is Unnecessary And Unreasonable

It would be facially unreasonable to issue injunctive relief against Mr. Tupper in addition to the other Respondents. "Courts have long recognized that the Commission has considerable discretion in fashioning an appropriate remedial order, subject to the constraint that the order must bear a reasonable relationship to the unlawful acts or practices." *In re Daniel Chapter One*, No. 9329, Initial Decision, 2009 WL 2584873 at *101 (F.T.C. Aug. 5, 2009), pet. review denied, 405 Fed. Appx. 505 (D.C. Cir. Dec. 10, 2010) (citing *FTC v. Colgate-Palmolive Co.*, 327 U.S. 374, 394-95 (1965); *FTC v. Ruberoid Co.*, 343 U.S. 470, 473 (1952); *Jacob Siegel Co. v. FTC*, 327 U.S. 608, 612-13 (1946)). There must "be some relation between the violations found and the breadth of the order." *See Country Tweeds, Inc. v. FTC*, 326 F.2d 144, 148 -49 (2d Cir. 1964) (citing *FTC v. Mandel Bros., Inc.*, 359 U.S. 385 (1959); *FTC 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)).

Complaint Counsel is unreasonably overreaching in seeking to extend an Order to include Mr. Tupper personally. The Commission's proposed Order defines "Covered Products" as any food, drug or dietary supplements, including, but not limited to, the POM products. (CX001426_0022). That language, combined with the proscriptions in sections II and III of the Order, would effectively ensure that no company connected with foods, drugs or supplements would ever employ Mr. Tupper, because any finding of individual liability against Mr. Tupper would potentially impact any company he is associated with for the next twenty years. Given the undisputed evidence of Mr. Tupper's inability to ultimately control the conduct at issue, such a penalty would be overly broad, unfair, and constitutionally suspect.

Mr. Tupper did not sufficiently participate in the alleged conduct either. Specifically, Complaint Counsel focuses heavily on POM's early advertisements that ran between 2003 and 2006. (CX1426; Ads in the Record). To the extent any of those early advertisements are

problematic, and warrant an injunction several years after the fact, Mr. Tupper was not engaged in the marketing piece of the science-marketing dialogue during those years. (RFF 88). Prior to 2007, Mr. Tupper had only limited involvement regarding the relationship between science and marketing. (RFF 87).

Finally, even assuming that Mr. Tupper's participation at POM Wonderful was sufficient to show some level of individual liability, the proposed Order, as it relates to him personally, would still be overly broad and without a sufficiently reasonable relationship to the alleged violations. There are three factors which bear on whether the breadth of an order has a "reasonable relationship" to the actual violation: "(1) the seriousness and deliberateness of the violation; (2) the ease with which the claim may be transferred to other products; and (3) whether the respondent has a history of prior violations." *Telebrands Corp v. FTC*, 457 F.3d 354, 358 (4th Cir. 2006) (*citing Stouffer Foods Corp*., 118 F.T.C. 746, 811 (1994)). *See also Sterling Drug, Inc. v. FTC*, 741 F.2d 1146, 1155 (9th Cir. 1984); *Sears, Roebuck & Co. v. FTC*, 676 F.2d 385, 392 (9th Cir. 1982); *Standard Oil Co. v. FTC*, 577 F.2d 653, 662 (1978).

None of the three factors for the required "reasonable relationship" support the order against Mr. Tupper that Complaint Counsel seek to impose. First, POM funded many millions of dollars of scientific research by renowned scientists, resulting in over 70 peer-reviewed publications. (RFF 269). POM and Mr. Tupper rightfully believe in the merits of this science, and that all of the ads that POM has run are adequately supported by the extensive body of science available. (RFF 305). Complaint Counsel contends that the alleged false advertising was "serious" because it involved significant health issues. (CCPTB at 59). However, Complaint Counsel has not provided any evidence of falsity and/or produced competent evidence that the Challenged Products (POM Wonderful 100% Pomegranate Juice, POMx Pills and POMx Liquid) are not nutritious and safe food products.

Nor can Complaint Counsel establish a "reasonable relationship" exists under the second factor -- the ease with which the claims may be transferred to other products. Mr. Tupper, as represented to this Court, has retired; he left POM Wonderful at the end of 2011 and does not

work for any of the Roll companies. (RFF 106-107). He is not in a position to transfer claims to other products and he never had such authority when employed by POM. (RFF 94, 99).

The third factor, a history of prior violations, again cuts powerfully against finding a "reasonable relationship." Mr. Tupper, with years of business experience, has no history of prior violations.

Applying a "reasonable relation" standard, Mr. Tupper does not pose an independent false-advertising threat that could rationally justify his inclusion as a Respondent, particularly now that he is no longer affiliated with POM. Only as a POM employee did Mr. Tupper have any connection to the disputed advertising claims, yet any issued order would have a significant effect on his career for many years to come.

For all of the reasons stated above, Complaint Counsel have not met their burden and cannot show that Mr. Tupper is individually liable for any violation of the FTC Act. As such, no liability should attach to Matthew Tupper and no order should issue against him.

IV. COMPLAINT COUNSEL'S PROPOSED ORDER IS OVERLY BROAD AND BEARS NO REASONABLE RELATION TO THE ALLEGED VIOLATIONS[121]

No order should issue against any of the Respondents in this case. Substantial credible evidence, including under the FTC's "competent and reliable" standard, supports the health benefit claims of pomegranates and the Challenged Products. Complaint Counsel seek unprecedented forms of relief in their proposed order that are overly aggressive, unwarranted, and unconstitutional. Rather than proposing injunctive relief that is rationally-related to the alleged violations, Complaint Counsel seek to punish a broad range of Respondents' products and companies that are wholly disconnected from the alleged violations. Assuming *arguendo*, that an order is issued, at a minimum, the following requested provisions and references sought by Complaint Counsel in the proposed order should be denied:

[121] This Section addresses Section IIIC of Complaint Counsel's Brief. Respondents' response warrants a separate section for the Commission's ease of review.

1. The requirement of prior FDA approval in Part 1 of the Proposed Order. At a minimum, the requirement is both unwarranted and unconstitutional.

2. The specific references in the proposed order to prostate cancer, erectile dysfunction, and cardiovascular disease, including by decreasing arterial plaque, lowering blood pressure, improving blood flow to the heart and prolonging PSADT that as written, suggest that merely citing studies with this language or with these types of references or endpoints conveys "treat," "prevent," or "reduce the risk" claims in a drug sense, that, pursuant to the terms of the Order, require FDA approval. This constitutes an unconstitutional shift in the government's burden of proof.

3. Any reference that suggests by inference that large RCTs are required to substantiate health benefit claims, contrary to *Matrixx*, and contrary to the expert testimony in this matter. *Matrixx*, 131 S.Ct. at 1320 ("[M]edical professionals and researchers do not limit the data they consider to the results of randomized clinical trials or to substantially significant evidence."). Respondents respectfully request that the Commission affirmatively deny in any order that such a fixed RCT requirement exists under *Pfizer* or even the FTC's own "competent and reliable" standard.

4. The definition of "Covered Products" that, as written, would cover products beyond those of POM Wonderful, *that do not concern the pomegranate or the science of pomegranates* and that are very different from pomegranates including but not limited to wine (Justin Winery), citrus (Paramount Citrus), nuts (Paramount Farms), and bottled water (FIJI).

5. The inclusion of Roll and Matt Tupper as Respondents. As previously submitted, while Respondents deny that it is appropriate to issue an order against <u>any</u> Respondent in this matter, and it is especially inappropriate to issue an order against Respondent Roll or Matt Tupper.

6. A 20 year period for the order is unconscionable given that the primary focus of Complaint Counsel's claims in its briefing and at the trial have been advertising that occurred (and ceased) more than 5 years ago.

7. The Commission may and should determine not to bar <u>any</u> speech of Respondents. *See Pearson I, supra*, 164 F.3d at 657 (this tribunal should favor "disclosure over outright suppression."); *Alliance for Natural Health*, 714 F. Supp. 2d at 52-53 ("under the First Amendment commercial speech doctrine, there is a 'preference for disclosure over outright suppression.'"); *Whitaker I*, 248 F. Supp. 2d at 9 ("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.").

8. The Commission may and should determine not to bar any speech of Respondents based on advertisements or claims that have long since ceased. *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 to likely to recur.").

Complaint Counsel desire to impose their first-of-its-kind order against Respondents bears absolutely no relation to the alleged violations and their request for an order should be barred outright. Respondents have a reasonable basis for their claims, as required under *Pfizer*, which properly applied, incorporates the FTC's own "competent and reliable" evidence standard, but not improperly subsumed by it, such that *Pfizer's* other provisions are rendered meaningless. In addition, Complaint Counsel's FDA "prior approval" condition is, on its face, unconstitutional as a prior restraint on protected speech. This Court should reject Complaint Counsel's efforts to interject this requirement in any order, which would, at a minimum, constitute an unconstitutional ban on protected speech.

Despite having wide latitude in structuring remedies, the Commission's discretion to formulate an order is not unlimited. *Standard Oil Co. v. FTC*, 577 F.2d 653, 662 (1978). The order must bear a "reasonable relation to the unlawful practices found to exist", including consideration of the following factors: (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. FTC*, 741 F.2d 1146, 1155 (9th Cir. 1984); *Sears Roebuck & Co. v. FTC*, 676 F.2d 385, 391-92 (9th Cir. 1982); *Standard Oil Co. v. FTC*, 577 F.2d 653, 662 (1978) ("Among the circumstances which should be considered in evaluating the relation between the order and the unlawful practice are whether the respondents acted in blatant and utter disregard of the law, and whether they had a history of engaging in unfair trade practices."). As discussed below, all the factors weigh heavily against the relief sought in the Proposed Order.

A. The Evidence Does <u>Not</u> Establish the Seriousness of Respondents' Alleged Violations

Complaint Counsel argue that Respondents, as a group, have met the "seriousness" prong of the rational relation test by virtue of the fact that the claims relate to significant diseases. (CCPTB at 59). However, the record does not reflect that any consumer suffered adverse health effects from the alleged false advertising. Other than the fact of the alleged deception itself,

which Respondents concede may be actionable if present, no evidence exists of any danger or harm to consumers either by consuming the product or by the allegedly advertising that the product should be consumed as a substitute or replacement for conventional medical therapies, which the evidence clearly shows was never conveyed in the ads. (*See* Reply Ad Appendix; Tupper, Tr. 3018). POM's products are completely natural and derived entirely from the pomegranate fruit, which has been consumed safely for thousands of years. (PX0192-0013, 0018, 0042). Additionally, not only has POM never offered its products as a substitute for medical care, but it has written policies in place, that repeatedly make clear that its products are not to be offered as substitutes for conventional medical care or therapies, and that such a practice would be a cause for termination. (Tupper, Tr. 3018; S. Resnick, Tr. 1871). Indeed, as a matter of practice, in responding to certain of its consumer inquiries, POM affirmatively encourages its consumers to consult with his or her doctor. (Tupper, Tr. 3018-19; CX0308_0003-0005). Accordingly, this is not the situation addressed previously in *Daniel Chapter I.*

Furthermore, assuming *arguendo* that liability is appropriate, in the worst-case-scenario, POM's consumers, and only a small portion of them, could have been only nominally harmed by purchasing the Challenged Products, perhaps in the form of not getting what they paid for, although there is no evidence of this. However, POM's products are low-cost items, conferring relatively very little cost to consumers (or profitability to the Respondents for each individual sale).[122] Unlike the high cost of some drugs, POM Juice sells for only four or five dollars, and POM Pills are sold for less than a dollar each. (CX0221_0007; CX1379_0009-10, *in camera*) Thus, this potential harm, even if it existed, does not itself warrant the outrageously broad order for relief sought by Complaint Counsel and is not "reasonably related" the alleged violations.

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[122] *See Sears, Roebuck & Co*., 676 F.2d 385, 394 (9th Cir. 1982) **(**Court justified multi-product order covering major home appliances stating that the advertising campaign related "to a single widely used, high-cost product".) The court also pointed out that the false and unsubstantiated claims related to a "major ticket item, with great benefit to the merchant but at great cost to consumers." *Id*.

In assessing the seriousness of the violation, Courts have considered, among other factors, the duration and dollar amount spent on advertising, the effectiveness of the advertising campaign and whether or not consumers can assess for themselves the accuracy of the advertising statements. *Kraft Inc. v. FTC*, 970 F.2d 311, 326-27 (7th Cir. 1992).

Between 2002 and 2006, POM only spent approximately 14 million dollars in advertising, which Mrs. Resnick described as a "very very, very very small budget." (CX1362 (L. Resnick, Coke Dep. at 61-62). For every year after 2006, POM spent approximately 10 million dollars or less in advertising not just on the Challenged products but on *POM's entire line of products*, including products not subject to the allegations in the Complaint. (CX1348; Perdigao, Coke Dep. at 47). By comparison, in cases where Courts have affirmed the seriousness of false advertising claims, the investment in advertising involved substantially greater sums than POM has ever budgeted for or spent. *See Bristol-Myers Co. v. FTC*, 738 F.2d 554, 561 (2nd Cir. 1984) (between 1960 and 1973, Bristol-Myers spent over 250 million dollars on advertising its products); *American Home Products, Corp. v. FTC*, 695 F.2d 681, 708 (3rd Cir. 1983) (AHP spent $210 million between 1960 and 1970 advertising Anacin). The alleged "seriousness" of Respondents' alleged violation should not rest on the small amount of money spent by Respondents in advertising POM's entire product line.

Moreover, it is not, as Complaint Counsel argue, apparent that consumers purchase the Challenged Products because they believe the product will "prevent," "treat" or "reduce the risk" of disease in any way that is different than people believe blueberries and a healthy diet may help "treat," "prevent" or "reduce the risk" of disease. (*See* II.D.) Indeed, Complaint Counsel have no such evidence and consumers, in fact, purchase POM's products for a variety of reasons unrelated to health. (PX0356 (Reibstein, Dep. at 114)). There exists absolutely no evidence that approximately 200 million dollars of POM products were purchased to "prevent or treat disease" boldly claimed by Complaint Counsel. In fact, Dr. Reibstein's survey, for example, revealed that a mere 1% of POM's consumers may have purchased POM to prevent, cure, or treat any disease. (Reibstein, Tr. 2493). Additionally, to support their bald assertion that a much larger number of

consumers purchased the product because they believed it was a "silver bullet" against disease, Complaint Counsel cite only to broad sales numbers and to quite literally, a handful of consumer inquiries out of more than 24,000 inquires that POM received, and most of these inquiries primarily asked when or whether a product might be available in a certain location. (CCPTB at 59; CX0485). This is not enough.

The evidence also does not establish that consumers were unable to assess the accuracy of POM's advertisements. *Kraft Inc. v. FTC*, 970 F.2d 311, 326-27 (7th Cir. 1992) (Court considered in its analysis consumers' inability to assess the accuracy of the advertising statements). There is no evidence that POM attempted to confuse consumers, and, if anything, the evidence is just the opposite. POM presents health information in a very simplistic manner. POM presents the research findings succinctly and clearly often by identifying the key study on which the information is based. (PX0436; PX0437; PX0440). POM now also uses direct quotes from a study or refers to the language of the research studies themselves as opposed to making generalized statements about the findings. (*See* PX0436; PX0437). Most significantly, POM's consumers have access to all of the published research sponsored by POM through a related website, whereby each consumer can assess independently the accuracy of the ad statements and look at the studies for themselves. (POM's published research is available at www.wonderfulpomegranateresearch.com). This factor does not weigh in favor of Complaint Counsel.

In determining the proper scope of the Commission's order, Courts also consider the total number of misleading advertisements. *Chrysler Corp. v. FTC*, 561 F.2d 357, 364 (D.C. 1977) (noting Respondents' violations were confined to two out of a campaign of fourteen advertisements). In their post-trial brief, Complaint Counsel revealed for the first time that they were challenging only a very small percentage of POM's overall disseminated advertising. (*See* Appendix A to CCPTB). Indeed, Complaint Counsel challenge only forty-three out of hundreds and hundreds of advertisements disseminated by POM over a period of slightly less than a decade. (*See* Appendix A to CCPTB; RFF 2228-2229.).

Moreover, Complaint Counsel, at trial and, in its briefing, have focused most heavily and based the majority of their case on what Respondents term as "outlier" advertisements *that ceased years ago and are no longer used in POM's marketing or advertising*.[123] 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 is overly broad and not appropriate. *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.").

In addition, some of these advertisements were issued as a result of unintended mistakes or errors in proofreading and were pulled immediately upon discovery. (Tupper, Tr. 1041, 3003). Complaint Counsel have presented no evidence that it is likely that Respondents would run these advertisements again or that Respondents' more formalized advertising review would not eliminate the probability that these inadvertent mistakes would occur again. (Tupper, Tr. Tupper, Tr. 1041, 2977-78, 3003). Thus, an order based, even in part, on these "outlier" advertisements bears no reasonable relation to the alleged violations because Complaint Counsel have failed to demonstrate any likelihood on the part of Respondents to run these or similar advertisements again.[124]

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[123] The "outlier" advertisements include (1) Cheat death (CX0036_0001); (2) Drink and be healthy (CX0016_0001); (3) 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.

[124] "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 144, 148-49 (2d Cir. 1964) (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).

B. The Evidence Does Not Establish the Deliberateness of Respondents Alleged Violations

POM has made many efforts as a company to make certain that any of the benefits communicated to consumers through the advertising messages were both truthful and accurate. Mr. and Mrs. Resnick have designed a rigorous research program and sponsored a large body of diverse studies of the highest scientific integrity. Mr. Resnick consults and meets with scientific experts in their respective fields in order to guarantee the competency and reliability of each of the reports. (RFF 326-27, 329, 333-34, 335-36, 340-45). Mr. Resnick, even when advised by his scientific advisors that the research is good and shows positive or statistically significant results, has, on repeated occasions, double-checked those results by employing the use of blinded independent reviewers. (RFF 436-39, 443). POM has also not advertised every positive research result from every study, and the evidence is that they do not suggest a human benefit until a larger body of scientific evidence is available. (RFF 452-53, 284-90). Even the NIH, for example, has referred to POMx by advising on its website that "Pomegranate Extract May Be Helpful for Rheumatoid Arthritis," which potential health benefit has not been advertised by POM. (*See* nccam.nih.gov/research/results/spotlight/120508.htm). Thus, Mr. Resnick's "reasoned" reliance on the expertise of his scientific experts, with his added doses of restraint, certainly do not suggest a "deliberate" nature to any purported violations of the FTCA.

Complaint Counsel also argue by implication that if Respondents understood that POM's science was not likely adequate for FDA drug approval, then similarly it should have known that its science was not sufficiently credible or sufficiently "competent and reliable" under the FTCA, thus ignoring "warning" signs. To this end, Complaint Counsel cite to a New York Attorney General inquiry letter, NAD findings, an email from NBC, correspondence from Institutional Review Boards ("IRBs"), the FTC inquiry, and a FDA Warning Letter for this proposition. Additionally, Complaint Counsel point to POM's own internal documents examining POM's science, which are also innocuous and which certainly do *not* suggest a deliberate willingness to "flout the law." (CCPTB at 59-60; CX1029; CX1081).

However, as demonstrated below, Complaint Counsel's reliance on these statements and inquiries is misplaced as they certainly do not support an allegation of "continuous, knowing dissemination" of false or misleading claims under *Brake Guard*.[125] In significant part, the third party letters and rulings rely heavily on the FDA drug approval RCT "standards" that Respondents have presented significant compelling evidence establishing that such standards are neither required nor appropriate in this action. Indeed, there exists neither a legal nor scientific basis for such requirements—especially in the context of safe, whole food products like the Challenged Products. Unlike the authorities cited by Complaint Counsel, Respondents have reliable and competent science to support POM's claims, and are not aware of any information suggesting the claims were false or misleading.

1. 2005 New York Attorney General Inquiry

In March 2005, the New York Attorney General sent an inquiry letter to POM asking whether it had substantiation for certain representations made in its advertising. (CX1419_0002). The Attorney General, however, did not take issue with the validity of the underlying science or draw any conclusions about the representations made in the advertisements. (CX1419_0002-0003). Indeed, the Attorney General was simply requesting information about POM's advertising—not advising POM that it was violating the law. (CX1419_0002-0003). Moreover, in April 2005, counsel for POM responded to the letter. That was the last word on the subject--the New York Attorney General never followed up or suggested it had issues with POM's response. (CX1419_0004-0013). *The inquiry letter was sent to POM over five years before Complaint Counsel initiated this action and addresses advertisements that ceased running in that same time period*. For example, the letter addressed "Amaze Your Cardiologist" and "Floss Your Arteries. Daily" advertisements that have not run

[125] *See Brake Guard Prods., Inc.*, 125 F.T.C. 138, 213 (1998) (deliberateness found where record showed "respondents' continuous, knowing dissemination of claims designed to sell their products regardless of whether they had sufficient information to support the truth of these claims, and despite substantial information that they were false").

since 2004 and 2005. (Tupper, Tr. 2996-97; CX1353 (Tupper, Dep. at 131)). If anything, the evidence suggests that POM responded appropriately, at least in part, by making changes in its advertising, which is apparent from a facial review of its most recent advertising. (RRFF 662; 685). Notably, Complaint Counsel also does not (and cannot) cite to any testimony of Respondents' regarding the NY AG inquiry. They only raise this issue for the first time, after one and a half years of litigation, and after trial, here, presenting no evidence, including deposition testimony, in support of their argument that this inquiry is evidence of Respondents' "intentional disregard of the law." Complaint Counsel have not presented evidence sufficient to support the large and severe inferences from the letter alone that they are now asking the Commission to adopt.

2. NAD Findings

In 2005, the National Advertising Division ("NAD") found only that POM did not adequately "qualify" the science that was being described in the "Amaze your cardiologist" and "Floss your arteries" advertisements. The NAD recognized, in part, that the advertisements were supported by competent and reliable science. (CX0037_0010-0011). For example, the NAD expressed satisfaction that Dr. Aviram's 2004 CIMT study, which served as the basis for these ads, was "sufficiently powered and did not find that the number of participants here rendered the results unreliable." (Tupper, Tr. 2983; CX0037_0007; CX0611). The NAD further "acknowledged the promising research, offering encouraging results suggesting that pomegranate juice consumption can offer a wide protection against cardiovascular diseases." (CX0037_0010). Similarly, the NAD also acknowledged that "the role that antioxidant pomegranate juice can play in the reduction in the risk of free radical-related diseases, in particular, *the reduction* of artery-clogging plaque. (CX0037_0010). The NAD also stated that, in connection with the statement "Just eight ounces a day can reduce plaque by up to 30%!" it "*was not an 'establishment claim'* (i.e., a "clinically proven" claim)." (CX0037_ 0007). The NAD also stated in connection with the "Amaze Your Cardiologist" advertisement that it

> "acknowledged that for those individuals in the marketplace that suffer from carotid artery stenosis (severe arterial plaque buildup), elderly or otherwise, the message conveyed contains *valuable information* for that population, information that the advertiser *should be free to tout*."

(CX0037_0009, emphasis added). Despite disagreeing with these aspects of the ruling recommending greater qualified language in its advertising, POM responsibly took the findings into account in its future advertising. (CX0037_0011; Tupper, Tr. 2996). POM, in fact, completely stopped running the "Floss Your Arteries" and "Amaze Your Cardiologist" advertisements in 2004 and 2005. (Tupper, Tr. 2996-97; CX1353 (Tupper, Dep. at 131)). Respondents also began using more qualified language in its advertising. (RRFF 662-665, 685) This 2005 NAD finding certainly does not support Complaint Counsel's position that Respondents flouted the law.

Complaint Counsel, in their Findings of Fact, grossly mischaracterize the advertisements reviewed by the 2006 NAD decision by cobbling together claims and advertisements to construct an argument of notice and intent. (*See*, CCFF 668). For example, Complaint Counsel proposed the following finding of fact:

> "Some of the advertising claims reviewed in the 2006 NAD decision included claims that are found in the "Cheat Death" advertisement ("Cheat death…. [POM Juice] can help prevent premature aging, heart disease, stroke, Alzheimer's, even cancer. Eight ounces a day is all you need.") (CX0036) as well as the "10 Out of 10 People Don't Want to Die" advertisement ("98% of heart attacks are due to atherosclerosis . . . . To keep your heart healthy . . . drink 8 ounces of POM Wonderful Pomegranate Juice.") (CX0029)."

(CCFF 668). However, The 2006 NAD decision did not include a review of the claim "("Cheat death…. [POM Juice] can help prevent premature aging, heart disease, stroke, Alzheimer's, even cancer. Eight ounces a day is all you need.")" and it also did not review the "10 out of 10 People Don't Want to Die" advertisement. Separate and apart from those advertisements the NAD reviewed the claims:

> "[POM Juice] can help prevent premature aging, heart disease, stroke, Alzheimer's, even cancer. Eight ounces a day is all you need."
>
> "Remember: heart disease is America's number one killer. For women as well as men. 98% of all heart attacks are due to atherosclerosis, or too much plaque in the arteries….To Keep your heart healthy:…drink 8 ounces of POM Wonderful Pomegranate Juice."
>
> (CX0055_0001). However, the NAD discussed those claims as they were made in other advertisements—not the Cheat Death or the "10 out of 10" ads. In fact, In fact, the NAD did not even discuss the cited Cheat Death ad (CX0036) or the "10 out of 10" (CX0029) advertisements.

(CX0055_0001).

Moreover, the 2006 NAD ruling found that many of POM's advertising headlines and imagery constituted puffery. (Tupper, Tr. 2983-84; CX0055_0047). The NAD, however, did not making any findings about the validity of the underlying science referenced in POM's advertising. (Tupper, Tr. 2983-84; CX0055_0038-39). While the NAD did find that POM discussed its research in terms that were too general (CX005_0039, 0047), it also found that POM's scientific evidence on cardiovascular health might be sufficient to support more narrowly tailored qualified claims. (CX0055_0047). Specifically, the NAD explained, "Although results of one recent study conducted in vitro in cultured human coronary artery and in vivo in hypercholesterolemic mice tended to show that pomegranate juice may prevent atherosclerosis and may promote a sustained correction of atherosclerosis in vitro and in vivo" that evidence could not support unqualified claims—the type of claims that POM has never made. (CX0055_0045; RFF 2457, 2463, 2465, 2478, 2534, 2542, 2215, 2216, 2347, 2466, 2469). Indeed, the "substantial modification" that the NAD recommended is the very type of qualifiers that POM directly implements in its advertising. (*See, e.g.,* CX0471). Indeed, this position is in direct opposition to Complaint Counsel's position that POM's qualifying terms are inadequate to offset the alleged violations in the advertisements.

Since the 2006 decision, POM has made changes to its advertising in line with the NAD recommendations. (Tupper, Tr. 29858-87). Despite disagreeing with the NAD, POM began

describing POM's research in less general terms as noted by the NAD, as a matter of company policy. (Tupper, Tr. 2986-87). Additionally, as a result of the NAD's decisions, Respondents now also direct consumers back to their website to read the full scientific study. (Tupper, Tr. 2985).

Finally, but significantly, Complaint Counsel's reliance on non-binding, non-judicial NAD decisions to support its "notice" argument, is misplaced here. While it is not clear what "standards" the NAD sometimes evokes, it is clear that Respondents' dispute the appropriateness of requiring two RCTs (one to "duplicate" the previous RCT), as sought by Complaint Counsel and that this dispute goes to the crux of this case. Similarly, rulings by any adjudicatory body (including the NAD) that adopt, in some fashion, a more rigid approach for drug approvals to a fruit or whole fruit product, without recognizing the *type of product* at issue, e.g., apple, pomegranate, blueberry, are not decisions that, in this case, can support a finding of "continuous, knowing dissemination" of false or misleading claims. *See Brake Guard Prods, Inc.*, 125 F.T.C. at 213 ("continuous, knowing dissemination" require for finding of deliberateness) Complaint Counsel's reliance on these NAD decisions is not, therefore helpful under the specific circumstances of this case.

3. 2009 Blood Pressure Statements on POM's Website

Complaint Counsel also point to POM's use of the "Decompress" advertisement on its website in 2009 as evidence that POM continued to make blood pressure claims despite having research results that indicated there was no reduction in blood pressure from the use of POM Juice or POMx. (CCPTB at 60). As a matter of company policy, POM stopped making references to blood pressure reduction several years ago because, although there were encouraging results in some of the early research, POM decided to focus on areas of science there were more fully developed. (Tupper, Tr. 2993-93). Importantly, there is no reference to "blood pressure" in any version of the "Decompress" advertisements let alone in the website caption identified by Complaint Counsel. (CX0103). Moreover, as testified to by Mr. Tupper, Respondents never intended to convey that POM Juice could treat or prevent high blood pressure

by this advertisement. (CX0103_0001; CX0459_0001; Tupper, Tr. 3004, 3005). At trial, Mr. Tupper explained that POM intended to convey that "this is a product that is backed by serious science, and in particular there is some good, encouraging information and promising results" in connection with the sponsored cardiovascular research. (Tupper, Tr. 3005). In the context of the "Decompress" advertisement terms, "be healthy," with the blood pressure cuff served as a visual cue alerting consumers to the fact that POM had sponsored cardiovascular research. (Tupper, Tr. 3005). Complaint Counsel's facial analysis of this advertisement (and every facial analysis by Complaint Counsel) also ignores the dominant fact that the product being advertised is a 100% fruit juice, hardly capable of the interpretation that consuming it will prevent, treat or reduce the risk of disease like a "silver bullet." Thus, Complaint Counsel's reliance on this web advertisement as proof of "deliberateness" is not compelling. (RRFF 442-578).

4. NBC Statements

Complaint Counsel also cite an email discussing NBC's internal guidelines as evidence that Respondents were flagrantly violating the law or that POM was warned that its science was not up to par. (CCPTB at 60; CX0193_0002). NBC's internal guidelines are not "legal" guidelines and, there exists absolutely no evidence before the Commission that suggests what NBC's standards are, if they are fixed, or how they are applied. (*See* CX0193_0001). Moreover, NBC suggested the very type of qualified language that Complaint Counsel argues should be ignored in this case. (CX0193_0002-0003). For example, from the exhibits cited by Complaint Counsel, it appears that at one time NBC revised POM's proposed language "Pomegranate contains powerful antioxidants needed to promote prostate and heart health" to read "Pomegranate contains powerful antioxidants that *may* promote prostate health and heart health." (CX0193_0002-0003) (emphasis added). This does not help Complaint Counsel's position on the proposed order, which asks the Commission to ignore either (1) the effectiveness of qualifiers in POM's current advertising or (2) ignore the possibility of the mandated use of certain qualifying language in POM's health benefit advertising, as an alternative to the more

severe aspects of the proposed order. *Pearson v. Shalala*, 130 F. Supp. 2d 105, 121 (D.D.C. 2001) (court concluded that FDA suppressed First Amendment rights in suppressing Plaintiff's claim rather than proposing a clarifying disclaimer to accompany the claim). NBC also took no issue with and approved the phrase "Pomegranate contains powerful antioxidants needed to keep you health[y]." and "Pomegranate contains powerful antioxidants to keep you healthy." (CX0193_0002 [sic]). Indeed, NBC, unlike Complaint Counsel, did not construe Respondents' representations about their science to mean "clinically proven." (CX0193)

5. Dr. Pantuck's Statements

Complaint Counsel also rely on two emails written by Dr. Allan Pantuck as evidence that POM intentionally disregarded warnings by outside parties that there were problems with POM's advertising. (CX0072; CX1080). Complaint Counsel, however, intentionally distort the meaning of the emails by cherry-picking statements from the documents to artificially construct a story about warning and intent.

No testimony supports Complaint Counsel's inferences. First, Complaint Counsel cite to an August 2006 email from Dr. Pantuck for their argument that Dr. Pantuck was concerned about "POM's misuse of his prostate cancer study in their advertising." (CCPTB at 60). But that is not what happened, and Dr. Pantuck never said that in his deposition or testified to that.

In August 2006, POM drafted a press release that adopted quotes made by Dr. Pantuck in articles featured on WebMD and in the New York Times in July 2006. (CX0071). The title of the August 2006 draft press release was "Wonderful variety pomegranate juice shows promise for prostate cancer." (CX0071_0001). That press release was the basis for the August 2006 email discussion between Dr. Liker and Dr. Pantuck cited to by Complaint Counsel. (CX0071_0001; CX0072). Indeed, Complaint Counsel misconstrue the meaning of the statements made by Dr. Pantuck in the August 2006 email. (CX0072). Dr. Pantuck was not concerned with POM's marketing claims or the further publicizing of his study generally. (CX0072_0001). Dr. Pantuck, in fact, never raised any issue with the substance of his quotes in

an article featured on WebMD that were attributed to him. In the WebMD article, "Pomegranate Slows Prostate Cancer," and Dr. Pantuck there made the following statements:

- "The juice seems to be working[.]
- "Pantuck says that pomegranate juice may allow 65-to 70-year old men treated for prostate cancer to outlive their risk of dying from their cancer."

(*available at* http://www.webmd.com/prostate-cancer/news/20060705/pomegranate-slows-prostate-cancer).

Dr. Pantuck also did not take issue with the following description of his study in a 2006 New York Times Article, also referenced in the email: "Findings from a small study suggest that pomegranate juice may one day prove an effective weapon against prostate cancer." (CX0071_0001; *available at* http://www.nytimes.com/2006/07/04/health/04test.html?scp=1&sq=testing:%20linking%20pomegranates%20to%20prostate%20health&st=cse). Indeed, Dr. Pantuck was not concerned about the claims POM was making about his research—he was concerned about POM's use of his quotes *on POM's website*. He therefore writes, "I am very concerned that my legitimacy will be affected by displaying my name in such a manner: am I a spokesperson for the company, am I independent from the company? I was just quoted in Newsweek saying that POM was not using the study merely to sell juice, now I am on their website making claims?" (CX0072_0001). Thus, the main concern expressed by Dr. Pantuck in this email exchange was that he did not want to be considered a spokesperson for POM, which is what he thought consumers would take away from the website, because doing so might affect his credibility as an objective researcher. (CX0072_0001). Consequently, Mrs. Resnick's statement, which was quoted by Complaint Counsel, that Dr. Pantuck was "not a marketing person" makes absolute sense when her statement is put into this correct context—Mrs. Resnick did not think consumers would take away what Dr. Pantuck though they would – that he would be deemed a "spokesperson" for the Company. (L. Resnick, Tr. 212; CCPTB at 61). His concern was <u>not</u> about a disagreement with the very substantive statements about the health benefits of POM's juice that he made in the articles that were later copied on the press release.

Complaint Counsel also rely on a July 2009 email between Dr. Pantuck and Dr. Liker for the proposition that "Dr. Pantuck has told Respondents that the likelihood of obtaining a drug treatment claim with a PSA endpoint is remote[.]" (CCPTB at 61; Tupper, Tr. 3013; CX1080). This is not a nefarious email. On its face, Dr. Pantuck is conveying to POM that POM would not likely get FDA drug approval based on PSA kinetic changes or PSADT, a surrogate marker not approved by the FDA (although the best marker available). Dr. Pantuck, in fact, shares the same view as POM and recognizes a disconnect between the FDA's position on drug approval and the value of PSADT in a patient care setting. For example, when asked in deposition whether PSADT is accepted by most scientists in the field of prostate cancer, Dr. Pantuck testified that PSADT "from a patient care standpoint, [is] extremely important" but "from a *regulatory drug approval stand point* completely irrelevant." (CX1341 (Pantuck, Dep. at 255)). Complaint Counsel improperly suggest here that Dr. Pantuck warned POM that it could not make a "claim". Nothing can be further from the truth. "Claims" are not discussed anywhere in this email, which was written at the same time POM began assessing its science in anticipation of seeking botanical drug approval from the FDA. (CX1080; Tupper, Tr. 3011). Dr. Pantuck was not sending this email to advise POM that there was a remote likelihood of getting a "drug claim" with a PSA endpoint. (CX1080). Rather, Dr. Pantuck was assessing the usefulness of PSADT and PSA as endpoints in POM's research in the context of the FDA's limited recognition of surrogate markers. (CX1080).

6. Statements from Institutional Review Boards

Complaint Counsel's reliance on requests for Investigational New Drug Applications ("INDs") by university Institutional Review Boards ("IRBs") as evidence of both POM's knowledge and intent to mislead consumers is also unsupported by the record. (CCPTB at 60, 65). Complaint Counsel completely mischaracterize the university requests for INDs as "notice" that its advertisements were making "disease" claims. IRBs do not review advertising. The purpose of an IRB is to review protocols and factors associated with a study and to ensure the safety of the study participants--not to regulate advertising claims. (Dreher, Tr. 578). IRBs have

in the past requested that POM file an IND with the FDA because of the science, i.e., the study design and protocols—not because of POM's advertising. POM conveyed accurately to the IRB that it did not intend to market the POM products as drugs. (CX0774; CX0811; CX0936; CX0975; CX1020; CX1056; CX1340 (Carducci, Dep. at 179-80)). When the IRB looks at the study's endpoints, and it sees that it is measuring effects on a cancer population of participants, for example, it (and/or the FDA) will sometimes request an IND to further ensure the safety of the conduct of the study, regardless of the actual safety of the product. (CX1066-0002). Contrary to Complaint Counsel's outrageously false suggestion that POM refused to comply with FDA requirements until forced to, POM responded appropriately to these requests indicating that, despite the study design, the product was not an "unsafe" drug. There is simply no basis for asserting that POM's dialogue with IRBs regarding the necessity of INDs for the safety of a study design put POM on notice that it was making "disease" claims in its advertising. Moreover, all of the IRBs except for the IRB at Johns Hopkins University were satisfied with POM's response and did not require that an INDA be filed. (CX1340 (Carducci, Dep. at 179-80)).

In addition, the FDA did not require an IND for the Johns Hopkins study because of POM's past or present marketing claims. In response to an email from Dr. Carducci, Dr. Shaw Chen of the FDA wrote, "Whether an IND is required for a marketed dietary supplement depends on the "intended use" in the *proposed protocol*, not on"…"*its marketing history*." (CX1066_0002 emphasis added). Dr. Chen also wrote, "*In your case, even if the company has no plan to make any claim, the objective of the study is to prevent recurrence of prostate cancer*..." (CX1066_0002). Complaint Counsel's reliance on statements made by the IRB that it took issue with "advertising representations" made in connection with the studied products effectively distorts the basic function of IRBs. The IRBs never made any such determination.

7. 2008 FTC Inquiry

Complaint Counsel cite to the 2008 inquiry letter from the FTC to POM (which only addressed POMx, not POM Juice) as evidence of a warning and Respondents' subsequent

disregard of the law. (JX0001). In essence, Complaint Counsel argue that by virtue of Respondents' choice to litigate and unwillingness to settle on the terms proposed by Complaint Counsel, that Respondents are now forever subject to the allegation that they "intentionally" flouted the law. This position is not sustainable logically or constitutionally. The record reflects that the statements in POMs response letter are supported by the evidence, and the vast body of science in support of POM's claims. (CX0967_0004, 0008, *in camera*). Moreover, Complaint Counsel's insistence that POM had study results in its possession that were contrary to or inconsistent with claims that the Challenged Products had heart and prostate benefits is simply untrue. This entire argument is premised on the notion that a null or negation result in a study supports the opposite conclusion of the hypothesis studied. It does not. Complaint Counsel's own experts, in addition to Respondents', testified clearly that Complaint Counsel's theory is not scientifically supported. (RFF 50).

8. 2010 FDA Warning Letter

In February 2010, POM received a warning letter from the FDA expressing concerns about consumer testimonials and the reprints and summaries of the published studies available on POM's website. (Tupper, Tr. 2981-2981; CX0344_0001). However, the FDA 2010 Warning Letter did not take issue with POM's underlying science and, despite disagreeing with the FDA's position, POM responsibly and adequately responded to the letter. (Tupper, Tr. 2981; CX0344; CX0346, *in camera*). POM provided a written response to the FDA stating that it respectfully disagreed with the FDA's contention that POM was marketing its product as a drug by making the studies available on its website. (Tupper, Tr. 2982-83). Additionally, out of an abundance of caution, POM also made other changes to its website in accordance with the FDA's letter. (Tupper, Tr. 2982-83). Indeed, since POM made those changes, the FDA has not expressed any further concerns. (Tupper, Tr. 2983).

Moreover, by its plain terms, the warning letter does not evaluate the scientific studies or assess the strength of the scientific evidence supporting claims made by POM. Indeed, nowhere in the warning letter does the FDA state or even suggest that POM's statements are false,

misleading, or that the scientific studies cited fail to substantiate them. (CX0344). The warning letter also does not establish that POM has violated any law or regulation and has no legal effect as the FDA itself has declared that a "Warning Letter is informal and advisory." FDA, *Regulatory Procedures Manual* § 4-1-1, *available at* http://www.fda.gov/ICECI/Compliance Manuals/RegulatoryProceduresManual/ucml76870.htm. Thus, the FDA's warning letter is certainly not, as Complaint Counsel argue, evidence of Respondents' willingness to violate the law.

9. POM's Candid Self Review of its Science from an FDA Drug Approval Perspective

Complaint Counsel erroneously point to POM's January 2009 Medical Research Portfolio Review, unaccompanied by any deposition or trial testimony from its authors, as evidence that POM knew its science was not sufficient for its advertising. (CX1029). However, as testified to at trial, this document, and others like it, reflect an analysis of the science only from a narrow FDA drug approval perspective, which is not and has never been the standard by which health benefit claims are substantiated under the FTCA. The FDA, unlike the FTC, does not concern itself with whether claims are true or supported by credible or competent and reliable scientific evidence.

As part of its internal preparation to potentially submit an application to the FDA for drug approval, POM reviewed its entire science portfolio to examine whether and to what extent POM's research would meet the FDA requirements for *drug approval*, pursuant to the FDA's current limited recognition of surrogate markers used in POM's research.[126] (Tupper, Tr. 3011). During this preparation, as a discussion piece for an internal meeting with Mr. Resnick and his advisors, Respondent Matt Tupper and POM's Chief Science Officer, Mark Dreher, drafted a document titled, "Medical Portfolio Review" dated January 13, 2009. (Tupper, Tr. 942, 939, 3008-09; CX1353 (Tupper, Dep. at 248-49); Dreher, Tr. 556). Both Mr. Tupper and Mr. Dreher

[126] Again, the fact that POM was interested in obtaining FDA drug approval at this time does not mean that POM believed it was making "drug" claims, but only that it wanted an edge against competitors. (Tupper, Tr. 3007-08).

testified that the document was used solely to evaluate the strength of POM's science under the narrow parameters of FDA drug approval—not for the strength of the science generally, or as support for POM's health claims. (Tupper, Tr. 3008-3010).

Despite ample contrary testimony by the document's two authors that its analysis did not address whether its claims were supported, Complaint Counsel point to the following statement on the page of the review discussing POM's body of cardiovascular research: "Issue: current body of research only viewed as "3" on a scale of 1-10 by MDs" as evidence that Respondents recognized that they "lacked sufficient research to make treatment, prevention or reduction of risk claims" for heart disease. (CCPTB at 60; CX1029_0003). That is not what the document says. The testimony of the only witnesses on this subject, Mr. Tupper and Mr. Dreher, who entered into a consent agreement with the FTC, deny this interpretation, dismantling Complaint Counsel's knowledge and intent arguments.

Both Mr. Tupper and Mr. Dreher testified that the "3/10" reflects the viewpoints of doctors oriented to the FDA's very limited recognition of surrogate markers for FDA drug approval and that the rating does not reflect the strengths of POM's cardiovascular research. (Tupper, Tr. 985-87, 3011; Dreher, Tr. 561-62). Mr. Dreher testified, in fact, that he was personally responsible for putting the "3/10" comment in the document, that they were "comments from a pharmaceutical perspective," and that "MDs" referred to "doctors in the pharmaceutical perspective" and that he was asked to be "as hard as possible" in assessing the body of research. (Dreher, Tr. 561-62). Additionally, Mr. Tupper explained that the assessment was based on the few markers and measures even recognized by the FDA sufficient to warrant drug approval: "if you're the FDA or in fact, if you're one of the cardiologists involved in drug registrational trials, there are essentially a very small handful of measurements that the FDA will rely upon to approve a drug for heart disease." (Tupper, Tr. 3011). Mr. Tupper also testified that this ranking did not reflect the majority of the cardiologists reviewing POM's research, but instead was intended to represent a "subset" of cardiologists focused on pharmaceutical trials and interventions. (Tupper, Tr. 986-87). Similarly, in response to a statement that POM's

cardiovascular research "has holes", Mr. Tupper testified that the reference is a product of POM's interaction with "doctors whose experience is in running drug trials for pharmaceutical drugs" looking for research using endpoints such as "heart attack and stroke" and whose "*skepticism goes up regardless of how strong the body of evidence is beneath it*" because the research is studying a food as opposed to a drug. (Tupper, Tr. 985-86). Putting aside the strict FDA requirements and FDA lens, however Respondent Matt Tupper personally ranked POM's body of cardiovascular science as an eight on a scale of ten when evaluating the caliber of the science generally. (Tupper, Tr. 3012).

Complaint Counsel also cite to the page of the Medical Research Portfolio that assesses POM's body of prostate health research as evidence for the argument that Respondents recognized that the research was not sufficient to substantiate POM's advertising claims. (CCPTB at 60; CX1029_0004). Again, however, the Medical Research Portfolio review just analyzed the possibility of obtaining FDA drug approval, given the FDA's narrow recognition of only a few surrogate markers in connection with such approvals. The point addressed in the document was whether the FDA accepted the surrogate marker, not whether the scientific community did. Dr. Dreher affirmed this reading of these statements at trial and testified: "I believe that was the FDA's position, that it – that they didn't currently accept PSA as a – as an official endpoint for prostate cancer. But I think in the scientific community, PSA is well accepted in the totality of the research." (Dreher, Tr. 564). Mr. Tupper also corroborated Mr. Dreher's trial testimony and further testified that these statements were made because of POM's "belief as to actions, worst-case actions in certain senses, associated with getting a drug approval from the FDA". (Tupper, Tr. 977-78).

Moreover, the assessment of the prostate health research included a statement that POM's prostate cancer research had a "gap," relating to preventing prostate cancer rather than mitigating it. (CX1029_0004). At trial, Mr. Tupper explained that this statement does not accurately assess POM's prostate research because "when you include the in vitro and the preclinical animal studies as well as the general understanding of the biology of the prostate" the research does

"speak to the reduction of risk of the disease, which in men who have not yet been diagnosed could be relevant as well." (Tupper, Tr. 995). As was established at trial, competent and reliable evidence supports the conclusion that the same mechanism shown in the in vitro and animal studies and in the Pantuck and Carducca human studies also showed with a high degree of probability that the Challenged Products inhibit the clinical development of prostate cancer cells in men who have not been diagnosed. (deKernion, Tr. 3126; PX0351 (deKernion, Dep. at 76-77); PX0206 at 12; Heber, Tr. 2156).

Moreover, Complaint Counsel's argument that Respondents recognized that the prostate research could not support POM's research claims is unsupported by the record. Indeed, Mr. Tupper testified that, like the cardiovascular research, he ranks POM's body of prostate health research as an eight on a scale of ten in helping healthy people with regard to prostate conditions and in helping with prostate cancer. (Tupper, Tr. 3012-3013). Additionally, even despite the FDA's narrow recognition of surrogate markers, POM has applied for FDA botanical drug approval through this health indication and believes that it will be successful in obtaining such approval from the FDA.

Furthermore, Complaint Counsel's reliance on assessments made by Dr. Brad Gillespie in his research is similarly misguided as those statements also reflect a review of POM's science from an FDA drug approval lens. (Tupper, Tr. 3014). (CCPTB at 60; CX1080_0006). As part of its shift in direction and interest in pursuing FDA drug approval, Respondents hired Dr. Brad Gillespie as POM's Vice President of Clinical Development in 2009. (CX1353 (Tupper, Dep. at 28)). As a part of POM's process of reviewing the viability of obtaining FDA drug approval, Dr. Gillespie prepared generalized summaries of POM's past research, and it is in one of these summaries that Complaint Counsel point to a statement where he made the following assessments of the erectile health research: "It will be difficult to further publicize existing data as it is relatively weak, and not fresh." (CCPTB at 61; CX1081_0006). Again, this statement regarding POM's erectile research was also made in the context of reviewing the research for FDA botanical drug approval. (Tupper, Tr. 3014). Importantly, Dr. Gillespie was hired, in some

part, because he had experience in working with the FDA on behalf of pharmaceutical companies who were seeking FDA drug approval, and Dr. Gillespie's background was appropriate to help POM explore the possibility of FDA botanical drug approval in connection with POMx. (CX1359 (S. Resnick, Dep. at 29). Indeed, Dr. Gillespie was employed, in part, for the very purpose of candidly assessing the likelihood of obtaining FDA drug approval. Thus, his statements do not support Complaint Counsel's argument that Respondents were on notice of the inadequacies of their erectile health research.

10. Respondents' Alleged "Lack of Remorse"

Complaint Counsel misconstrue POM's concerns about the difficulty of obtaining FDA drug approval, and mischaracterize those concerns as establishing that Respondents knew that POM's science therefore did not support its advertising claims. (CCPTB at 60-61). That is a facial *non sequitur*; Respondents cannot be charged with lack of remorse because of Complaint Counsel's pretense that POM's debate about whether it should obtain FDA approval for drug claims means that (a) POM's advertising actually makes drug claims; and (b) such drug claims are not substantiated under the competent and reliable scientific standard.

As to Complaint Counsel's contention that Respondents should feel "remorse" for what it calls "misleading impressions that POM's advertising allegedly left on consumers," that is outrageous in light of the defense that POM has presented in this action. Respondents are not required to feel "remorse" for disagreeing with Complaint Counsel's mistaken and faulty allegations. Complaint Counsel argues that Mr. Resnick was not remorseful because he testified that if consumers interpret the "Decompress" ad as indicating that POM's juice lowers blood pressure "[i]t's not my problem … it's their problem." (CCPTB at 60). A full quotation of Mr. Resnick's cited testimony shows, rather spectacularly, how misleading and disingenuous Complaint Counsel's contention is:

> Q. So as to the 14 percent of people who are getting this message of lowering blood pressure from the ad, is POM Wonderful committing fraud?
>
> A. No.

Q. Why not?

A. Because they're misinterpreting it. It's not my problem. I mean, it's their problem. First of all, it's -- you know, it's -- it's -- you can -- there's a certain amount of puffery around. By the same token, 86 percent don't see it that way. So, you know, I can't be responsible for everybody's interpretation. We're not talking about 60 percent of the people. We're talking about some small amount.

(S. Resnick, OS Dep. at 310). Mr. Resnick thus was pointing out that even if a small portion of consumers take an incorrect reading of the advertisement away, he cannot be held responsible, because some small portion of consumers always takes away unreasonable interpretations. That is why the law requires analyzing what reasonable consumers take away, not every possible subset of consumer. It is also why the law limits liability pursuant to the puffery doctrine, and tends to interpret such low percentages as evidence that consumers are not misled.[127] And this, incredibly, is what Complaint Counsel presents as evidence of bad intent. Mr. Resnick's opinion was perfectly consistent with the law, and by distorting this testimony as their lead example of Respondent's alleged lack of remorse, Complaint Counsel greatly overreach.

Similarly, Complaint Counsel's reliance on Mr. Tupper's testimony at trial that POM continues to feel comfortable using the results of the Aviram 2004 study after receiving the results of the Davidson CIMT study is not evidence of "lack of remorse." In fact, Dr. David Heber, Dr. Aviram, and *Dr. Michael Davidson* testified in this case that the results of the two studies are consistent with one another and each showed an improvement in risk factors associated with heart disease. (Heber, Tr. 1975-76, 1983-84; CX1348 (Aviram, Dep. at 74);

[127] When evaluating surveys that measure whether consumers are confused or misled, an issue that federal courts have primarily addressed in the context of trademark surveys, "figures below 20% become problematic because they can only be viewed against the background of other evidence weighing for and against a conclusion of likely confusion." 6 J. Thomas McCarthy, *McCarthy on Trademarks and Unfair Competition*, § 32:188 (evidence of likelihood of confusion). Yet even where such other evidence is very strong, the rock-bottom level of consumer confusion or deception that has been found sufficient to serve as evidence of consumer deception was 8.5%: "[t]he lowest reported figure is 8.5% …where other evidence was also strongly supportive." *Id.* In fact, "[w]hen the percentage results of a confusion survey dip below 10%, they can become evidence which will indicate the confusion is not likely." *Id.*, § 32:189. The Seventh Circuit, reviewing cases that found low percentage results, found that a finding of 7.6% consumer confusion is "a factor weighing against [trademark] infringement." *Henri's Food Products Co. v. Kraft, Inc.*, 717 F.2d 352, 220 U.S.P.Q. 386, 391 (7th Cir. 1983).

CX1336 (Davidson, Dep. at 227-28)). Moreover, POM, Respondents, and Dr. Michael Davidson are thrilled with the results of the Davidson study, which showed: (1) a statistically significant benefit at 12 months; (2) showed a statistically significant benefit in the subgroup of high risk patients at 18 months, which participant population reflects tens of millions of people in the United States alone. (RFF 1470). Complaint Counsel's stone throwing and recitation to incomplete and misleading snippets of testimony cannot be the basis for the serious and severe relief they are asking from the Commission.

As to Complaint Counsel's contentions about POM's willingness to "continue making the same claims," the Respondents have presented in great detail the scientific evidence relating to the health benefits associated with consuming pomegranate juice and pomegranate extract. Respondents have introduced numerous eminent medical scientists who have testified about the scientific research at issue, and have set forth what that science shows in their proposed findings of fact. Respondents do not agree that their advertising leaves misleading impressions, and for very good reasons presented in this action believe that Complaint Counsel's case is contravened by the applicable law and science. That belief does not justify injunctive relief.

C. POM's Changes in Internal Procedures To Address and Improve Its Advertising Review Process

In assessing the deliberateness of Respondents' actions, the Commission should also consider the internal procedures that POM used to evaluate its advertisements and science. *Standard Oil Co. v. FTC*, 577 F.2d 653, 663 (1978) (in modifying Commission's order the Court considered the procedures petitioners used to evaluate advertisements before they were aired). The evidence shows that POM's advertising review process has evolved and improved over time. Moreover, Mr. Resnick, in a conscientious and deliberate effort to both obtain the best research and to understand it, is advised by multiple groups of highly esteemed scientists to ensure the competency and reliability of POM's research as a basis for supporting any of POM's advertising representations.

The evidence is also undisputed that POM has improved its advertising review process and now has more formal internal review policies in place to ensure POM's compliance with the law and to help prevent mistakes in its advertising that POM concedes have occurred. (Tupper, Tr. 962, 1041, 2993, 3003). First, POM has made changes in its advertising over the years, in part, as a result of the 2005 and 2006 NAD decisions. Although Respondents disputed the merits of the 2010 FDA Warning Letter, some changes were made as a result of that letter. (Tupper, Tr. 2982-83). Mr. Tupper also testified at trial that the process POM has used to connect the science to the advertising has also changed over time. (Tupper, Tr. 2977-78). Specifically, the process is now more "formalized" and includes a "checklist of individuals who need to review and sign off on those ads, ultimately culminating in a legal review." (Tupper, Tr. 2977-78). Additionally, Mr. Resnick's stated policy on advertising representations that concern specific health conditions requires that (a) the advertising accurately represent the scientific conclusions, and (b) that the supporting science includes published clinical research. (CX1353 (Tupper, Dep. at 134); Tupper, Tr. 2979). This more formalized process also acts as a guard against misleading or unsupported advertising. Indeed, POM's intended goal with this new process is to "ensure that nothing falls through the cracks." (Tupper, Tr. 2977-78).

Additionally, the competency and reliability of POM's research is further ensured by Mr. Resnick's consultations with scientific experts to assess the research results and to set the future directions of POM's research program. (S. Resnick, Tr. 1859; Liker, Tr. 1892-93). Mr. Resnick is advised by multiple groups of scientific experts to assist him in the selection and understanding of the sponsored science. (Liker, Tr. 1889-91). This is a deliberate and disciplined effort by Mr. Resnick to ensure that the integrity of the research program and the resulting science. To this end, Mr. Resnick consults with his internal advisors, attends POM's research summits, and consults with POM's scientific advisory boards in assessing the selection of the studies and ensuring that POM has competent and reliable research supporting the advertisements. (Liker, Tr. 1889-91). Mr. Resnick has also engaged esteemed experts in particularized health or disease areas to ensure that POM's research in these areas (e.g., prostate

and heart) is of the highest caliber. (Liker, Tr. 1889-93). POM's advisory boards are made up by individuals such as the world-renowned cardiologist, Dr. P.K. Shah, Dr. Phillip Kantoff, who runs the Dana-Farber Cancer Institute at Harvard Medical School, and many other revered experts in the fields of prostate and cardiovascular medicine. (Liker, Tr. 1892-93; Kantoff, Tr. 3257).

The competency and reliability of POM's research is further supported by the fact that of the hundred or more studies that POM has sponsored, more than seventy of those have been vetted by esteemed individuals during the peer-review process and published in some of the most revered scientific journals in the country. (CX1353 (Tupper, Dep. at 47-49); Tupper, Tr. 2979-81); Liker, Tr. 1887-88). Respondents relied, in part, on the peer-review process, including the publication in prestigious journals as an indication that the sponsored science was both credible and reliable. (Liker, Tr. 1899-1900; *Daubert v. Merrell Dow Pharms*, 43 F.3d 1311, 1318 (9th Cir. 1995) ("That the research is accepted for publication in a reputable scientific journal after being subjected to the usual rigors of peer review is a significant indication that it is taken seriously by other scientists, i.e., that it meets at least the minimal criteria of good science.")). Complaint Counsel's insistence that Respondents knew that POM's research was flawed and did not provide sufficient support for the representations made in its advertising is unfounded. Indeed, the selection and findings of POM's research has been vetted by experts of the highest integrity and reviewed by some of the best scientific journals in the world, ensuring the excellence, competence, and reliability of POM's research results.

Thus, the overwhelming weight of the evidence does not show that Respondents deliberately and willingly disregarded the law or failed to observe notice that there was something misleading about POM's advertising. *See Sears, Roebuck & Co.*, 676 F.2d 385, 392 (9th Cir. 1982); *see also Kraft, Inc.*, 970 F.2d at 327.

D. The Evidence Does Not Establish the Alleged Violations Are Transferrable

Complaint Counsel have failed to show that the alleged violations are "transferrable" to any of Roll's non-POM products. In order to meet the transferability prong of the reasonable

relation test, Respondents must be proven to have a tendency to engage in violations similar to those challenged here. *American Home Products Corp. v F.T.C.*, 695 F.2d 681, 711 (3rd Cir. 1983)(court modified order where evidence did not support an inclination or tendency to misrepresent non-comparative claims where comparative claims were found to be in violation of the FTCA. The "transferability" prong of the reasonable relation test is not met here because: (1) the Challenged Products make up only a minor component of Respondents' entire line of food and beverage products; (2) the Challenged Products are inherently different from Roll's non-POM's products; and (3) Respondents have no history of making similar advertising claims with respect to the non-POM Roll Products. This overly broad scope is not reasonably related to the alleged conduct and violations. If any order issues, it should be limited to POM Juice and POMx products at issue, and perhaps their derivative products, not Roll non-POM products.

1. The Challenged Products Make Up Only a Small Portion of the Covered Products

In assessing the transferability of the violation, Courts consider the overall number of covered products in relation to the total number of challenged products. *Standard Oil Co. v. FTC*, 577 F.2d 653, 661 (1978) (modifying multi-product order applied to diverse and extensive products). The Challenged Products make up only a minor component of the total number of food and beverage products sold by POM and the other Roll companies. Complaint Counsel challenge claims made in connection with just three of POM's products. (CX1426_0003). But POM alone has approximately 20 or more products, making the total number of Challenged products only a very small percentage of all of the products sold by POM.[128] And POM is just one of the Roll affiliated companies; the others sell a large range of different products that would

[128] These products are 100% POM Juice, POM/Cranberry Blend, POM/kiwi Blend, POM/Nectarine Blend, POM/Blueberry Blend, POM/Cherry Blend, POM/Mango Blend, POM Lite Pomegranate, POM Lite Blackberry, POM Lite Black Currant, POM Lite Dragon Fruit, POMx Tea Blackberry, POMx Tea Lychee Green Tea, POMx Tea Peach Passion White Tea, POMx Pills, POMx Shots, POMx Liquid, POM Fresh, POM POMs Fresh Arils, POM 100% Juice Concentrate, POMx Bars.

potentially be covered by the injunction Complaint Counsel seeks, even though there is no plausible argument for transferability. For example:

- Teleflora (floral wire service)
- FIJI Water (bottled artesian water
- Paramount Citrus (citrus fruits)
- Suterra (pheromone-based pest control)
- Paramount Farms (nuts and nut processing)
- POM Wonderful (pomegranate products)
- Neptune Pacific Line (commercial shipping services)
- Justin Vineyards (winery)

(*See* www.pomwonderful.com/products/ for list of available POM products).

None of these other companies sell products which contain pomegranate. The Challenged Products only constitute a small fraction of the products sold by Roll's affiliated companies.[129] (Product pages available through www.roll.com).

2. The Challenged Products Are Dramatically Different from the Unchallenged POM and Roll Products

In assessing the transferability of the violation, Courts consider whether and to what extent the challenged products are similar to the other products sold. *Standard Oil Co. v. FTC*, 577 F.2d at 661; *see, e.g., American Home Products Corp. v. FTC*, 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). The non-POM Roll companies have nothing to do with the alleged violations, and the products are completely different from the Challenged Products. The Notice Order includes extremely broad fencing-in

[129] These products are Pistachios, Accent Almonds, Almonds, Navel Oranges, Lemons, Valencia Oranges, Clementines, Minneolas, Pummelos, Blood Oranges, Cara Cara Oranges, Grapefruit, FIJI Water, **Red Wines:** Isoceles, Cabernet Sauvignon, Justification, Malbec, Reserve Cabernet, Reserve Tempranillo, **White Wines:** Chardonnay, Reserve Chardonnay, Sauvignon Blanc, Viognier, **Other Wines:** Syrah, 2006 Malbec, Reserve Tempranillo, Svant, **Dessert Wines:** Deborah's Delight, Obtuse, The Sweet One.

provisions (Parts II and III) that apply to all Roll Global companies. Current Roll Global companies include: (1) Teleflora (floral wire service); (2) FIJI Water (bottled artesian water); (3) Paramount Citrus (citrus fruits); (4) Suterra (pheromone-based pest control); (5) Paramount Farms (nuts and nut processing); (6) POM Wonderful (pomegranate products); (7) Neptune Pacific Line (commercial shipping services); and (8) Justin Vineyards (winery). *See* www.roll.com. However, none of the products sold, manufactured, or distributed by any of these companies, other than POM, contain pomegranate or pomegranate derivative and none are either dietary supplements or juice. (*See* list of Roll products as cited in IV.D.1.). Yet the Covered Products, as defined by the Notice Order, include pistachios, almonds, water, citrus fruits, and even alcohol. *Products of the Roll-affiliated companies are so dissimilar from POM's products that it would be arbitrary to use POM's research to understand any components of the Roll-affiliated products, let alone use that research as a basis to support any representations made in connection with those products*. There is also no evidence that any of the Roll companies are attempting to construct a research program similar to, or as extensive as, POM's, nor any explanation from Complaint Counsel about why the other Roll entities would suddenly begin changing their advertising to include the challenged aspects of POM's advertising, or their equivalent.

Moreover, the other Roll companies are engaged in various business relationships with third parties, including cooperatives and joint ventures, which places the other Roll companies in a different situation than the specific entities that have been the subject of this proceeding. The record is not sufficient to justify impairing those third-party relationships with injunctive relief, and there is no reason to believe that the conduct at issue here would be transferred to the other Roll companies. This cuts against a finding of transferability.

Finally, the Order would extend to other <u>future</u> Roll companies as well, including acquisitions and mergers, which further evidences the gulf between the conduct at issue here and the overbroad scope of the Order that Complaint Counsel seeks. There is no reason to believe

that the claims at issue would be transferred to future companies in very different lines of business.

3. The Evidence Does Not Show That the Challenged Claims are Transferrable to Non-POM Products Sold By Other Roll Entities or That Claims That Form the Heart of Complaint Counsel's Case, and That Occurred and Stopped More Than 3 to 8 Years Ago, Are Likely to Be Repeated

Complaint Counsel have failed to show there is any tendency on the part of either Roll or POM to make similar claims in connection with any of Respondents' products that remain unchallenged. Complaint Counsel have further failed to show that the alleged violations are likely to be repeated. *See American Home Products, Corp. v. FTC*, 695 F.2d 681, 711 (3rd Cir. 1983) (court modified order where evidence did not support an inclination or tendency to misrepresent non-comparative claims where comparative claims were found to be in violation of the FTCA).

Although Respondents have sponsored research exploring the health benefits of Wonderful Pistachios and Fiji Water, the affiliated Roll companies have never made any health representations concerning heart, prostate, and erectile health, other than the qualified heart health claim approved by the FDA to market Wonderful Pistachios. Indeed, POM has a history of finding many positive results in its sponsored research but not advertising those benefits until the science is sufficiently developed. (Tupper, Tr. 2979-81).

Complaint Counsel also cite to POM's *unchallenged* health representations as evidence that Respondents have a tendency to engage in future unlawful health advertising. Specifically, Complaint Counsel note that they are not challenging representations concerning Alzheimer's, stroke, premature aging, and sports recovery. (CCPTB at 61). However, Complaint Counsel unsurprisingly fails to mention a reason why these claims were never challenged--*POM has not made them for years*. The advertisements that Complaint Counsel cite to were either never disseminated to the public or only saw the light of day between 2003 and 2006. (CX0016; CX003; CX0036). Additionally, Complaint Counsel cite to purely reactive statements and opinions of Mrs. Resnick during her 2008 appearance on *The Martha Stewart Show* as evidence

that POM made claims about Alzheimer's well into 2008. (CX1426, Exh. E-6). Indeed, POM stopped making references to Alzheimer's earlier because, although POM had sponsored preliminary research looking the disease and the formation of plaques in the brain that ultimately lead to Alzheimer's, POM decided to focus its advertisements on areas of science that were more fully developed. (Tupper, Tr. 2994). Mrs. Resnick's opinions and genuine belief in the Challenged Products is hardly proof that POM continued to make claims about Alzheimer's.

4. The Evidence Fails to Show that Respondents' Health Advertising Was More Than a Minor Component of Respondents' Overall Advertising Strategies

Transferability also is not appropriate when the challenged claims are "peripheral" to the advertising strategy for a product. *See American Home Products, Corp. v. FTC*, 695 F.2d at 711 (in modifying scope of the order and finding that claims made about Anacin were not transferrable to Arthritis Pain Formula the Court reasoned that attempts to misrepresent some qualities of the Arthritis Pain Formula challenged products "seem to have been somewhat peripheral to its advertising strategy, even if such attempts led to serious violations."). POM has always emphasized that the Challenged Products are either 100% fruit products or 100% derived from whole fruit, with nothing added. (Respondent's Ad Appendix). POM has used a variety different advertising campaigns and marketing strategies that are unrelated to health. For example, most recently, POM has again shifted away from health advertising and used history and sexuality to market POM Juice in its 2010 television campaign. http://www.youtube.com/watch?v=uNEdgcmVubk. Thus the challenged claims are relatively peripheral to the advertising strategy for POM's other products like coffee, chocolate bars, and teas.

Moreover, the other Roll-affiliated companies also engage in many other types of advertising campaigns, and the best challenged advertising is extremely peripheral for them, at best. For example, Wonderful Pistachio's have been marketed in humorous television

commercials using controversial figures such as Rod Blagojevich and Levi Johnston.[130] Furthermore, the record is void of any showing that either Justin Winery or Paramount Citrus have ever used *any* health messaging in their advertising.

Thus, Complaint Counsel have failed to show that the alleged violations are "transferrable" to any of Roll's unchallenged products.

E. Respondents Have No History of Past Violations

Despite the collective scale of their respective business activities over many years, Respondents have no history of previous violations. Indeed, the five Respondents have never been party to an FTC proceeding or subject to an order by the Commission in more than fifty years of conducting business. (CX1363 (S. Resnick, Coke Dep. at 15) (Stewart Resnick started his first business in 1955 or 1956)). Nor do any of the various non-POM Roll companies have any history of previous violations. Respondents' long history of operating many companies in diverse business lines without running afoul of false advertising laws is facially incompatible with Complaint Counsel's belligerent demand for broad fencing-in relief that extends across all the Respondents. Complaint Counsel's speculation that Respondents would be "back in litigation in short order" is not just unsupported, it is completely unreasonable given Respondents lack of past violations as determined by any other state or federal regulatory body. (CCPTB at 64-65).

Complaint Counsel thus fail to justify their request for fencing-in relief, which should be denied. *See*, *e.g., Grove Laboratories v. FTC,* 418 F.2d 489 (5th Cir. 1969); *American Home Products Corp. v. FTC,* 402 F.2d 232 (6th Cir. 1968).

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[130] Available at www.buzzfeed.com/akdobbins/levi-johnstons-pistaciho-commercial ad and www.myfoxchicago.com/dpp/news/metro/rod-blagoojevicih-former-governor.pistachios-nuts-commercial-emerald-innocently20101101.

F. Complaint Counsel's New "FDA Pre-Approval Required" Bright-Line Standard For Health Benefit Claims Is Unlawful.

Complaint Counsel urges this Court to adopt a remedy that would require Respondents to seek FDA pre-approval before making certain health benefit claims. *See* Proposed Order, Part I. In their Post-Trial Brief, Complaint Counsel candidly and expressly stated the Commission's strategy in this case: to establish a new "bright-line" standard for health claims that would "significantly increase [the] enforceability" of its Orders. (CCPTB at 64-65). It is true that such a rigid and invariant standard would be more convenient for the agency from a bureaucratic perspective, particularly in the aftermath of the Lane Labs litigation in which a federal district court disagreed with the Commission's assessment of a body of scientific substantiation. But Congress did not permit the agency to shirk its duties in that manner. Such a bright-line standard flatly contravenes the agency's responsibilities under the FTC Act, creates a thoroughly unworkable and unlawful intermeshing of FDA and FTC practice (with attendant unreasonable burdens on food producers), and creates an unconstitutional restraint on speech.

As a legal matter, the Commission has no authority under the FTC Act to require FDA pre-approval for health benefit claims. It is black letter law that only the FDA may enforce the Food, Drug and Cosmetic Act (FDCA) and require approval under its terms. *Buckman Co. v. Plaintiffs' Legal Committee*, 121 S.Ct. 1012 (2001). The Commission's grant of authority in the consumer advertising context is limited to enforcing the specific prohibitions in the FTC Act; it does not have the authority to adopt and enforce the provisions of another agency's statute. Accordingly, while the Commission has statutory authority to prohibit claims that are false, deceptive, or misleading, it cannot, as Complaint Counsel urges, prohibit Respondents from making claims (which may be truthful, non-deceptive, and non-misleading) merely because Respondents have not undertaken the FDA drug approval process. The agency might just as well inquire whether Respondents' delivery staff have current drivers' licenses or are in compliance with myriad other laws and regulations. It has been well-established since the tenure of Chairman Pertschuk that the FTC has no such authority. Indeed, to prohibit Respondents from making claims because they have not been approved by FDA would facially exceed the

Commission's authority under Sections 5 and 12 of the FTC Act, in part, because it would bar truthful claims that for whatever reason were not approved by the FDA. Tellingly, nowhere in Complaint Counsel's lengthy brief does it even attempt to address Respondents' argument, which they have advanced throughout this case, that requiring FDA pre-approval would have the effect of prohibiting non-misleading and non-deceptive claims and would therefore exceed the FTC's jurisdiction under the FTC Act and violate the First Amendment.

Complaint Counsel's attempt to paint its new "bright line" standard as an extension of the Commission's existing jurisprudence, as opposed to a wholly new standard for substantiation, is simply specious. In their public statements, FTC senior staff members have not been shy about the fact that their efforts to implement a new "bright line" standard in proposed orders arose when the Commission litigated -- and lost -- a case before a federal district court in Lane Labs. *FTC v. Lane Labs-USA, Inc*., 2009 WL 2496532 (D.N.J. Aug. 11, 2009) *aff'd and rev'd* in part, by *FTC v. Lane Labs-USA, Inc.,* 624 F.3d 575 (3d Cir. 2010). Instead of being satisfied with the Commission's ability to appeal the district court's decision, almost immediately after the district court's decision in Lane Labs, Consumer Protection Bureau Director, David Vladeck, announced a new standard for advertising substantiation and an effort to adopt new order provisions, apparently designed to usurp the court's independent role and discretion in evaluating the evidence supporting each challenged claim. Following Vladeck's announcement, the Commission entered into three Consent Orders with publicly held food and/or supplement companies that contained the new bright line provision requiring FDA pre-approval for certain health claims with the hope that it could obtain court approval for its new approach in future cases. This is the first case where Complaint Counsel's novel "bright line" FDA pre-approval approach is being tested in litigation.

In the midst of the Bureau's cavalier efforts to require FDA approval for certain health claims, the industry reacted with alarm. There has been a general outcry that the new proposed provisions requiring FDA approval will curtail free, frank, and useful communication about

health benefits and other information absent onerous pharmaceutical testing and pre-approval from FDA.

In sharp contrast to Complaint Counsel's position in this case, the Commission has historically resisted efforts to curtail such communication and has criticized any scheme or regulation by FDA that would prevent the dissemination of truthful information. Indeed, requiring a "bright line" pre-approval standard is a sea change from the longstanding multi-factor inquiry set forth by the Commission in *In re Pfizer Inc.*, 81 F.T.C. 23 (1972) and its progeny. As the Commission and courts have held on multiple occasions, a bright-line standard is not workable given the variety of products, claims, and fields of science that are implicated in the Commission's actions. Indeed, in stark contrast to Complaint Counsel's position in this case, the Commission has expressly rejected requests for such bright-line inflexible substantiation standards for dietary supplements, noting that refinement of the Commission's longstanding "competent and reliable scientific evidence" standard "would result in greater rigidity and overbroad regulation." *See* Letter from Donald S. Clark to Jonathan W. Emord Denying Petition for Rulemaking, November 30, 2000 available at http://www.ftc.gov/os/2000/12/dietletter.htm. Courts have agreed. *See, e.g.*, *Bristol-Myers Co. v. FTC*, 738 F.2d 554, 560 (2d Cir. 1984) ("[A]bsolute precision is not possible in certain FTC orders…."). Most recently, the United States Supreme Court in *Matrixx* declined to adopt a bright-line categorical approach to evaluating the significance and usefulness of medical science and data in evaluating causation. *Matrixx Initiatives, Inc. v. Siracusano*, 131 S.Ct. 1309 (2011). Complaint Counsel's proposal that Respondents seek FDA pre-approval for their claims flies in the face of this well-established law and Commission past practice.

Stretching to find support of its new position, Complaint Counsel cites three consent orders signed by parties and four sentences in the Commission's opinion in *Thompson Medical*. (CCPTB at 63-64). But, the consent orders referenced by Complaint Counsel were not the result of a litigated case where a court heard extensive evidence regarding scientific support for the claims at issue and, to date, no Court has required FDA pre-approval as part of a remedy in a

case under the FTC Act. Complaint Counsel's reliance on *Thompson Medical*-- which involved a medicinal product, not a food -- fares no better. Nowhere in *Thompson* or in any other litigated case has the Commission gone so far as to require that a Respondent obtain FDA approval to substantiate a claim under the FTC Act. In *Thompson*, the Commission merely noted that the evidence that it required Respondents have to make certain treatment claims was consistent with the standards that FDA would require. Here, unlike in *Thompson*, Respondents have a vast body of competent and reliable scientific evidence to support their claims. That Complaint Counsel is proposing a remedy in this case (where Respondents have an unprecedented amount of scientific support for their claims) that is more drastic than in prior cases, including *Thompson*, further demonstrates the misguided nature of the Proposed Order.

Moreover, the United States Appeals Court for the D.C. Circuit rejected Thompson's attempt to argue that the FTC should defer to the FDA with regard to advertising claims, noting the breadth of the Commission's jurisdiction and independent expertise as to claims. *Thompson Medical Co., Inc. v. FTC*, 791 F.2d 189, 192 (D.C. Cir. 1986) ("[T]he FDA will never have occasion to consider the full range of issues dealt with by the FTC in its proceeding against Thompson…. Hence, no conceivable doctrine of deference or expertise would justify awaiting the result of the FDA's over-the-counter drug evaluation program."). That Complaint Counsel is now advocating for a standard that would surrender its independent judgment and jurisdiction over claims to the FDA further illustrates the novel and problematic nature of the proposed remedy. Complaint Counsel's reliance on the Commission's Enforcement Policy on Food Advertising is equally unavailing, as that Policy does not stand for the bold proposal, urged by Complaint Counsel in this case, to delegate its judgment on food advertising claims to the FDA. Indeed, that Statement expressly contemplates that the Commission "will carefully scrutinize health claims for…foods to ensure that the claims are truthful and adequately qualified." The Statement also states that the FTC will not prohibit all claims that do not meet FDA standards. *Id.*

Not only are there multiple legal infirmities in Complaint Counsel's proposed new "bright line" approach, but the factual record also counsels against the proposed remedy. As Complaint Counsel's own experts admitted at trial, there are a variety of types of evidence that can be used to support the claims at issue in this case -- some of which may not be recognized by the FDA's drug approval standards. *See*, *e.g.*, RFF 208-212, 224, 229, 233-236. Complaint Counsel's "bright-line" approach of requiring that Respondents meet FDA approval standards as a pre-condition for substantiation is, thus, not factually supported by the record in this case.

G. Complaint Counsel's New "FDA Pre-Approval Required" Bright-Line Standard For Health Benefit Claims Is Unworkable.

Even if the Commission were legally permitted to adopt and enforce a rigid, bright-line approach to advertising substantiation, the "FDA pre-approval" approach advocated by Complaint Counsel is unworkable. Each of the FDA regulatory routes proposed by Complaint Counsel is very costly and time consuming. The application of those pharmaceutical regulatory procedures to food products is highly questionable and controversial. As the Commission has acknowledged in the past, the FDA imposes virtually insurmountable hurdles to securing approval of health claims. Even when the agency does authorize qualified or even "unqualified" health claims, it generally requires language so long and cumbersome that the claims have no practical value. For these and other reasons, the Government Accountability Office (GAO) recently noted that health claims are rarely approved by the FDA and, even after approval, rarely used in food labeling. GAO Report to Congressional Committees; Food Labeling: FDA Needs to Reassess Its Approach to Protecting Consumers from False or Misleading Claims 12, GAO-11-102 (January 14, 2011), available at http://www.gao.gov/assets/320/314473.pdf.

The Commission has historically taken the position that the FDA's regulatory scheme and priorities are drastically different than the FTC's. Courts have agreed with the Commission and have resisted attempts, ironically often advocated by Respondents, to apply FDA standards in an FTC action. *See Bristol-Myers Co. v. FTC*, 738 F.2d 554, 560 (2d Cir. 1984) ("FDA requirements and regulations ... simply do not govern this case. Not only is a different regulatory

scheme involved, but generally speaking, the FDA is concerned only with evaluating absolute safety and efficacy, and not with questions of comparative safety and efficacy that arise in OTC drug advertising."); *Thompson Medical Co., Inc. v. FTC*, 791 F.2d at 253 (D.C. Cir. 1986) ("[T]he FDA will never have occasion to consider the full range of issues dealt with by the FTC in its proceeding against Thompson…. Hence, no conceivable doctrine of deference or expertise would justify awaiting the result of the FDA's over-the-counter drug evaluation program."). The Commission has never required that Respondents take the drastic and costly measure of obtaining FDA approval as a prerequisite to making a health claim in advertising -- even in cases where Respondents had little substantiation for their claims -- and to do so here would prevent Respondents from making substantiated and truthful claims during the course of a lengthy and expensive approval process, and may prevent Respondents from making such claims altogether.

Moreover, as many experts testified at trial, the FDA's standards for pharmaceutical and over-the-counter drug approval do not and should not apply to food products that are safe and pose no risk to consumers. Respondents' expert, Dr. Miller, testified 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 a more flexible standard than that which would be required for FDA drug approval is appropriate, and that basic science alone can be enough to substantiate health claims. RFF 744. Complaint Counsel's own expert, Dr. Stampfer, testified similarly. RFF 624-628. Complaint Counsel's proposed approach of requiring FDA pre-approval before certain health claims can be made is inappropriate, and most especially so in regards to food products, such as the ones at issue here.

Finally, the cost of obtaining FDA approval for health claims can be enormous, rendering a pre-approval process effectively unworkable for companies that sell natural food products. Food products ordinarily do not come with monopolistic intellectual property rights, like the patent claims that protect pharmaceutical products. RFF 375. Because they have such patent rights, pharmaceutical companies have been willing to spend billions of dollars in getting the FDA to approve drugs. RFF 373. The trials involved in the approval process are often

incredibly expensive. Complaint Counsel's expert, Dr. Stampfer, characterized randomized controlled trials as a "huge expense," and stated that even the very simple ones are "very expensive." RFF 367. Such trials can cost anywhere from 6 to 600 million dollars each. RFF 369. The FDA approval process is simply unworkable for natural health products because a seller of such products cannot recover these enormous costs. Complaint Counsel's proposed approach effectively means that commercial funding of scientific research on nutrition will be silenced, and commercial speech on the health benefits of nutrition will be eliminated except for just repeating the pronouncements that the Federal government elects to make regarding nutrition. Not only is that a draconian and unwarranted result, it far exceeds the FTC's statutory authority to regulate advertising.

H. Complaint Counsel Has Not Met Its Burden To Show That The Claims Cannot Be Adequately Qualified, As The First Amendment Requires Before An "FDA Approval" Prior Restraint Could Be Imposed.

In the landmark *Pearson I* case, the D.C. Circuit held that the government bears the affirmative burden to prove that that no qualification will suffice as a less restrictive alternative to outright suppression of a health claim. *See Pearson v. Shalala*, 164 F.3d 650, 659 (D.C. Cir. 1999) ("*Pearson I*") (applying commercial speech test from *Central Hudson Gas & Electric Corp. v. Public Service Comm'n of New York*, 447 U.S. 557 S. Ct. 2343 (1980)). It is not incumbent on the claim's proponent to establish that its claim may be suitably qualified. *Id.* Moreover, in this analysis, the Court should prefer "disclosure over outright suppression." *Id.* at 657. Even if POM's advertising was found deceptive, Complaint Counsel thus could not obtain an "FDA-approval" prior restraint against Respondents unless Complaint Counsel also established that no qualification could correct the deceptiveness. *See Pearson I*, 164 F.3d at 659; *Pearson v. Shalala*, 130 F. Supp. 2d 105, 112-13, 118-19 (D.D.C. 2001) ("*Pearson II*"); *Pearson v. Thompson*, 141 F. Supp. 2d 105, 112 (D.D.C. 2001) ("*Pearson III*"); *Alliance for Natural*

Health v. Sebelius, 714 F. Supp. 2d 48 at 53, 62, 65 (D.D.C. 2010); *Whitaker v. Thompson*, 248 F. Supp. 2d 1, 14 (D.D.C. 2002) ("*Whitaker I*").[131]

Complaint Counsel have not only failed to satisfy their affirmative burden, they have not even attempted to satisfy it. Complaint Counsel presented no evidence or argument whatsoever regarding using qualification to address the challenged aspects of Respondents' advertising. As a matter of law, Complaint Counsel have therefore failed to establish that Respondents' future health claims may be subjected to the "FDA approval" requirement sought by their proposed order.

Even if Complaint Counsel had attempted to meet their burden, moreover, they would have failed. Complaint Counsel did not establish which specific aspects of POM's advertising convey the alleged disease benefit claims. Instead, Complaint Counsel tried to prove that POM's advertising has *generally* made claims about curing/treating/preventing disease, focusing on the Respondents' alleged subjective intentions. Complaint Counsel thereby failed to establish a factual basis for determining that qualification cannot eliminate that misleading message, as required for the prior restraint they seek.

The government cannot suppress accurate scientific statements simply because some consumers might potentially misunderstand those statements:

> As best we understand the government, its first argument runs along the following lines: that health claims lacking "significant scientific agreement" are inherently misleading because they have such an awesome impact on consumers as to make it virtually impossible for them to exercise any judgment at the point of sale. It would be as if the consumers were asked to buy something while hypnotized, and therefore they are bound to be misled. We think this contention is almost frivolous. We reject it.

Pearson I, 164 F.3d at 655-56; *Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 503 (1996) ("[t]he First Amendment directs us to be especially skeptical of regulations [of indisputably non-

[131] Unable to distinguish this precedent, Complaint Counsel cites only old prior restraint cases that were decided before *Pearson I* and its progeny. (CCPTB at 58).

misleading information] that seek to keep people in the dark for what the government perceives to be their own good").

Any alleged misleading message could certainly be cured by much less restrictive means than requested by Complaint Counsel. Complaint Counsel have overreached, and their request for an "FDA approval" prior restraint against Respondents' future advertising is impermissible.

V. CONCLUSION

Complaint Counsel would like to use this litigation as a vehicle to establish some new and startling propositions of advertising law and Commission jurisdiction, including the following: (a) a blanket requirement for advertisers to obtain virtually unobtainable FDA approval before making health claims for nutritious food products; (b) applying a blanket substantiation standard of randomized, placebo-controlled clinical trials for health claims; (c) a new automatic rule that any reference to "studies" or "research" converts a claim into an "establishment claim" that then must be supported by, again, randomized placebo-controlled clinical trials. Complaint Counsel have provided no rationale for these objectives, and Respondents have demonstrated each is unlawful and contrary to the record in this litigation. Respondents respectfully request the Complaint be dismissed.

Respectfully Submitted,

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Counsel for Respondents

Dated: February 7, 2012

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

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

CERTIFICATE OF SERVICE

I hereby certify that this is a true and correct copy of Respondents' **REPLY TO COMPLAINT COUNSEL'S POST-TRIAL BRIEF**, and that on this 7th day of February, 2012, I caused the foregoing to be served by FTC E-File, hand delivery and e-mail on the following:

Donald S. Clark
The Office of the Secretary
Federal Trade Commission
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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' **REPLY TO COMPLAINT COUNSEL'S POST-TRIAL BRIEF**, and that on this 7th day of February, 2012, I caused the foregoing to be served by e-mail on the following:

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