UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

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

COMPLAINT COUNSEL'S POST-TRIAL REPLY BRIEF

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COMPLAINT COUNSEL'S POST-TRIAL REPLY BRIEF

"Brevity is an essential principle of message creation."

Lynda Resnick, in *Rubies in the Orchard, The POM Queen's Secrets to Marketing Just About Anything* (CX0001_00020)

I. INTRODUCTION

Complaint Counsel will heed Mrs. Resnick's advice and strive to keep this Reply as brief as possible. Despite Respondents' attempt to twist the facts and tangle the analysis in their post-trial filing (which includes a 107-page brief, 2,799 proposed findings of fact, and an appendix containing an additional 618 advertising-related findings), the issues before this Court are straightforward: 1) did the net impression of each challenged ad convey the health establishment and efficacy claims challenged; 2) were the challenged health claims material to consumers; 3) were the health claims false and unsubstantiated as charged; and 4) is the remedy appropriate? As detailed in Complaint Counsel's brief and proposed findings of fact, the answer to each question is yes.

Rather than argue their case following the well-paved path of advertising law, Respondents invite this Court on a trek through precarious terrain where they present a constricted view of ad interpretation, a novel and selective approach to scientific substantiation, and misapplication of the law. Respondents' trail is replete with pitfalls and dead end arguments. In addition, their brief and proposed findings of fact are filled with assertions that are unverifiable (no citation), incorrect, or supported by non-record evidence in violation of this Court's Order on Post-Trial Briefs.[1] The Court should reject Respondents' arguments for the

[1] *See* Attachment A listing Respondents' 300 proposed findings that violate the Court's Order.

reasons set forth in Complaint Counsel's Post-Trial Brief, Proposed Findings of Fact and Conclusions of Law, and this Reply, and issue a decision and order in favor of Complaint Counsel.

II. RESPONDENTS' INCOMPLETE AND INACCURATE ACCOUNT OF THE PARTIES' PRESENTATION OF EVIDENCE (Resp't Br. Section II)

Respondents limit their summary of evidence to the trial testimony of the expert witnesses. (Respondents' Post-Trial Brief ("Resp't Br.") Section II). However, the record evidence includes testimony of 24 trial witnesses (Resp't Br. at 9), as well as 26 deposition transcripts and a wealth of other exhibits replete with party admissions that go to the heart of Complaint Counsel's case.

A. The Fact Witnesses' Trial Testimony

Ten fact witnesses testified at trial (Lynda Resnick, Stewart Resnick, Matthew Tupper, Harley Liker, M.D., Mark Dreher, Elizabeth Leow, Michael Perdigao, Fiona Posell, Jeffrey Rushton, and Phillip Kantoff, M.D.), each of whom had direct knowledge of Respondents' marketing and/or scientific research activities for the POM Products. Numerous of these witnesses offered significant admissions regarding the establishment and efficacy claims conveyed in Respondents' advertising and the materiality of those claims.

For example, Lynda Resnick testified that for marketing purposes, part of the intrinsic value of POM Juice is its power to heal people; that it has been shown to reduce arterial plaque and factors leading to atherosclerosis; and that it has been shown to have a powerful effect against prostate cancer. (CCFF ¶ 283). Mrs. Resnick also admitted that POM emphasized the scientific research in its marketing, and that directly telling consumers in the advertising the amount of money spent on research communicated that the product had gone through rigorous

scientific testing. (CCFF ¶¶ 309, 311). These statements were confirmed by POM's president, Matthew Tupper, and by the creative director of Fire Station, Liz Leow. (CCFF ¶ 310 (Tupper testimony that the purpose of the "backed by" ads was to communicate the seriousness, breadth, and depth of the science); CCFF ¶ 295 (Tupper testimony that the POM ads conveyed serious health benefit messages); CCFF ¶ 306 (Leow testimony that POM included scientific information in advertising to help sell the product because the scientific information gave consumers a "reason to believe")). Mrs. Resnick, Mr. Tupper, and Fire Station executives testified to dissemination of POM Product advertising and promotional materials, including several of the challenged ads. (CCFF ¶¶ 226 (POM Juice cover wraps placed in waiting areas of urologists' offices), 227, 230-31 (POMx Pill ads and brochures), 253-54 (banner ads), 299 (print ads), 256 (social media ads), 265-67, 271-73 (dissemination of marketing-driven public relations promotional materials), 228-29 (Respondents' methods of tracking ad dissemination)).

Several fact witnesses testified at trial on issues pointing to the materiality of the Challenged Claims. For instance, Lynda Resnick, Matthew Tupper, and Michael Perdigao (the president of Fire Station) admitted that ads with more detail regarding science or specific health conditions were more compelling and generated more sales. (CCFF ¶¶ 636-37). At trial, Mr. Tupper admitted that POM continued to run advertisements promoting a 30% reduction in arterial plaque purportedly shown by the Aviram CIMT/BP Study (2004) even after POM was aware, as early as 2006, of the inconsistent results of the Davidson CIMT Study (2009). (CCFF ¶ 420). Mr. Tupper testified that POM did not make any specific changes to its marketing in response to receiving a warning letter from the FDA about drug claims for POM Juice and POMx or in response to receiving a letter from the FTC expressing concerns about POMx advertising claims. (CCFF ¶ 684; *see also* CCFF ¶¶ 678, 681-82 (letters from FTC, FDA), 691

(Mrs. Resnick testified that if she had heard of Dr. Pantuck's concerns about POM's use of his prostate cancer research in advertising, she would have disregarded the concerns because Dr. Pantuck "is not a marketing person")).

B. The Expert Witnesses' Trial Testimony

1. Respondents' Experts

Notably, Respondents' science experts failed to provide direct testimony on the adequacy of Respondents' research to substantiate the Challenged Claims – that the POM Products treat, prevent, or reduce the risk of heart disease, prostate cancer, and erectile dysfunction and that science establishes these benefits. (*See, e.g.*, CCFF ¶¶ 146-47, 729-32, 746, 750, 754 (Respondents' experts not asked to opine on Challenged Claims)).[2]

Respondents called as a substantiation standard expert, Dr. Miller, who admitted that he did not actually evaluate any of Respondents' advertising claims, nor was he asked to evaluate any of the science, and that he based his opinion on a legal advocacy paper provided to him by Respondents. (CCFF ¶¶ 1114-16). He testified that Respondents do not need well-controlled human clinical trials (RCTs) to substantiate whatever unspecified claims they make for the POM Products because they are "safe, pure fruit products." (Miller, Tr. 2194). This contradicts Dr.

[2] To the extent that Respondents' experts testified that Respondents' research substantiated the Challenged Claims, they were only willing to provide highly qualified opinion testimony. (*See*, *e.g.*, Heber, Tr. 2012-13 (POM likely to lessen risk of CVD and ED, likely to defer prostate cancer recurrence, likely to lower prostate cancer risk); Ornish, Tr. 2354 (his studies showed that POM lessens risk of and prevents CV problems); deKernion, Tr. 3061 (POM likely to improve chances of avoiding or deferring recurrence, likely to inhibit clinical development of prostate cancer in men never diagnosed); Burnett, Tr. 2255 (likely that POM Juice has beneficial effect on erectile function); Goldstein, Tr. 2605 (reasonably competent science to show POM Juice reduces the risk of or ameliorates erectile dysfunction if caused by endothelial dysfunction, blood flow impairment, or oxidative stress)).

Miller's 2009 testimony in *Daniel Chapter One*, in which he explained "that in order to constitute competent and reliable scientific evidence that a diet supplement treats, cures, or prevents cancer, the products' efficacy and safety must be demonstrated through controlled clinical studies (tests on humans)." (CCFF ¶ 1112).[3] Indeed, in *Daniel Chapter One*, Dr. Miller testified that a cancer treatment claim for *orange juice* – a safe, pure fruit product not unlike pomegranate juice – would require such scientific evidence. (CCFF ¶ 1112). Dr. Miller's testimony in this matter defies credulity.

Respondents claim that their nutrition expert, Dr. Heber, opined that POM's unspecified health claims can be properly substantiated without RCTs.[4] Dr. Heber's current "expert" opinion is fascinating, given that he testified he never advised Respondents during the entire nine years he has been on "retainer" as their scientific advisor that they need not spend their money on RCTs. (CCFF ¶¶ 724, 1110). In fact, he helped Respondents plan their research strategy and next steps, including their sponsorship of eight completed RCTs pertaining to the diseases at issue, three of which were conducted by Dr. Heber himself.[5] Dr. Heber and Respondents,

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[3] *See also Daniel Chapter One*, No. 9329, 2009 FTC LEXIS 157, at *110 (Aug. 5, 2009) (Dr. Miller's report stated that "[o]nly data from well-designed, controlled, clinical trials will substantiate a claim that a new therapy is safe and effective to treat, cure, or prevent cancer").

[4] Respondents also claim that he said RCTs are "expensive and often unreliable in dealing with foods, as opposed to drugs." (Resp'ts' Proposed Findings of Fact ("RFF ¶ __") ¶ 125). In fact, Dr. Heber did not use the term "unreliable" when describing RCTs on foods. Instead, he said that RCTs should not be required because they have "drawbacks." (Heber, Tr. 1949-50).

[5] RCTs on heart and erectile endpoints sponsored by Respondents during Dr. Heber's tenure include those discussed in CCFF ¶¶ 824-54 (Ornish MP Study), 855-71 (Ornish CIMT Study), 879-911 (Davidson CIMT Study), 912-19 (Davidson BART/FMD Study), 929-45 (San Diego Study), 946-49 (Heber/Hill Diabetes Studies (two)), 1063-78 (Forest ED Study). Dr. Heber himself conducted the San Diego and Diabetes studies. (CCFF ¶¶ 929, 945). Additionally, Dr. Heber has conducted RCTs for Respondents on cognitive function and sports performance. (*See* CCFF ¶ 1110).

however, failed to submit the results of his studies for publication after obtaining null results. (CCFF ¶¶ 933, 938, 948-49). Dr. Heber also admitted that he is not an expert in cardiovascular disease, cardiovascular disease treatment, prostate cancer treatment, or erectile dysfunction treatment. (CCFF ¶ 728). Dr. Heber's testimony suffers from his close and longstanding relationship with Respondents. Dr. Heber's Center for Nutrition at UCLA and his University Medical Research Foundation have received more than $2.7 million from Respondents. (CCFF ¶ 724). His hypocritical view of a substantiation standard that allows him to discount and ignore the very research he condoned and participated in on behalf of Respondents lacks credibility.

According to Respondents, their cardiovascular science expert, Dr. Ornish, opined that "the totality of Respondents' scientific studies conducted on the cardiovascular system convinces him that pomegranate juice is effective in reducing the risk of cardiovascular problems." (Resp't Br. at 12). Dr. Ornish, however, testified at trial that his opinion was based on just the two studies that he conducted for Respondents (Ornish MP Study and Ornish CIMT Study). (Ornish, Tr. 2354-55). Perhaps his direct testimony was limited by Respondents to this narrow analysis because in his report and deposition, his basic views of Respondents' heart studies were in keeping with those of Complaint Counsel's expert, Dr. Sacks. For example, Dr. Ornish described the two human cardiovascular studies by Dr. Aviram, which Respondents rely on and feature in their advertising, as limited, uncontrolled, and inconclusive. (CCFF ¶¶ 804, 807, 816, 820). Dr. Ornish agreed that the Davidson CIMT Study showed no significant differences in CIMT progression rates between the active and placebo groups. (CCFF ¶ 905; PX0025 (Ornish, Report at 0019-20)). Finally, during cross examination, Dr. Ornish testified that he was the one who encouraged Respondents to conduct RCTs. (Ornish, Tr. 2386). He also testified that RCTs

are the best evidence of a causal link. (CCFF ¶ 771). Certainly, Dr. Ornish did not testify that his studies proved that POM Juice reduces arterial plaque or blood pressure, or provided evidence regarding POMx. (*See* Ornish, Tr. 2354-55).

Respondents argue that their experts in sexual medicine, Drs. Burnett and Goldstein, opined that POM Juice improves or can aid erectile health and function. (Resp't Br. at 12-13). Respondents omit relevant information in describing their ED experts' opinion and testimony. (Resp't Br. at 61-62). Dr. Goldstein identified antioxidant effects on endothelial health as a "hypothetical mechanism through which pomegranate juice promotes erectile health." (PX0189-0008, 0013 (stating that the basic research studies suggest a "probable benefit of pomegranate juice on erectile health")). Dr. Goldstein also limited his opinion to the use of pomegranate juice in the doctor-patient relationship and specifically noted that he was not discussing the use of the juice in the context of a consumer "who just goes to . . . a supermarket and just drinks pomegranate juice for no reason." (CCFF ¶¶ 1094-95). According to Drs. Burnett and Goldstein, one cannot infer efficacy for treatment of erectile dysfunction in humans based on Respondents' *in vitro* and animal studies on nitric oxide. (PX0349 (Burnett, Dep. at 56-57); Goldstein, Tr. 2644 (stating that you have to study humans to make statements about humans)). Dr. Burnett stated that claims that a product treats ED would require support by two to three RCTs. (Burnett, Tr. 2262-66). According to Dr. Goldstein, data from RCTs provide the best evidence of a causal relationship between a nutrient and a disease outcome in humans. (CCFF ¶ 771). When asked, Respondents' ED expert, Dr. Burnett, agreed with Complaint Counsel's expert, Dr. Melman, that there was insufficient evidence to conclude that drinking eight ounces of POM Juice daily treats, prevents, or reduces the risk of erectile dysfunction in humans. (Burnett, Tr. 2300-01; CCFF ¶ 1088).

According to Respondents, their prostate expert, Dr. deKernion, concluded that "there was a high degree of probability that . . . POM products lengthened PSA doubling time and, thus may defer death from prostate cancer." (Resp't Br. at 14). However, at trial, Dr. deKernion admitted that many men with increases in PSA after initial therapy do not die of prostate cancer, and there are no studies demonstrating that modulating PSADT, as POM Juice and POMx appeared to do in the Pantuck and Carducci studies, changes the natural history of prostate cancer by delaying the development of metastases or death from the disease. (deKernion, Tr. 3088, 3093; CCFF ¶¶ 978, 983). Respondents fail to acknowledge Dr. deKernion's concession that even where the *in vitro* and animal evidence is strong and shows that an agent's mechanism of action works, this evidence does not prove that the agent works in humans. (deKernion, Tr. 3063-64).

Respondents offered a linguistic expert, Dr. Butters, who testified about ad meaning, and Dr. Reibstein, a marketing expert who conducted a purchase motivation study. According to Respondents, Dr. Butters concluded none of Respondents' ads explicitly or implicitly stated that the POM Products treat, prevent, or cure disease. (Resp't Br. at 14-15). However, at trial, Dr. Butters testified that a reasonable viewer could take from specific challenged ads (CX0016, CX0274)[6] that POM Juice can reduce or help reduce the risk of heart disease or protect prostates from disease. (Butters, Tr. 2900-01, 2929-30). He also stated that the Rated X POMx Ad (CX0351/CX0355) meant POMx "was suppose to correct erectile dysfunction." (Butters, Tr. 2946). He conceded that imagery in the challenged ads could symbolize drugs and medicine (Butters, Tr. 2944, 2947; *see* CX0033 displaying intravenous drip bottle; CX0396 displaying

[6] CX0274 was identified at trial as CX1426_0029.

caduceus medical symbol), that the quotations from doctors and a cited journal could affect how consumers viewed the study and its implications, and that the term "medical research" which appears in numerous challenged ads, has a very strong positive connotation for consumers. (CCFF ¶¶ 312, 615).

Respondents assert that Dr. Reibstein's market survey demonstrated that very few consumers would buy POM Juice based on a belief it cures or prevents a specific disease. (Resp't Br. at 15). Dr. Reibstein's survey, however, failed to expose consumers to the challenged ads or the Challenged Claims, failed to ask follow-up questions to consumers who responded they would buy POM Juice because it is "healthy," and did not address POMx ads. (CCFF ¶¶ 654, 657-61). Most importantly, Dr. Reibstein testified that, in fact, the Challenged Claims would likely be important to consumers' purchase decisions. (CCFF ¶ 638). Thus, his opinion based on his flawed survey is undermined by his own pragmatic testimony that the challenged claims are material to consumers.

2. Complaint Counsel's Experts

Contrary to Respondents' assertions (Resp't Br. at 15-17), Complaint Counsel's expert witnesses on substantiation (Dr. Meir Stampfer, Dr. Frank Sacks, Dr. James Eastham, and Dr. Arnold Melman) and rebuttal experts on claim interpretation and materiality (Drs. David Stewart and Michael Mazis) offered highly relevant and instructive opinions during their testimony and in their reports. Drs. Stampfer, Sacks, Eastham, and Melman specifically addressed the level of scientific substantiation experts in the field would expect to support the Challenged Claims and opined that Respondents' science does not meet it. Rather than reiterate these opinions here, we direct the Court's attention to Section II.C of Complaint Counsel's Post-Trial Brief and Sections VII.C.4, D.4, E.3, and F.1 of Complaint Counsel's Proposed Findings of Fact. *See also infra*

Section IV. Dr. Stewart and Dr. Mazis testified about the flaws in Dr. Butters' and Dr. Reibstein's analyses, respectively, that render their opinions of little value to the Court. Again, we direct the Court's attention to Sections V.G.2 and VI.D of our Proposed Findings of Fact, which outline our experts' opinions. *See also infra* Section V.F.

III. RESPONDENTS' SELECTIVE DESCRIPTIONS OF THE POM PRODUCTS, THEIR SCIENCE PROGRAM, AND THEIR APPROACH TO ADVERTISING (Resp't Br. Sections III-V)

A. The "Whole" Story: The Manufacturing of the POM Products and Marketing as Drugs (Resp't Br. Section III)

While POM Juice and POMx are derived from pomegranates, they are not "whole fruits" (Resp't Br. at 19) – *i.e.*, fruits with little or no processing or refining.

(CCFF ¶ 124). Prior to sale, the concentrate is reconstituted with water and pasteurized to create POM Juice. (CCFF ¶ 125). The final "100%" juice contains over 85 percent water, 10.6% total sugars, and 0.2-1.0 percent polyphenols. (CCFF ¶ 125). Unlike a fresh pomegranate, POM Juice does not contain dietary fiber or vitamin C. (CCFF ¶ 126). POM Juice also does not qualify as "healthy" under FDA labeling regulations because it does not contain at least 10% of the daily value of vitamins A for C, calcium, iron, protein, or fiber, nor does it fall within the fruit and vegetable exception to those regulations. (PX0268_0002). A serving (8 ounces) of POM Juice contains 140 calories and 34 grams of sugar – the sugar content of two and a half pomegranates. (CCFF ¶¶ 127, 129).

POMx is even further removed from its pomegranate "whole fruit" roots. Respondents admit it is not a conventional food under FDA definitions, but a dietary supplement. (PX0268_0002). Whereas POM Juice contains a variety of polyphenols, including 80-90% ellagitannins and gallotannins, 8-15% anthocyanins, and 2-5% ellagic acid, POMx, because of

the production process, contains no anthocyanins. (CCFF ¶ 130). Thus, due to their manufacture and processing, neither POM Juice nor POMx are "whole foods" like broccoli or blueberries as Respondents would have this Court believe. (*See* Resp't Br. at 72-73; *see also* discussion Section V, *infra*).

Respondents are quick to distance the advertising and marketing of the POM Products from those of over-the-counter (OTC) drug products, such as Tinactin (for athlete's foot) and Ben Gay (topical pain relief). (Resp't Br. at 18-19). While the POM Products may appear in a different aisle of the grocery store than these OTC products, their advertising and labeling are regulated under the same laws – the FTC Act (false and deceptive advertising) and the Food, Drug, and Cosmetic Act (*e.g.*, misbranding), which by their nature are structured to examine *the claims* made for the products. Indeed, the Court in *FTC v. QT, Inc.* found that because the Defendants made a medical, health-related claim for their inert, harmless bracelet, the Court saw no difference between the QT advertising and the advertising for Tylenol – both requiring a heightened level of substantiation. 448 F. Supp. 908, 961 (N.D. Ill. 2006), *aff'd*, 512 F.3d 858 (7th Cir.). Despite Respondents' protests that they have not marketed the POM Products as drugs, the FDA reached a different conclusion in 2010. In its warning letter to the company, the FDA wrote "[b]ased on *claims* made in the labeling for this product on your website, we have determined that your POM Wonderful 100% Pomegranate Juice product is promoted for conditions that cause the product to be a drug." Likewise, FDA found that "*therapeutic claims* [for POMx] on your [pompills.com] website establish that these products are drugs because they are intended for use in the cure, mitigation, treatment, or prevention of disease." (CCFF ¶ 681; CX0344_0001) (emphasis added)). As a result, FDA cited POM for marketing the POM Products as unapproved and misbranded drugs. (CX0344_0004). As charged in the Complaint,

the Commission has also alleged that Respondents advertised the POM Products to treat and prevent specific disease conditions such that the claims cause the products to fall under the definition of a "drug" found in Section 15 of the Federal Trade Commission Act.[7]

B. Respondents' Investment in Scientific Research Is Not a License to Make Deceptive Claims (Resp't Br. Section IV)

Section IV of Respondents' brief emphasizes that the Resnicks have invested more than $35 million in scientific research with prestigious institutions and researchers, and this investment has resulted in over 100 pomegranate studies, including 17 published human studies. (Resp't Br. at 21). This mantra is uncannily similar to that found in the vast majority of Respondents' challenged marketing directed to consumers concerned about their health. (*See, e.g.*, CCFF ¶¶ 380 ("Only P♥M is backed by $25 million in medical research conducted at the world's leading universities"), 415 ("P♥Mx is made from the only pomegranates backed by $25 million in medical research at the world's leading universities")).

However, quantity and a running expense tab do not equate to scientific results of the quality necessary to support Respondents' claims. (*See* CCFF ¶¶ 950-65, 1037-42,1074-95). For example, of the 44 institutions noted by Respondents as conducting research, two institutions – UCLA (including Dr. Heber) and Technion Institute (including Dr. Aviram) – combined are responsible for forty percent of Respondents' studies. (Complaint Counsel's Response to Respondents' Proposed Findings of Fact ("CC Resp. to RFF ¶ __") ¶ 268; CX1241; *see also* CCFF ¶¶ 319-24). Dr. Heber and Dr. Aviram have been on "retainer" as Respondents' scientific

[7] Complaint Counsel addresses Respondents' argument about the safety of the POM Products in Section IV.A, *infra*.

consultants since 2003, resulting in payments to them or their institutions in excess of $2.7 million and $4 million, respectively.[8] (CCFF ¶¶ 724,790).

Although Respondents claim to have 17 published human studies (Resp't Br. at 21), they have never provided a clear answer to the Court about how many human RCTs they have commissioned, completed, submitted for publication, had rejected from publication, or chosen not to publish, and the total cost of these studies.[9] (Liker, Tr. 1905-06). In the areas of heart disease and ED, we know that approximately eight RCTs were completed,[10] but only four were published: the Davidson CIMT study (CCFF ¶ 882) and the Forest ED study (CCFF ¶ 1063) are negative studies, the Ornish MP study (CCFF ¶¶ 834-37) contains only interim partial positive results, and the Heber San Diego Overweight study (CCFF ¶¶ 933-38) failed to publish the negative antioxidant results from the study. The other four studies – Ornish CIMT (CCFF ¶¶ 855-57), Davidson BART (CCFF ¶¶ 912-17), and the two diabetes studies (CCFF ¶¶ 946-49) –

[8] The consulting fees and research money paid to these two doctors are included in the $35 million "backing" Respondents' claims. Additional amounts were paid to UCLA for research conducted by Dr. Pantuck. (CX1276).

[9] Respondents claim that they do not interfere with publication of their research, but this position is inconsistent with many of the research contracts, which required the researchers to get Respondents' permission prior to publication of any results (*see*, *e.g.*, CX0665_0005; CX0613_0003); with the fact that Mr. Resnick refused to allow the Davidson CIMT study to be published for over two years (CCFF ¶¶ 892-98); and with several action points listed in the 2009 Medical Research Summary that stated, as one example, "[i]f positive, publish and communicate results aggressively." (CX1029_0006).

[10] Respondents' argument that the cost of RCTs is too great is belied by their own experience. The well-conducted 289 person Davidson study cost roughly $2.9 million. (CCFF ¶ 378). The Forest ED study that Respondents refused to fund properly cost under $300,000 (CCFF ¶ 1063); the two Ornish studies that were purportedly underfunded cost $1.2 million (CCFF ¶ 823); and the Carducci study, which Respondents refused to fund as designed with a placebo arm, cost $97,000 (CCFF ¶ 1013). The problem appears not to be the expense of the studies, but with Respondents' self-described "scatter gun" approach to research. (S. Resnick, Tr. 1711).

that were not published had negative results. In the prostate cancer area, Respondents have commissioned four human studies, including two RCTs. (CCFF ¶ 1026). The RCTs have yet to be completed, even though they began in 2006 and 2008. (CCFF ¶¶ 1026, 1033). The Pantuck Phase II published study touted in Respondents' ads is an exploratory study and not an RCT. (CCFF ¶ 992). Their human dose response study has been completed, but not yet published. It showed no dose response despite a three-fold difference in dosage – an indicator that the active agent is not efficacious. (CCFF ¶¶ 1017-25). The trends observed in these studies in totality do not support the Challenged Claims.

Respondents and their litigation experts turn a blind eye to the material weaknesses of the research that scientific experts, including the peer reviewers and the study authors, acknowledge. Instead, Respondents imply that because they have vetted some of their research through the peer review process, this validates their science as rigorous enough to support the Challenged Claims. (Resp't Br. at 22-23). On the contrary, both the peer review comments received and the peer edited studies themselves support Complaint Counsel's experts' views that the research is not accepted by the scientific community as establishing a basis for Respondents' claims. For example, the Ornish MP Study was rejected by two peer-review journals. Among the reasons cited were that: 1) "[m]ultiple qualified, blinded graders scored this abstract below acceptable range"; and 2) "the study appears very preliminary, with small sample size, apparent baseline imbalances between groups, use of an intermediate endpoint as main outcome measure, and modest differences with large variability." (CCFF ¶¶ 840-41). These peer reviewers' opinions are virtually identical to Dr. Sacks' and Dr. Stampfer's concerns with the study. (CCFF ¶¶ 843-54). Subsequently, the editor of the *American Journal of Cardiology*, a friend of Dr. Ornish, accepted Dr. Ornish's manuscript *without* peer review. (CCFF ¶ 842).

The Davidson CIMT study was only published in the *American Journal of Cardiology* after Dr. Davidson revised his manuscript to address concerns raised by peer reviewers that the study needed to be reported as a negative study "as it is," and that Dr. Davidson had not conducted any statistical correction for the multiple comparisons run on the subgroup analyses. Thus, the discussion section of the report emphasizes the possibility of Type I error, the exploratory nature of the findings, and cautions in interpreting the subgroup analysis. (CCFF ¶¶ 890-91). Again, Dr. Sacks' opinions track the peer review comments as well as Dr. Davidson's own revisions to his report. (CCFF ¶¶ 887, 903-11).

The Pantuck Phase II prostate cancer study also was only published after Dr. Pantuck revised the report based on a peer review comment that the manuscript was "excessively advocatory of pomegranate juice as a treatment for prostate cancer." (CCFF ¶ 990). Again, Dr. Eastham and Dr. Stampfer agree with the cautions expressed by Dr. Pantuck in his final report that the study cannot be considered proof that pomegranate juice treats prostate cancer. (CCFF ¶¶ 995-96, 1002-04).

Finally, a peer reviewer for the *International Journal of Impotence Research* stated that the Forest ED Study (2007) was "a negative study, not a positive study, and should be presented that way." (CCFF ¶ 1072). Indeed, Dr. Padma-Nathan disclosed the limitations of the study in his published report. (CX0626). Again, both Complaint Counsel's expert and Respondents' two experts agreed that the study had negative results. (CCFF ¶¶ 1076-77).

Respondents next argue that they relied on the positive statements of a few of their researchers as support for their claims. (Resp't Br. at 23-26). The record evidence indicates, however, that many of the positive statements were provided specifically for use as quotes in Respondents' marketing materials. (*See, e.g.*, CCFF ¶ 791; PX0511). In fact, Dr. Liker testified

that none of the third party scientific advisors offered opinions on whether or not the research would support POM's claims. (Liker, Tr. 1928; *see also* CC Resp. to RFF ¶ 378).

Complaint Counsel takes no position on how Respondents choose to invest in scientific research. (Resp't Br. at 26-31). Of relevance are Respondents' representations in advertisements and promotional materials about the efficacy of the POM Products and whether or not their science provides an adequate basis for the claims.[11]

C. POM's Approach to Advertising the POM Products (Resp't Br. Section V)

Respondents assert that they have "proceeded conservatively" in advertising the POM Products, waiting until the science is "sufficiently developed" before using their research results in advertising. (Resp't Br. at 31). Respondents do not explain the term "sufficiently developed," but state that Mr. Resnick's policy was to make health-related claims "if POM's *human* research sufficiently demonstrates that a benefit exists." (Resp't Br. at 28, n.5) (emphasis added). This, of course, is contrary to Respondents' litigation position as espoused by Drs. Miller and Heber that human research is unnecessary. (*See* RFF ¶¶ 571-72, 618, 622, 649, 652). As for how well this policy worked, the Aviram 2004 study is the prime example of its failure. This unblinded, uncontrolled, small pilot study with patients with severe heart disease, with results that were not replicated in larger well-designed, well-controlled studies conducted in 2005 and 2006, was the

[11] Respondents argue that publicizing POM-sponsored research in advertising to sell the POM products is akin to government and medical research centers disseminating nutrition and health information to the public (Resp't Br. at 30-31). Complaint Counsel disagrees. First, Respondents support this notion with non-record evidence and thus, the Court should afford it no weight. Second, if the Court looks at the cited materials, we urge the Court to review Resp't Website Ex. 6 at 2-3 (CDC states "there is limited evidence to support use of antioxidant supplements to prevent disease.) and Resp't Website Ex. 22, (Mayo Clinic's Dr. Castle states too early to say if pomegranate juice slows growth of prostate cancer or alters the course of prostate cancer and there is evidence that it affects metabolism of several prescription medications, including blood thinners and some drugs used to treat high blood pressure and high cholesterol.)

study cited by Respondents in their advertising from 2003 through 2010 to show the POM Products can treat, prevent, and reduce the risk of heart disease.[12] Complaint Counsel addresses Respondents' remaining arguments about its care in advertising (Resp't Br. at 31-32) in Section V.A.

IV. RESPONDENTS' FLAWED ANALYSIS OF SUBSTANTIATION AND ITS APPLICATION TO THE CHALLENGED CLAIMS (Resp't Br. Sections VI-VIII)

A. The Substantiation Standard (Resp't Br. Section VI)

Respondents argue that: 1) because POM Products are foods or dietary supplements, basic science and small, pilot studies can be relied on as competent scientific evidence for their health claims and RCTs are not necessary (Resp't Br. at 32-33, 35-38); and 2) findings that do not achieve statistical significance should be considered as supporting evidence for their claims (Resp't Br. at 33-35). These novel tenets conveniently allow Respondents to disavow their most rigorously conducted science in favor of their basic *in vitro*, *in vivo*, and small exploratory human research. Complaint Counsel maintains that FTC law does not permit Respondents to play favorites with the science in this way.

As detailed in Complaint Counsel's brief and proposed findings of fact, most of the challenged POM Juice ads and all of the challenged POMx ads make establishment claims by conveying the net impression that the POM Products have been scientifically proven to treat, prevent, or reduce the risk of disease. (*See* CCFF ¶¶ 328, 335, 340, 348, 361, 367, 371, 376, 384, 388, 405, 414, 418, 424, 429, 434, 441, 471, 494, 500, 535, 548, 555, 562, 567, 573, 575,

[12] Even Respondents' brief states that the Aviram study "**showed an amazing 30% reduction of arterial plaque**" (Resp't Br. at 26), which mimics statements in their advertising, such as "a glass a day [of POM Juice] **can reduce plaque by up to 30%!** . . . Trust us, your cardiologist will be **amazed**." (CX0034; *see also* CCFF ¶¶ 329-48 (emphasis added)).

577; CCCL ¶ 40). For these claims, Respondents must possess "a level of proof sufficient to satisfy the relevant scientific community of the claim's truth," in other words, "competent scientific proof." *Removatron Int'l Corp.*, 111 F.T.C. 206, 297-99 (1988); *aff'd*, *Removatron Int'l Corp. v. FTC*, 884 F.2d 1489, 1498 (1st Cir. 1989) (stating that "a 'reasonable basis,' when one makes establishment claims, means well-controlled scientific studies"); CCCL ¶ 65.[13] Courts have routinely found or upheld that double-blind, placebo-controlled studies are necessary to provide adequate substantiation for such claims. *See, e.g.*, *FTC v. Direct Mktg. Concepts, Inc*., 569 F. Supp. 2d 285, 303 (D. Mass. 2008), *aff'd*, 624 F.3d 1 (1st Cir. 2010); *Removatron Int'l Corp. v. FTC*, 884 F.2d at 1499-1500; *Schering Corp.*, 118 F.T.C 1030, 1080, 1115-16 (1991) (initial decision). (*See also* CCCL ¶ 68).

Despite Respondents' protestations to the contrary, the Commission "consider[s] all forms of competent and reliable scientific research when evaluating substantiation." (CX1014_0014-19 (*Dietary Supplements: An Advertising Guide for Industry*)). The FTC and the FDA "look to well-designed studies, including clinical research and other forms of reliable and probative scientific evidence," and to the surrounding body of evidence. (CX0002_0006 (*FTC Enforcement Policy Statement on Food Advertising* ("Food Policy Statement")); *see also* CX1014_0012). A guiding principle regarding the sufficiency of the scientific evidence is what experts in the relevant field generally consider to be adequate.[14] (CX1014_0012; CX0002_0006).

[13] Moreover, if advertisements "expressly or impliedly promise[ ] a scientific level of substantiation," then a *Pfizer* analysis is not required and the ads' claims must be supported by scientific proof. *Removatron Int'l Corp*., 111 F.T.C. at 297-98, 306.

[14] When examining substantiation of unqualified health claims – the types of claims Complaint Counsel challenges in this case – the FTC looks to FDA's "significant scientific agreement"

Here, Complaint Counsel's experts have opined as to the type of evidence that would scientifically establish Respondents' claims and have evaluated whether Respondents' science is adequate. *See, e.g.*, *FTC v. Direct Mktg. Concepts*, *Inc.*, 624 F.3d 1, 9 (1st Cir. 2010). The experts reviewed the research, examining the scientific merit of each study and evaluating the studies in the context of the entire body of relevant evidence. In reaching their conclusions, Complaint Counsel's experts considered all of the scientific evidence available to them, including *in vitro*, animal, and human studies. (CX1293 (Stampfer, Report at 0016, 23); CX1291 (Sacks, Report at 0015-16); Eastham, Tr. 1317-19; CX1289 (Melman, Report at 0011-18)). Statistical significance was among many indicia of reliability (*e.g.*, validated measures, replication, clinical significance, evidence of a dose response) that Complaint Counsel's experts considered when evaluating the totality of Respondents' research. Their conclusions are that the science presented by Respondents as the basis for their claims is woefully lacking.

Respondents attempt to apply a recent Supreme Court case and make two policy arguments for their novel view that they can skirt the government's statutory rubric for the labeling and advertising of food. (Resp't Br. at 1, 3, 7, 29, 35). Respondents blatantly state on page one of their brief that "In *Matrixx Initiatives, Inc. v. Siracusano*, 131 S. Ct. 1309 (2011), the Supreme Court recognized that RCTs are <u>not</u> required to show a causal relationship between a health benefit and a product," (Resp't Br. at 1) and use this gross misinterpretation of the decision throughout their brief. (Resp't Br. at 3, 7, 29, 35). The *Matrixx* case has nothing to do with non-RCT data establishing a health benefit for a product. The issue before the Supreme Court in *Matrixx* was whether a pharmaceutical company's failure to disclose to its shareholders

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standard as the principal guide to what experts would consider reasonable substantiation. (CX0002_0006 (Food Policy Statement)).

a less than statistically significant number of adverse event reports associated with its OTC drug Zicam was nevertheless material and thus gave rise to an investor claim of securities fraud.[15] In finding that less than statistically significant data should not deter the disclosure of adverse event reports, the Court noted that statistically significant data are not always available because adverse events may be subtle or rare and ethical considerations may prohibit conducting RCTs designed to prove an adverse effect is caused by a product. 131 S. Ct. at 1321. The Supreme Court also noted that the FDA, understandably, may act on a safety risk to the public with evidence short of RCTs. *Id*. at 1320; *see cf*. CCCL ¶¶ 71-73.

Respondents miss the core theme of the *Matrixx* decision that is relevant to this case – whether or not the maker of Zicam was properly forthcoming with its investors regarding material information. Matrixx attempted to argue that its failure to report the adverse event data was caused by its need to confirm the validity of those data, much like Respondents argue they failed to publish the Davidson CIMT study for two years to confirm its conclusions. *Matrixx*, 131 S. Ct. at 1324. The Court stated that this excuse rang hollow when Matrixx was simultaneously issuing misleading press releases about the issue. *Id*. Here, Respondents were deceptively touting that the POM products were shown to treat or prevent heart disease through a study showing a 30% reduction of plaque when they knowingly had far more reliable information to the contrary. The transparency found by the Supreme Court as necessary to avoid a securities fraud suit is the same transparency with consumers that Respondents studiously avoided in touting the studies on their products.

[15] Given their premise that the level of substantiation should differ for foods versus OTC drugs (*e.g.*, Tinactin), it is ironic that Respondents turn to *Matrixx* – a case involving an OTC drug – to argue against the need to rely on RCTs and statistical significance for claim substantiation.

Although Complaint Counsel agrees with Respondents that the POM Products are generally recognized as safe, this doesn't lead to a free pass on proper substantiation if they make hard hitting efficacy claims. *See FTC v. QT, Inc*., 448 F. Supp. at 962. In fact, Complaint Counsel's experts noted "signals" in some of Respondents' sponsored research that suggest, from a scientific standpoint, that pomegranate juice and pomegranate extract have not been demonstrated to be safe. (CC Resp. to RFF ¶¶ 201, 1033). Moreover,

which prompted remarks by a fellow researcher that the patients whose disease appeared to accelerate from taking the pomegranate extract are an issue of concern. (CCFF ¶¶ 1020-21).

Finally, Respondents claim that dissemination of public health recommendations for a diet rich in vegetables and fruits, and surgical procedures utilized as the accepted standard of care in the absence of RCTs,[16] justify publicizing the health benefits of the POM Products absent RCTs. (Resp't Br. at 37-38). Respondents fail to appreciate the significant distinction between the facts of this case and the factors they cite. Respondents advertise and sell commercial products to consumers and reference their sponsored studies in advertising to further sales of

[16] Respondents also cite research by the USDA's Agricultural Research Service and approval of certain oncology drugs under FDA's Fast Track Program. These references are irrelevant. For example, the FDA's fast track approval is a unique drug approval process to expedite patient access to a new drug "intended for the treatment of a *serious or life-threatening condition* and [that] demonstrate[s] the potential to address *unmet medical needs*." 21 U.S.C. § 356 (2012) (emphasis added).

those products. They admit that their health claims are intended to set the POM Products apart from the competition (CCFF ¶ 1120), and that their pursuit of a drug approval from FDA is to "distinguish their products from their competitors in the marketplace." (Resp't Br. at 30). Clearly, if Respondents truly desired to enhance public health, the lawful approach for marketing the POM products based on these specific health benefits would be for Respondents to submit their research to the FDA to obtain either an unqualified or a qualified health claim for the products. The record is clear that Respondents understood the regulatory system, but chose to ignore it, risking a regulatory action by either the FDA or the FTC. (CCFF ¶ 683). Mr. Tupper made it quite clear in both his testimony and in his 2009 medical research summary that: 1) from a marketing standpoint, an FDA qualified claim would have been too weak and would have offered no benefit to POM over competitors; 2) defects in Respondents' science could have precluded the FDA from approving such a claim; and 3) the best option was simply "to publicize what we have." (CCFF ¶ 683; Tupper, Tr. 3032-33).

None of Respondents' theories supports overturning established FTC law requiring well-conducted human clinical studies to support serious disease prevention and treatment claims, especially when the theme of Respondents' advertising is that they have established these benefits through specific human studies and $35 million dollars worth of medical research.

B. Level of Substantiation for the Challenged Claims (Resp't Br. Section VII-VIII)

1. Polyphenol Antioxidants in the POM Products (Resp't Br. Section VII)

Respondents argue that they have presented substantial evidence on the potency of polyphenol antioxidants in the POM Products, and that Complaint Counsel has failed to rebut that evidence. (Resp't Br. at 38-41). As Complaint Counsel's expert explained, evidence on the

relationship between antioxidant intake and disease is conflicting. (CCFF ¶ 1006). Most tellingly, Respondents' effort to show that POM Juice or extract supplementation reduced markers of oxidative stress or inflammation in humans were generally unsuccessful. (*See* CCFF ¶ 825 (Ornish MP Study), 884 (Davidson CIMT Study) (indicators of inflammation and oxidative stress showed no significant differences), 915 (Davidson BART Study), 933 (San Diego Study), 949 (Heber/Hill Diabetes Studies)).[17]

Respondents are correct that Drs. Stampfer and Eastham did not opine directly about the bioavailability of the POM Products' antioxidants nor their general nutritional benefits because these issues are irrelevant to the analysis required in this case. (Resp't Br. at 40-41; *see* CCFF ¶¶ 699-700, 715-16; *see also* CC Resp. to RFF ¶¶ 910-14). Complaint Counsel's experts were asked to determine whether the materials submitted by Respondents were sufficient to support the challenged cardiovascular, prostate cancer, and ED claims, not to opine on general nutrition issues. By analogy, Fiji Water may be bioavailable, metabolized, and safe, but if Respondents make "backed by science" type establishment claims that the water prevents arthritis, those efficacy claims must be accurate and appropriately substantiated.

[17] Regarding the purported bioequivalence of POM Juice and POMx, Complaint Counsel disagrees that Respondents have established their bioequivalence. (*See* CCFF ¶¶ 125-26 (POM Juice contains 8-15% anthocyanins, sugars), 130 (Heber testimony that extracts contain no anthocyanins), 395 (Dr. Aviram stated that "I feel that it is important to learn more about the relationships between POM ([Juice], and the Pill, which, unlike PJ, we know very little on it from mechanistical point of view"), 964-65 (POM Juice and POMx are not the same; Heber says that anthocyanins "undoubtedly" contribute to antioxidant capacity of POM Juice); Sacks, Tr. 1524 (noting that preliminary research suggests that anthocyanins may have effects on vascular function); Eastham, Tr. 1312-13 (testifying that POM Juice and POMx are not identical); *see also* CC Resp. to RFF ¶¶ 915-58). Moreover, if neither product has the claimed benefits established by science, the issue of bioequivalence is of no consequence.

2. Substantiation for Respondents' Heart Claims (Resp't Br. Section VIII.A)

Respondents argue that their cardiovascular research (basic science and human science) "demonstrates" that POM Juice and POMx are "likely to be beneficial in maintaining cardiovascular health and help reduce the risk of cardiovascular disease by reducing arterial plaque, lowering blood pressure, and improving blood flow." (Resp't Br. at 45). However, none of Respondents' cardiovascular research examined the potential of the POM Products to maintain cardiovascular health in healthy persons. Moreover, Complaint Counsel's experts conclude that Respondents' science is insufficient to support the proposition that POM Juice and POMx reduce the risk of cardiovascular disease by reducing arterial plaque, lowering blood pressure, and improving blood flow.[18] (CCFF ¶¶ 950-65).

The remaining portions of this Section of Respondents' brief contain so little meaningful analysis as to whether or not the medical research conducted can demonstrate the established treatment, prevention, or reduction of risk benefits touted to the public in their ads that a reply is unnecessary.[19] For example, Respondents note that they have sponsored approximately ten human published studies, and then address in a cursory fashion only two – the Ornish MP Study and the Davidson CIMT Study. (Resp't Br. at 46-47). Their two-sentence summary of the Ornish study reads like their promotional material. (Resp't Br. at 47 ("After three months, patients drinking POM Juice experienced a 35 percent comparative benefit in blood flow.")).

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[18] Indeed, blood pressure, the only valid surrogate measure used by Respondents, was an endpoint in five of their RCTs and no benefit was shown in any of these studies. (CCFF ¶¶ 785, 829, 858, 883, 915, 932, 955-58).

[19] For the proper and detailed analysis of the research vis-à-vis the heart claims at issue, *see* Section II.C.1 of Complaint Counsel's Post-Trial Brief and CCFF Section VII.C.

Perhaps indicative of how they would like a POM Juice ad to be read, Respondents chose only to speak of the Davidson CIMT *post hoc* subgroup analysis in their brief. (Resp't Br. at 47). This skewed description fails to explain how the well-controlled 289-person Davidson CIMT Study showing no significant influence of 18 months of pomegranate juice consumption over placebo on CIMT progression and no statistically significant changes in blood pressure or tested measures of inflammation or oxidative stress can be reconciled with Respondents' establishment and efficacy claims for heart disease. (CCFF ¶ 882). The simple answer is it cannot.[20]

3. Substantiation for Respondents' Prostate Claims (Resp't Br. Section VIII.B)

Respondents assert that they did not advertise the POM Products to treat or prevent prostate cancer but, even if they did, their basic and clinical research support such claims. (Resp't Br. at 50).[21] First, they claim that PSADT is a valid surrogate marker for recurrence and/or death from prostate cancer and disagree with Dr. Eastham's expert opinion regarding the limited use of PSADT. (Resp't Br. at 50-53). Actually, Respondents' experts and researchers agree with Dr. Eastham that while PSADT has value as a prognostic tool, there are no studies demonstrating that an agent that modulates PSADT changes the natural history of prostate cancer by delaying the development of metastases or death from the disease. (*See* CCFF ¶¶ 980-83; 994-95; CX1340 (Carducci, Dep. at 89-90 (stating that slowing PSADT has not been proven to be beneficial))). A Carducci Study reviewer also stated that "[PSADT] has never been

[20] Respondents' failure to address the limitations of their science in a candid manner to the Court does not bode well for their willingness to temper their claims to consumers short of an order requiring them to do so.

[21] To be consistent with the structure of Respondents' brief, Complaint Counsel addresses the advertising claims in Section V.

prospectively validated to slow anything in terms of clinical outcome."[22] (CCFF ¶ 1021). Moreover, experts in the field of prostate cancer (including Respondents' expert, Dr. deKernion, and researchers Drs. Pantuck and Carducci) agree that PSADT is not an accepted surrogate endpoint for survival or prostate cancer-specific mortality in prostate cancer treatment clinical trials. (CCFF ¶¶ 978, 1021; *see also* CC Resp. to RFF ¶¶ 231, 390).

Unlike Respondents' brief, Dr. Pantuck's published report accurately places his study in perspective. According to the published report, the study was "an open-label, single-arm clinical trial," meaning it was not an RCT and did not have a placebo group.[23] (CCFF ¶ 992). It further acknowledges that "[i]t remains controversial whether modulation of PSA levels represents an equally valid clinical endpoint" and that "further research is needed to . . . determine whether improvements in such biomarkers [including PSADT] are likely to serve as surrogates for clinical benefit." (CCFF ¶¶ 994-95). Finally, the report states that the study results need to be tested further in a randomized, double-blind, placebo-controlled study, in which the ability of pomegranate juice to produce an alteration in PSA kinetics is compared with the change observed in a control group. (CCFF ¶ 995).

Although originally designed as a placebo-controlled study, the Carducci dose-response study was not carried out that way based on "more of a business decision than a scientific decision" by Respondents. (CCFF ¶ 1016). According to Dr. Carducci, there was no statistically

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[22] Respondents claim the Carducci Study is "published in the highly respected *Journal of Oncology*." (Resp't Br. at 54). Actually, the study has not been published to date. (*See* RFF ¶ 1695).

[23] Respondents' expert Dr. deKernion acknowledged that the Pantuck Phase II Prostate Cancer Study (2006) did not employ a placebo arm although it was feasible to do so. (CCFF ¶ 1006). Dr. deKernion recognized the usefulness of a placebo-controlled study, for example, in light of other prostate cancer studies (*e.g.*, rosiglitazone and celecoxib) in which patients in the treatment and placebo groups both experienced a lengthening of PSADT. (CCFF ¶ 1007).

significant treatment difference (p=.920) in PSADT between the one capsule and three capsule dose groups, suggesting a lack of efficacy. Dr. Carducci testified that without a placebo, he cannot be sure that the effect on PSADT observed by the within-group measurements was attributable to POMx. (CCFF ¶ 1018). Again, Respondents' brief contains no new information requiring further analysis here.[24]

4. Substantiation for Respondents' ED Claims (Resp't Br. Section VIII.C)

Respondents argue that "competent and reliable scientific evidence demonstrates" that POM Juice and POMx "provide[] a positive benefit to erectile health and erectile function." (Resp't Br. at 58). Respondents describe the Forest/Padma-Nathan ED human study on which they rely (Resp't Br. at 59-60), but omit material information that Dr. Padma-Nathan himself acknowledged. Dr. Padma-Nathan testified that it was a pilot study, underpowered, and relied on a non-validated measure (the GAQ questionnaire) as its primary measure. (CCFF ¶¶ 1057, 1060-61, 1064, 1066-67, 1071). Experts in the erectile dysfunction field require the use of a validated measure like the IIEF because such a measure ensures "reliability, responsiveness, and discriminant and predictive validity." (CCFF ¶¶ 1057-58). According to Respondents' expert, Dr. Burnett, the Forest/Padma-Nathan study IIEF results were "nowhere near approaching statistical significance" and the study does not support the conclusion that POM Juice treats erectile dysfunction. (CCFF ¶¶ 1076-78, 1086). Finally, contrary to Respondents' characterization of when RCTs are needed for substantiation (Resp't Br. at 61), Respondents' and Complaint Counsel's experts all opined that RCTs would be needed before concluding that

[24] *See* Section II.C.2 of Complaint Counsel's Post-Trial Brief and CCFF Section VII.D.

pomegranate juice treats, prevents, or reduces the risk of erectile dysfunction.[25] (CCFF ¶¶ 783, 1055, 1089, 1102; *see also* CCFF ¶ 1073).

V. RESPONDENTS' NARROW ARGUMENTS REGARDING THE CHALLENGED CLAIMS (Resp't Br. Section IX)

On page 65 of their brief, Respondents finally turn to steps one and two of the legal analysis – whether the ads and promotional materials convey the Challenged Claims and whether the claims are material. Respondents practically concede that, at a minimum, their advertisements convey that the POM Products reduce the risk of heart disease, prostate cancer, and ED, but attempt to argue that the message is nothing more than that consumers should consume the POM Products just as they would any whole fruits and vegetables as part of a healthy diet and exercise regime to reduce the risk of disease. (Resp't Br. at 69-72). Respondents also concede that many of their ads used "aggressive" language (in Complaint Counsel's view, a strong indication that Respondents admit the ads indeed made treat, prevent, and reduce the risk of heart disease and prostate cancer claims) but argue that the Court should deem these so-called "outlier" ads non-actionable. Respondents erroneously argue that the claims in those ads had been discontinued prior to 2007. (Resp't Br. at 67-69).

In turn, Respondents incorrectly assert that Complaint Counsel is required, but failed, to present extrinsic evidence to prove that any of the Challenged Claims were, in fact, conveyed. (Resp't Br. at 66-67, 72-74). They next attempt to divide the ads into three categories (ads that reference specific studies; ads that state the POM Products are backed by tens of millions of

[25] Respondents attempt to discredit Complaint Counsel's ED expert by mischaracterizing his testimony and portraying his opinions as outliers. (Resp't Br. at 62-64). *See* CC Resp. to RFF ¶¶ 2151-74 for a complete response to these spurious allegations. (CC Resp. to RFF ¶ 2024 (Dr. Burnett testified that he considered Dr. Melman to be an expert in the erectile dysfunction field and highly respected among urologists)).

dollars in medical research; and ads that claim benefits based on the antioxidant theory) and argue that these categories of ads fail to convey the "implied" Challenged Claims. (Resp't Br. at 74-82). The fallacy of this argument is that the categories by their very nature highlight that most of their advertising not only makes disease treatment and prevention claims, but does so through virtually express establishment claims.

Respondents also contend at length that Complaint Counsel has not shown that the alleged misrepresentations were material to consumers. (Resp't Br. at 82-92). Again, that argument is unavailing. Finally, despite having admitted in their Answer that certain promotions were advertising, Respondents now argue that these promotions do not fall within the definition of commercial advertising. (Resp't Br. at 92-96).

A. The So-Called "Outlier" Ads Are Actionable (Resp't Br. at 67-69)

Respondents correctly admit that they ran a number of aggressive ads, but incorrectly characterize them as outliers and wrongly claim that the ads were discontinued by 2006.[26] (Resp't Br. at 67-68). The record evidence shows that Respondents continued to make hard-hitting establishment and efficacy claims right up until the filing of the Commission's case (*see, e.g.*, CCFF ¶¶ 425-29, 494, 666, 668-74), using detailed references to the studies in ads because they generated more sales (CCFF ¶¶ 636-37). At least four of the eight ads Respondents deem outliers were disseminated in 2007, 2008, and 2009. (*See* CC Resp. to RFF ¶ 2258).

Respondents' assurance that "outlier" type ads are unlikely to reoccur due to a formalized ad review process (Resp't Br. at 68-69) rings hollow given the fact that three out of the eight

[26] Respondents claim their advertising changed significantly after the 2005 and 2006 NAD decisions from aggressive, generalized statements to more specific qualified representations. (Resp't Br. at 32).

"outlier" ads ran after the science and legal review process was purportedly put in place at least as early as 2007 or by 2008, according to Mrs. Resnick and Mr. Tupper. (*See* CC Resp. to RFF ¶ 2260). Moreover, several fact witnesses testified that Respondents' processes for vetting advertisements have been fluid and informal, rather than formalized. (L. Resnick, Tr. 182; Posell, Tr. 312; 367-68; Leow, Tr. 423-24, 484-85; Perdigao, Tr. 663). In addition, when asked at trial, none of Respondents' scientists supported the notion that part of their job was to vet advertising. Drs. Dreher, Liker, and Heber all distanced themselves from any role in POM's ad review. (Dreher, Tr. 530; Liker, Tr. 1906-08; Heber, Tr. 2085).

Tellingly, Respondents are unrepentant in their view that their standards are superior to federal regulatory standards. For example, Mr. Resnick testified at trial that he does not refer to any FDA or FTC standards in considering whether to make a claim. (S. Resnick, Tr. 1655-56 ("Well, I haven't seen any standard that we can adhere to for what we're doing, so I can't say that we're hitting your standard or not. We're hitting my standard, and my standard I think is a very, very critical one. . . . [W]e don't make any claims unless we're very comfortable that we've done adequate work and the results are adequate enough to make those claims."); s*ee also* CCFF Sections VI.E and VI.F).

The cases Respondents mention in this section of the brief are inapposite.[27] Respondents cite *FTC v. Evans Products Co*. (Resp't Br. at 68) for the proposition that past wrongs are insufficient to warrant an injunction; however, in that case, which involved a request for a

[27] This section of their brief purportedly deals with the question of liability for ad claims, yet Respondents jump to the issue of remedy, citing a handful of cases to argue that the "outlier" ads are ancillary to the proposed order. (Resp't Br. at 68-69). In keeping with the order of Respondents' brief, we will dispense with these cases here, rather than in Section VI on remedies.

preliminary injunction, the Commission had failed to request any findings on the likelihood of recurrence. *FTC v. Evans Products Co*., 775 F.2d 1084, 1085, 1087 (9th Cir. 1985). Unlike here, in *Country Tweeds*, the petitioners voluntarily ceased their illegal conduct well before the Commission issued its complaint, which was a factor affecting the scope of the order, not the need for an injunction. *Country Tweeds v. FTC*, 326 F.2d 114, 149 (2d Cir. 1964). In *Grand Union*, the court considered several factors, including the "highly uncertain area of the law" (novel application of Section 5 of the FTC Act to Section 2(d) of the Clayton Act), the cessation of the activity, and that there was "nothing in the record to suggest that Grand Union intends to resume this or any related activity" in limiting the scope of the injunctive relief. *Grand Union v. FTC*, 300 F.2d 92, 100 (2d Cir. 1962). By contrast, Respondents' conduct pertains to violations of well-established advertising law which did not cease, as evidenced by the record, and are likely to reoccur absent a well-defined order.[28] *See* Section VI, *infra*.

Moreover, in evaluating a company's voluntary cessation of offending activity, courts have recognized that discontinuance does not of itself bar a cease-and-desist order. *See, e.g.*, *American Home Prod*., 98 FTC 136, 406 (1981) ("It is well established that the Commission has the authority to enter an order even where the challenged practices have been voluntarily abandoned or revised"), *aff'd as modified*, 695 F.2d 681 (3d Cir. 1982); *Fedders Corp v. FTC*, 529 F.2d 1398, 1403 (2d Cir. 1976) (noting that even if respondent discontinued the practice before the Commission issued the complaint, it "does not bar a cease-and-desist order, where the

[28] Respondents also argue that there were "inadvertent mistake[s]" that are unlikely to reoccur. (Resp't Br. at 68). The court should not be swayed by Respondents' contention that such apparent aberrations are of minimal risk in the future. *See, e.g.*, *Rentacolor*, 103 F.T.C. 400, 437 (1984) (rejecting "the company's contention that these deviations were 'technical' and ought not be regarded as vitiating its 'substantial efforts' to comply").

public interest otherwise requires it"); *Southwest Sunsites, Inc.*, 105 F.T.C. 7, 165 (1985) ("voluntary discontinuance of practices by respondents – particularly when that occurs only in the face of an investigation or lawsuit – does not exonerate respondents or render the proceeding moot"), *aff'd*, 785 F.2d 1431 (9th Cir. 1986). More akin to the goal of Complaint Counsel's proposed order here, in *Giant Food*, the court noted that the Commission's order was meant to deal with the totality of Giant's advertising program, and that "voluntary abandonment of part of the program under the circumstances does not disable the Commission from formulating a rule of conduct for the future as broad as the derelictions of the past." *FTC v. Giant Food*, 322 F.2d 977, 987 (D.C. Cir. 1963).

B. Respondents' Constricted Analysis of the Law of Ad Interpretation (Resp't Br. at 69-72)

In Respondents' reductive view of the case law, establishment claims are limited to whether the ad contains the words "clinically proven" (Resp't Br. at 69-70) and implied claims are never reasonably clear from the ad itself (Resp't Br. at 70-72). The courts, however, offer more refined interpretations, recognizing, for example, that an ad's net impression may convey an establishment claim not only through phrases like "tests prove" but through references to clinical testing or visual aids. *See, e.g.*, *Removatron Int'l Corp.*, 111 F.T.C. at 298 ("R]eferences to clinical testing, research and case studies are express claims that the respondents' representations are supported by scientific evidence"); *Bristol-Myers Co.*, 102 F.T.C. 21, 321 (1983) (internal citations omitted), *aff'd*, 738 F.2d 554 (2d Cir. 1984) (establishment claims "may also be made through the use of visual aids (such as scientific texts or white-coated technicians) which clearly suggest that the claim is based upon a foundation of scientific evidence"). Similarly, courts recognize that "implied claims fall along a continuum, from those

which are so conspicuous as to be virtually synonymous with express claims, to those which are barely discernible." *FTC v. Febre*, No. 94 C 3625, 1996 U.S. Dist. LEXIS 9487, at *14 (N.D. Ill. July 3, 1996) (citing *Kraft, Inc. v. FTC*, 970 F.2d at 319) (magistrate judge's recommendation), *adopted by,* 1996 U.S. Dist. LEXIS 14297 (N.D. Ill. Sept. 25, 1996), *aff'd*, 128 F.3d 530 (7th Cir. 1997); *see also FTC v. Bronson Partners, LLC*, 564 F. Supp. 2d 119, 127-28 (D. Conn. 2008) (an advertisement's statements were "so clear, repetitive, and unambiguous that they constitute[d] the functional equivalent of express claims"), *aff'd*, 654 F.3d 359 (2d Cir. 2011).

In its brief and proposed findings of fact, Complaint Counsel has articulated in detail the challenged ads that convey establishment claims, all of which are either express or clearly implied. (CCFF Section V and App. A). Complaint Counsel's assessment of the ad claims is not "aggressive" (Resp't Br. at 69), but in line with established case law. Courts recognize that the interplay of ad language and imagery can convey that a product's efficacy has been established by a specific level of scientific support, absent use of words such as "tests prove."[29] *See, e.g.*, *FTC v Nat'l Urological Group, Inc.*, 645 F. Supp. 2d 1167, 1201 (N.D. Ga. 2008), *aff'd*, 365 F. App'x 358 (11th Cir. 2009) (finding an establishment claim based on an ad statement that "in preliminary testing, Spontane-ES's active components have been shown to be effective in nearly 90% of all men who have taken it," a reference to "research and development" conducted by "pharmacological staff at Warner Laboratories," and a letter from a doctor positively reviewing the product); (*see also* CCCL ¶ 23).

[29] The courts' developed understanding of consumer take away is consistent with Lynda Resnick's own view of ad messaging. As she states in her guide to marketing, *Rubies in the Orchard*, when it comes to creating messages that resonate with consumers, she approaches the task not with a "blunt instrument" but with a "surgeon's scalpel." (CX0001_0019).

Respondents argue that they have carefully qualified their ad claims. (Resp't Br. at 70). However, occasional words such as "may," "preliminary," and "pilot" buried in the body of Respondents' ads do not negate the net impression of an established level of scientific proof conveyed through such devices as bold headlines touting specific health benefits, selective and unquestionably positive descriptions of studies, and powerful "backed by" science statements. *See, e.g.*, *Daniel Chapter One*, 2009 FTC LEXIS 157, at *204; *Thompson Med. Co.*, 104 F.T.C. 648, 799 (1984), *aff'd*, 791 F.2d 189 (D.C. Cir. 1986). (*See* CCFF ¶¶ 336, 363, 368, 372, 397, 435-37, 440). In fact, the context in which Respondents use these so-called qualifiers is more apt to either increase the credibility of Respondents' claims (CCFF ¶ 612) or to not affect ad meaning (CCFF ¶¶ 611-15; CCCL ¶¶ 25-29). When describing study results, nowhere do the ads reflect cautionary language that the study authors themselves use. For example, Respondents' prostate ads for POM Juice make no attempt to concede, as does the Pantuck Phase II Study, that "further research is needed to . . . determine whether improvements in such biomarkers [including PSADT] are likely to serve as surrogates for clinical benefit." (*See, e.g.*, CCFF ¶¶ 368, 378, 415, 419, 432).

On the one hand, Respondents' brief assumes that reasonable consumers cannot recognize a "clinically proven" establishment or a "treat" or "prevent" efficacy claim unless presented with those precise words. (Resp't Br. at 69-72). On the other hand, the brief speculates that consumers have a highly nuanced understanding of POM's ad claims such that they will understand any claim conveyed by the ads to mean only that consuming the POM Juice or POMx will merely reduce one's risk of disease *as part of a healthy diet*. (Resp't Br. at 67-71). While advertisements can be susceptible to more than one reasonable interpretation, Complaint Counsel does not believe that Respondents' proposed reading of the ads is reasonable. The ads

do not convey the message that POM Juice is one component of a healthy diet rich in fruits and vegetables, and Respondents have offered no reliable empirical evidence to support such an interpretation. Rather, the ads emphasize that the specific health benefits of POM Juice and POMx (which are not the same as whole fruits, *supra* Section III.A) are unique and superior to other antioxidant-rich foods (*e.g.*, "made from the only pomegranates backed by $32 million in medical research at the world's leading universities").[30] (CX0331_0001). Even if some consumers did take away the meaning that Respondents proffer, "'[s]tatements susceptible of both a misleading and a truthful interpretation will be construed against the advertiser.'" *Bronson Partners, LLC*, 564 F. Supp. 2d at 127 n.6 (quoting *Country Tweeds, Inc. v. FTC*, 326 F.2d 144, 148 (2d Cir. 1964)) (brackets in original).

Respondents try to buoy their argument by drawing an imaginary line between reducing the risk of heart disease, prostate cancer, or ED via a drug versus a food. (Resp't Br. at 70, 72). Respondents cite no case law for this proposition, but rather the testimony of their linguistics expert Dr. Butters (Resp't Br. at 72), who offered no empirical support for his conclusions.[31] (Butters, Tr. 2811-2963; PX0350 (Butters, Dep. at 1-218); PX0158 (Butters, Report at 0001-43)). Sections 5 and 12 of FTC Act and Commission precedent make no such distinction.

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[30] Some challenged materials also lead with attention-grabbing statements about the prevalence of heart disease and prostate cancer in the U.S., thereafter offering POM as the unique solution. (CX0029_0002; CX0473 (Compl. Ex. E-2 at 00:30-00:35); CX0013_0002; CX1426_00041 (Compl. Ex. I at 4); CX1426_00050-51 (Compl. Ex. N at 2-3); CX0473 (Compl. Ex. E-8 at 05:55)).

[31] *See Thompson Med. Co.*, 104 FTC at 790 n.11 (considering "to be adequately supported [those] opinions that describe empirical research or analyses based on generally recognized marketing principles or other objective manifestations of professional expertise. Opinions not so supported may easily be contradicted by the contrary opinions of opposing experts and thus may be of little value in resolving the issue").

Section 5 applies to deceptive acts or practices generally and Section 12 applies to "any false advertisement" intended or likely to induce the purchase of "food, drugs, devices, services, or cosmetics." 15 U.S.C. §§ 45(a)(1), 52(a)(2) (2012). *See also Federal Trade Commission Policy Statement on Deception*, 103 F.T.C. 174, 175 (1984) (*appended* to *Cliffdale Assocs., Inc.*) ("*Deception Policy Statement*") (deception analysis begins with whether there was "a representation, omission or practice that is likely to mislead the consumer"); (CX0002_0002 (Food Policy Statement) ("first step in a deception analysis is to identify representations made by an advertisement")). The nature of the *claim*, rather than the nature of the *product*, is central to the deception analysis, and the Commission has applied this legal framework across the board to products making health benefit claims. (CCCL ¶¶ 81-85).

C. Extrinsic Evidence Is Not Required in this Case (Resp't Br. at 72-74)

This Court may rely on its owned reasoned analysis to determine the reasonably clear implied claims conveyed by the ads. (Resp't Br. at 66). *See Kraft, Inc. v. FTC*, 970 F.2d 311, 318 (7th Cir. 1992); *FTC v. Colgate-Palmolive Co.*, 380 U.S. 374, 385 (1965). Indeed, the Court should be able to "conclude with confidence," based on the face of the ads, that the Challenged Claims can reasonably be read from the ads. *Stouffer Foods Corp.*, 118 F.T.C. 746, 798 (1994) (citing *Kraft*, 114 F.T.C. 40, 121 (1991), *aff'd*, 970 F.2d 311, 318 (7th Cir. 1992) and *Thompson Med. Co.*, 104 F.T.C. at 789; *see also* CCFF Section V, App. A. The claims at issue are express and clearly implied. (*See* discussion, *infra* Section V.D; s*ee also* CCFF Sections V.D-V.F). Therefore, contrary to Respondents' assertions (Resp't Br. at 72-73), Complaint Counsel need not present extrinsic evidence and "the court need not look to extrinsic evidence to ascertain whether the advertisement made the claim." *FTC v. Nat'l Urological Group, Inc.*, 645 F. Supp. 2d at 1189.

Respondents incorrectly state that Complaint Counsel presented no evidence on ad meaning. (Resp't Br. at 72-73). In addition to analyzing the net impression of each of the challenged pieces, Complaint Counsel offered a wealth of evidence demonstrating Respondents' intent to make the Challenged Claims.[32] Respondents' brief also mischaracterizes Dr. Butters' testimony on ad meaning (Resp't Br. at 73-74). Dr. Butters did not define "treat" as a substitute for conventional medical treatment. (*See* CC Resp. to RFF ¶ 2211(h)). Moreover, Dr. Butters previously has concluded that the words "medical," "research," and "study" have highly positive connotations for consumers, and that, as a modifier, "medical" seems to be strongly associated with treatment. (CCFF ¶ 312).

Respondents blithely state "that many of the ads were meant to be hyperbolic, puffery and humorous" and incorrectly claim that Complaint Counsel did not present reliable evidence to rebut this "fact." (Resp't Br. at 73). Complaint Counsel indeed provided extrinsic evidence as to the Challenged Claims and the purpose and use of humor in Respondents' ads. (CCFF Sections V.C, V.D). Further, Respondents merely drop cites to the *Sterling Drug Inc. v. FTC* and *Thompson Medical Co.* decisions on the issue of puffery, without explaining the relevant holdings or applying them to the facts of this case. (Resp't Br. at 73). In *Sterling Drug*, the court described a puffery claim as "either vague or highly subjective, *e.g.*, 'Bayer works wonders.'" *Sterling Drug Inc. v. FTC*, 741 F.2d 1146, 1150 (9th Cir. 1984). That type of subjective claim is not present here. In *Thompson Medical*, the Commission likened puffery to

[32] Contrary to recognized case law, Respondents offer no legal basis to support their statement that it is erroneous to rely on evidence of intent. (Resp't Br. at 72-73, 88-91). Although intent is not required to find liability, a showing of intent is powerful evidence that the alleged claims in fact were conveyed to consumers. *See Telebrands Corp.*, 140 F.T.C. 278, 304 (2004), *aff'd*, 457 F.3d 354 (4th Cir. 2006); *Novartis Corp.*, 127 F.T.C. 580, 683 (1999), *aff'd*, 223 F.3d 783 (D.C. Cir. 2000); *see also Thompson Med. Co.*, 104 F.T.C. at 791.

"an objective product claim . . . so far-fetched that reasonable consumers would not believe it." 104 F.T.C. at 788-89 n.6. As the Commission noted in the *Deception Policy Statement*, "[s]ome exaggerated claims . . . may be taken seriously by consumers and are actionable."[33] *Deception Policy Statement*, 103 F.T.C. at 181. Claims that the POM Products treat, prevent, or reduce the risk of specific diseases are "objective claim[s] that can be scientifically tested," and are not puffery. *Novartis Corp.*, 127 F.T.C. at 693; *see also Direct Mktg. Concepts, Inc.*, 624 F.3d at 11-12 (stating that "'specific and measurable' claims and claims that may be literally true or false are not puffery") (quotation and internal citation omitted).

D. Respondents' Categorization of the Ads Supports a Finding That the Challenged Ads Convey Establishment Claims (Resp't Br. at 74-78).

Respondents' categorization of the ads supports Complaint Counsel's view that more than eighty-five percent of the challenged advertisements (38 of 43) convey establishment claims. (CC Br. at 20). As detailed in Complaint Counsel's findings, and as Respondents now readily admit, the vast majority of the challenged ads reference specific studies (Respondents' Category 1) and state that the products' benefits are backed by science (Respondents' Category 2).[34] Courts have held that such statements convey express or virtually express claims. *See, e.g.*,

[33] In the *Deception Policy Statement*, the Commission makes its point by describing a decision involving the claim "electronic miracle," stating that while "'the term miracle is commonly used in situations short of changing water to wine, we must conclude that the use of 'electronic miracle' in the context of respondent's grossly exaggerated claims would lead consumers to give added credence to the overall suggestion that this device is superior to other types of antennae.'" 103 F.T.C. at 181 (quoting *Jay Norris Inc.*, 91 F.T.C. 751, 847 (1978), *aff'd as modified*, 598 F.2d 1244 (2d Cir. 1979)). This is not unlike how consumers would interpret Mrs. Resnick's "magic elixir of our age" claim (CCFF ¶ 570) or Mr. Tupper's claim that "POM Juice is truly 'health in a bottle'" (CCFF ¶ 488) to mean that POM Products possess unique health benefits.

[34] Respondents' First Amendment citations are off point. (Resp't Br. at 76). The activity Complaint Counsel challenges does not involve dissemination of an excerpt from a peer-reviewed, scientific reference text. (*Wallach v. Crawford*, 2005 WL 6054963 (S.D. Cal. Mar.

Removatron Int'l Corp., 111 F.T.C. at 298 (1988) (stating that "references to clinical testing, research and case studies are *express claims* that the respondents' representations are supported by scientific evidence") (emphasis added); *Thompson Med. Co.*, 104 F.T.C. at 814 (finding that "references to tests by a medical specialist, or 'clinical tests,' are an *express reference* to the type of test acceptable to the medical scientific community" and it would be "reasonable for consumers to expect that the claims . . . would be substantiated in a manner acceptable to the medical scientific community") (emphasis added).

Respondents' third category, "antioxidant" ads, cannot be severed from the other categories. As with each of Respondents' categories, the individual elements (*e.g.*, statements about antioxidants) cannot be analyzed in isolation. (*See* CC Resp. to RFF Section XVII.G.3). The appropriate analysis is to look at the overall, net impression created by each advertisement discussing the antioxidant theory. The theory provides consumers a plausible mechanism of action to take away the impression that the specific health benefits touted in the ad are scientifically valid. (*See* CCFF Sections V.D-V.F and App. A).[35]

E. Respondents' Ads Convey Disease Claims That Violate the FTC Act (Resp't Br. at 78-82)

To argue that their ads do not convey the challenged disease claims, Respondents assert that Complaint Counsel conflates the terms prevent, treat, and reduce risk. (Resp't Br. at 78).

29, 2005)), speech "that is sold for profit" where "the speech is substance of the transaction" (*Edwards v. Dist. of Columbia*, 765 F. Supp. 2d 3, 13 (D.D.C. 2011), political speech (*Enten v. Dist. of Columbia*, 675 F. Supp. 2d 42, 49-50 (D.D.C. 2009)), or censorship of speech via licensing requirements (*Lakewood v. Plain Dealer Publ'g Co.*, 486 U.S. 750 (1988)).

[35] Complaint Counsel previously addressed the arguments that Respondents renew here (Resp't Br. at 78) that the ads should be viewed through a "food lens" and that many of the ad claims should be deemed nonactionable puffery. (*See supra* Section V.B).

To the contrary, Complaint Counsel's proposed findings of fact delineate where appropriate which of the challenged ads convey treatment, prevention, and/or risk reduction claims. (*See* CCFF Sections V.D-V.F and App. A).

Next, Respondents return to their themes that the POM Products are safe, whole foods, and are not sold like drugs (*e.g.*, Tinactin). (Resp't Br. at 80-82). They also reiterate their theory that consumers view their ads through a food lens (perhaps pomegranate-colored), and interpret their claims with the hidden knowledge that Respondents are merely encouraging them to purchase and consume the POM Products as part of a healthy diet and exercise. Complaint Counsel addressed these arguments in Sections III.A (manufacture and sale of POM Products) and IV.A (safety), and V.B (food lens argument) of this Reply, and will not repeat them here.

Respondents state that if their ads convey a prevention claim, it is carefully qualified (Resp't Br. at 80); if the ads convey a reduce risk claim, it is that the POM Products "improve your odds of staving off illness" (Resp't Br. at 81); and if the ads convey a treatment claim, it is not like a drug-treatment claim, *i.e.*, a substitute for conventional medical treatment[36] (Resp't Br. at 82). Complaint Counsel disagrees that the net impression conveyed by each of Respondents' ads is a well-qualified claim or a general claim. (*See supra* Section V.B and CC Br. at 15-25).

[36] The Complaint does not allege, and it is neither Complaint Counsel's contention nor its burden, to demonstrate that Respondents are selling the POM Products as a substitute for conventional medical treatment. FTC Act Section 15 does not further define the terms "treat," or "prevent." 15 U.S.C. § 55(c) (2012). These terms can be taken on their face as a reasonable consumer would understand them. It is nonsensical to presume that "treat" means a substitute for conventional medicine, when the statute is intended to cover any medicine (conventional or not) making a treatment claim.

F. The Claims Are Material (Resp't Br. at 82-92)

Respondents assert, without citing any legal precedent, that "for an advertising claim to be material requires the advertisement to actually affect consumer behavior" and that "[t]here is no evidence that any POM advertisement making a disease claim . . . had. . . 'many' exposures . . . to any consumer."[37] (Resp't Br. at 87). But as the Commission stated in *Novartis*:

> [T]his claim is irrelevant even if it were true. Materiality is not a test of the effectiveness of the communication in reaching large numbers of consumers. It is a test of the likely effect of the claim on the conduct of a consumer who has been reached and deceived. Materiality turns upon whether those consumers who have drawn the claim from the advertisement and been misled by it are also likely to have their conduct affected by the misrepresentation.

Novartis Corp., 127 F.T.C. at 691; *see also Thompson Med. Co.*, 104 F.T.C. at 814 n.39 ("[W]e reject as fundamentally erroneous the implicit suggestion that an advertiser may avoid responsibility for express representations by later claiming that the representations were not widely distributed. Such arguments . . . have no bearing on the issue of liability for deceptive acts or practices."). Moreover, "in the context of the materiality inquiry, it is the challenged claim that is at issue and not the ad as a whole." *Novartis Corp.*, 127 F.T.C. at 691 n.16.

When one properly focuses upon the materiality of the Challenged Claims themselves, it becomes apparent how ludicrous it is for Respondents to suggest that claims that a product treats, prevents, or reduces the risk of heart disease, prostate cancer, and erectile dysfunction would not likely be important to consumer purchase or use decisions. There is a strong presumption of materiality because the Challenged Claims unquestionably relate to health concerns, were often made expressly or so strongly implied as to be virtually express, were intended, and relate to the

[37] In making this assertion, Respondents mischaracterize the testimony of Drs. Mazis and Stewart. (CC Resp. to RFF ¶¶ 2696-2701).

central characteristic and purpose of using POMx Pills or POMx Liquid and a central characteristic of POM Juice as it was advertised. (CCCL ¶¶ 44-48).

Respondents' own marketing expert, Dr. Reibstein, admitted that the Challenged Claims regarding the treatment or prevention of heart disease, prostate cancer, and erectile dysfunction would likely be important to consumers. (CCFF ¶ 638). Respondents themselves believed their promised health benefits were important to their customers. (CCFF ¶¶ 629-34). Studies that Respondents commissioned in the ordinary course of business also demonstrate the importance of the Challenged Claims, and the Commission has relied upon similar survey evidence in the past in finding Challenged Claims to be material.[38] (CCCL ¶¶ 49-50). Materiality is also shown by the fact that Respondents premised their marketing strategy on convincing consumers that the claimed health benefits were the reason to buy their expensive products, by evidence that the challenged advertising led to increased sales, and by Respondents' persistence in using the Challenged Claims in the face of warnings that a deceptive message was conveyed. (CCCL ¶¶ 53-55).

Respondents assert that the Reibstein survey rebutted the presumption of materiality. (Resp't Br. at 83). The Reibstein survey, however, failed to provide evidence of the likely effect of the Challenged Claims on the conduct of consumers who have been reached by the claims (CCCL ¶ 56); and the survey failed to expose consumers to the Challenged Claims or to even the

[38] Respondents assert that Dr. Mazis conceded that one of Respondents' ordinary course of business studies was "seriously flawed." (Resp't Br. at 89). To the contrary, he did not see the cited flaw as a big issue. (CC Resp. to RFF ¶ 2732).

challenged ads (CCCL ¶ 57).[39] Even as a study of the purchase motivations of past purchasers of POM Juice, the Reibstein survey was flawed by its reliance on broad open-ended questions with no probing as to what survey respondents who said they bought POM Juice because it was "healthy" meant.[40] (CCCL ¶ 59).

Even if the Court were to give the Reibstein survey some weight, the predicate facts that give rise to the presumption of materiality are not negated and remain evidence from which materiality can be inferred. *Novartis Corp.*, 127 F.T.C. at 686-89. The vast, overwhelming evidence in the record supports a finding that the Challenged Claims are material. (*See* CCFF ¶¶ 625-685).

G. The Promotional Materials Are Commercial Speech and Actionable Under the FTC Act (Resp't Br. at 92-96)

Respondents erroneously argue that certain promotional pieces (CX1426, Ex. E-6; CX472_0003; CX1426, Ex. F; CX472_0002; and CX1426, Ex. E-7): 1) are not "advertisements" under the FTC Act; 2) are protected speech under the First Amendment; and 3) are not material to consumers' purchasing decisions.[41] Relevant to the first two arguments is that Respondents admitted in their Answer that the *Martha Stewart Show* appearance (CX1426, Ex.

[39] In *Novartis Corp.*, the Commission criticized a survey that exposed consumers to a challenged ad but failed to "ask [respondents] directly whether the [challenged] claim was important to them." 127 F.T.C. at 694-95.

[40] Respondents cite *Stouffer Foods Corp.* for the proposition that "closed-end questions . . . tend to elicit bias." (Resp't Br. at 83-84). The previous statement that they omitted was "The drawback of open-ended questions is that they are not as effective when the issue is the consumer's memory rather than the consumer's reaction. That is where close-ended questions are effective . . . ." *Stouffer Foods Corp.*, 118 F.T.C. at 781.

[41] Complaint Counsel does not challenge CX472_0002 as deceptive under the FTC Act, and therefore does not reply to Respondents' argument as to that exhibit. (*See* CC Resp. to RFF ¶ 2546).

E-6), *The Early Show* appearance (CX472_0003), the *Newsweek.com* interview (CX1426, Ex. F), and the Fox Business interview (CX1426, Ex. E-7) were among "advertisements and promotional materials" that they disseminated or caused to be disseminated. (PX0364_0002, Answer ¶ 9).

Respondents' contention that to be actionable under the FTC Act, the media appearances must have been paid interviews is incorrect. Neither Section 5 nor 12 limits the FTC's reach to paid-for advertising. *See* 15 U.S.C. § 55(a)(1) (2012) (defining "false advertisement" without requiring that the ad be paid for); *see also Daniel Chapter One*, 2009 FTC LEXIS 157, at *168. The Commission's authority to regulate advertising is circumscribed only by its statutory authority and the limits of the commercial speech doctrine. *See R.J. Reynolds Tobacco Co.*, 111 F.T.C. 539, 542 (1988) ("The more limited protection accorded commercial speech permits the FTC to act when necessary to challenge false or deceptive advertising" (citing *Thompson Med. Co. v. FTC*, 791 F.2d 189 (D.C. Cir. 1986)).

Respondents selectively quote from the Commission's decision in *R.J. Reynolds* to argue otherwise. (Resp't Br. at 93). In that case, the Commission did not declare that payment is a necessary element of commercial speech. The Commission merely pointed to payment as one of five *non-dispositive*[42] indicia of commercial speech. *R.J. Reynolds Tobacco Co.*, 111 F.T.C. at

[42] The Commission held that no single factor was dispositive in its determination: "The Commission considers it premature, particularly in the absence of a full record, to say which characteristics will be determinative in deciding whether the Reynolds advertisement constitutes commercial speech." *R.J. Reynolds Tobacco Co.*, 111 F.T.C. at 544. This approach is consistent with the Supreme Court holding in *Bolger v. Youngs Drug Prods. Corp.*, in which the Court found that three facts supported the conclusion that the pamphlets at issue were commercial speech: 1) they were conceded to be advertisements; 2) one of the pamphlets referred to a specific product; and 3) the advertiser had an economic motivation. 463 U.S. 60, 66-68 (1983). The Court added that all three characteristics need not be present for a finding that speech is commercial speech. *Id.* at 67 n.14.

544-46. The other four were whether the speech: 1) "contain[s] a message promoting the demand for a product"; 2) "refers to a specific product or service"; 3) conveys "information about attributes of a product or service offered for sale, such as type, price, or quality" or "health effects associated with the use of a product"; and 4) "benefit[s] or seek[s] to benefit the economic interests of the speaker by promoting sales of its products." *Id*. at 544-45. Thus, that Respondents' media interviews are not traditional, paid-for advertisements does not automatically render them fully protected speech, as long as the other indicia of commercial speech are present. *See Semco, Inc. v. Amcast, Inc*., 52 F.3d 108, 113 (6th Cir. 1995) ("Neither the Lanham Act nor any Supreme Court precedent requires that consideration be paid for something to constitute advertising.").

The challenged media appearances comfortably fit the indicia of commercial speech outlined by the Commission in *R.J. Reynolds*. Pursuant to Respondents' carefully planned marketing program,[43] these media appearances promoted demand for POM Juice by touting its efficacy in treating or mitigating certain health problems. (CX1426, Ex. E-6 (Mrs. Resnick on the *Martha Stewart Show* stating that POM Juice "helps circulation, it helps Alzheimer's," and

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[43] According to Mrs. Resnick, marketing was like a wheel with many spokes, and public relations was one of the marketing spokes for POM Wonderful. (L. Resnick, Tr. 82); *see also* (CX0001_00025-26 ("Public relations is the unsung hero of marketing.… we have become a staple on the morning news, with pomegranate recipes and decorating tips, but above all with medical breakthroughs from POM Wonderful."); L. Resnick, Tr. 139). Respondents quantified the value of their PR activities using an "advertising equivalency" metric, further demonstrating that PR was a marketing channel for the POM Products. (L. Resnick, Tr. 140; Posell, Tr. 337-40). Using this metric, POM estimated that, between 2002 and 2006, the company's PR activities in print and broadcast media had reaped $184 million in ad equivalent dollars. (CX0105_0036; Posell, Tr. 335-38). From a marketing standpoint, therefore, it was irrelevant that Respondents did not pay for the messages like traditional advertising. Television appearances and media interviews simply were alternative channels to disseminate claims about the POM Products. (*See also* CC Resp. to RFF ¶ 2549).

was "amazing" for prostate cancer); CX472_0003 (Mrs. Resnick on *The Early Show* stating, "There isn't a man in America that shouldn't drink 8oz. a day [of POM Juice] because it keeps you from getting prostate cancer or from your PSA from rising"); CX1426, Ex. E-7 (Mr. Tupper on *Fox Business* indicating that a published scientific study showed that POM Juice dramatically slowed the progression of prostate cancer among men in the advanced stages of the disease, and that other published studies showed that the juice dramatically improved blood flow to the heart in patients with atherosclerosis); Compl. Ex. F (Mrs. Resnick in the *Newsweek.com* interview posted on the POM Wonderful website advising the interviewer to consume POM Juice to keep his PSA level in check, adding that the juice also was "40 percent as effective as Viagra.")). During these appearances, Mrs. Resnick and Mr. Tupper: 1) conveyed explicit promotional messages for POM products; 2) referred to the POM brand and POM Juice; 3) made specific claims about the health effects associated with consuming POM Juice (*e.g.*, the effect on Alzheimer's, prostate cancer, and erectile function); and 4) furthered the economic interests of Respondents by promoting sales of POM Juice.

Respondents incorrectly apply *Oxycal Lab. v. Jeffers*, 909 F. Supp. 719, 723, 725 (S.D. Cal. 1995) to the facts of this case. The Court in *Oxycal Lab* found that to qualify as commercial speech the "primary motivation" of the seller is "to promote a commercial transaction." 909 F. Supp. at 724-25. Contrary to the unsupported factual statements in Respondents' brief (Resp't Br. at 93-94), the record evidence supports the conclusion that promoting sales of the POM Products indeed was Mrs. Resnick's and Mr. Tupper's primary motivation for their press appearances. (*See* discussion n. 43, *supra*). The court in *Oxycal Lab* understandably reached a different conclusion based on the facts presented there: 1) the purpose of the book was "to advance [the author's] theories on the causes of cancer and the ways to eliminate cancer[,]" and

the author's recommendations of certain products was secondary; and 2) explicit reference to the commercial product at issue occurred only three times in the 500-page book. *Oxycal Lab. v. Jeffers*, 909 F. Supp. at 725-26.

Respondents further argue that Mrs. Resnick's and Mr. Tupper's statements were "reactive" to journalistic queries (Resp't Br. at 94), citing the district court decision in *Boule v. Hutton*, 70 F. Supp. 2d 378, 389-90 (S.D.N.Y. 1999), *aff'd*, 328 F.3d 84 (2d Cir. 2003). However, the district court's analysis of the reactive/proactive distinction was based on a statutory construction of the Lanham Act. *Id.* at 389-90. In any case, a plain reading of the interview statements demonstrates that the challenged efficacy claims were not reactive, but gratuitous proactive representations about the purported effect of POM Juice on prostate cancer and other serious medical conditions. (*See* CCFF ¶¶ 570-578; *see also* CC Resp. to RFF ¶¶ 2558, 2572, 2589, 2616).[44]

Respondents also misapply *Koch v. FTC*, 206 F.2d 311, 314 (6th Cir. 1953), to argue that Mrs. Resnick and Mr. Tupper were merely expressing opinions. (Resp't Br. at 95). In *Koch*, while the court held that the FTC could not enjoin the dissemination of a book that was

[44] Respondents also cite the Second Circuit's affirmance in *Boule* (RCL ¶ 38), in which the court held that the defendants' statements in a press article were not commercial speech because they were "inextricably intertwined" with fully protected speech, namely, the reporters' article on a matter of public concern – fraud in the art market. *Boule v. Hutton*, 328 F.3d 84, 91 (2d Cir. 2003). The evidence clearly shows that Mrs. Resnick's and Mr. Tupper's statements were not inextricably mingled with noncommercial speech. In *Bd. of Trustees of State Univ. of N.Y. v. Fox*, 492 U.S. 469, 474 (1989), the Supreme Court explained that commercial and noncommercial messages are not "inextricable" unless there is some legal or practical compulsion to combine them. Here, no law required Ms. Resnick and Mr. Tupper to make factual representations about the purported health benefits of POM during a discussion about pomegranate recipes or interviews about the pomegranate industry or building a business. *See Semco,* 52 F.3d at 113 (misrepresentations in a journal article on the manufacturing process for beryllium-copper plunger tips were commercial speech because the disparaging statements about a competitor's products were irrelevant to the discussion).

"primarily matter of opinion" and a public address delivered by one of the petitioners, the court further held that booklets distributed to consumers were advertisements under the FTC Act because they contained cancer cure treatment claims that were "couched, not in the language of opinion, but in positive terms." *Id.* at 317-18. As the court elaborated, the claims were:

> a positive declaration that the drugs ha[d] the therapeutic value ascribed to them in the advertisements. To the lay person the declaration that a drug does or does not have a certain effect is a representation of fact. The statement that a cancer case has been cured is a statement of fact.

Id. at 318.[45] Like these booklets, Respondents' disease claims on *The Martha Stewart Show,* CBS's *Early Show*, and *The Fox News Show* -- though arguably surrounded by noncommercial speech -- were positive statements of purported fact about the efficacy of POM Juice, calculated to induce the public to purchase the product.

Accordingly, the Court should afford no First Amendment protection to the false and misleading efficacy claims in the challenged media appearances. (CCFF ¶¶ 568-578); *Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410, 432 (1993).

[45] *See also Nat'l Comm'n on Egg Nutrition v. FTC*, 570 F.2d 157, 163 (7th Cir. 1977) (holding that the egg industry trade association's advertisements concerning the relationship between cholesterol, eggs, and heart disease were misleading commercial speech because "they were not phrased as statements of opinion . . . and were made for the purpose of persuading the people who read them to buy eggs"); *FTC v. Nat'l Comm'n on Egg Nutrition*, 517 F.2d 485, 488 (7th Cir. 1976) (holding that industry association's paid advertisements representing that there is no scientific evidence that eating eggs increases the risk of heart disease or a heart attack were advertisements within the meaning of the FTC Act, because "they were representations concerning the qualities of a product and promoting its purchase and use") (citations omitted).

H. The Challenged Claims Are False and/or Unsubstantiated (Resp't Br. at 96-98)

Respondents incorrectly suggest that Complaint Counsel must prove the claimed benefits are affirmatively false (*i.e.*, the benefits do not exist) and that Complaint Counsel ignored the *Pfizer* factors.[46] Respondents are wrong on both counts.

Complaint Counsel does not have the burden of proving that the benefits do not exist. The First Circuit addressed this defense in a recent FTC advertising substantiation case for health claims, finding that "if these claims are not supported by sufficient scientific evidence, then liability follows" and also stating, "[t]he Defendants argue that there is a third prong to a deceptive advertising claim, asserting that the FTC was required – and failed – to prove that the infomercials were actually false. However, that argument is at odds with the cases cited above. Indeed, the Defendants cannot point to any source adequate to disrupt the FTC's and district court's firm grounding in case law." *Direct Mktg. Concepts, Inc.*, 624 F.3d at 8 (internal citations omitted). The court went on to apply the "reasonable basis" framework and uphold the district court's decision finding the defendants' misleading advertising violated Sections 5 and 12 of the FTC Act. *Id.* at 8-9.

As explained in Section IV of our Reply, *supra*, the challenged establishment claims are false because Respondents do not possess the level of science conveyed by the ads. Because the vast majority of Respondents' advertisements convey establishment claims, the *Pfizer* factors are not applicable. *Removatron Int'l Corp.*, 111 FTC at 297-98, 306. For the handful of advertisements making only unsubstantiated efficacy claims, the *Pfizer* factors have been met

[46] Complaint Counsel addresses Respondents' argument about remedy (*e.g.*, *Pearson* line of cases) in Section VI.

and the advertising is clearly deceptive under the law. (*See* discussion at CCCL ¶¶ 75-90; CC Br. at 31-36).

VI. THE PROPOSED REMEDY IS WITHIN THE FTC'S AUTHORITY AND DOES NOT VIOLATE THE CONSTITUTION (Resp't Br. Sections X-XI)

Respondents' erroneous contention that the Proposed Order exceeds the Commission's authority largely ignores an important point. If this Court finds that Respondents violated the FTC Act by disseminating false and unsubstantiated claims and that those violations are as serious and deliberate as Complaint Counsel contends, then the Commission has broad discretion in crafting a remedy to address Respondents' violations. (*See* CC Br. at 57-58). Respondents also argue that Part I of the Proposed Order violates the First Amendment of the Constitution because it prospectively enjoins Respondents' speech on the basis that the FDA's pre-approval has not been satisfied without first showing that it is not possible to craft a qualified claim that would render nutrient-disease claims non-deceptive. (*See* Resp't Br. at 100). Respondents' argument demonstrates that they misunderstand how the Proposed Order would apply to advertising claims they make in the future.

The Proposed Order allows Respondents to make qualified claims without FDA pre-approval. Part I applies to any future claims that any POM Product *is effective* in the diagnosis, cure, mitigation, treatment, or prevention of any disease. If Respondents make this type of *unqualified* disease claim in the future, then the substantiation they must possess for their claims would be FDA pre-approval. (*See* CC Br. at 62-64). Part III applies to future health claims for the Covered Products *other than* the unqualified disease efficacy claims covered by Part I. That is, if Respondents make a *qualified* claim, one that characterizes the limited scientific evidence supporting a relationship between a POM product and reductions in disease risk in a careful

manner that eliminates any misimpression that a POM product actually reduces risk, then the substantiation they must possess is competent and reliable scientific evidence for the well-qualified claim. (*See* CC Br. at 67). Therefore, no FDA pre-approval is necessary for carefully *qualified* claims that convey a net impression other than that the product is effective for the treatment, prevention, or reduction of risk of disease.

Respondents have cited *Pearson v. Shalala* and *FTC v. Brown & Williamson Tobacco Corp.*, in support of their assertion that Part I violates their First Amendment rights. However, both cases are distinguishable. In *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999), the court examined FDA's pre-approval process for *qualified health claims*. *Pearson v. Shalala*, 164 F.3d at 651-52. Here, Part I of the Proposed Order is a remedy requiring Respondents to have FDA approval to substantiate disease efficacy claims,[47] which will be imposed *only after* this Court has found that Respondents have violated the FTC Act. *Brown v. Williamson Tobacco Corp.*, 778 F.2d 35 (D.C. Cir. 1985), is similarly inapplicable. The order challenged in that case did not allow for the type of qualified claims permitted under Part III of the Proposed Order in this matter.

In addition, the FDA pre-approval requirement of Part I of the Proposed Order does not constitute an imposition of "prior restraint" in violation of the First Amendment, as Respondents suggest. (*See* Resp't Br. at 100). It is well settled that a Commission Order's injunctive requirement of prior substantiation is not "prior restraint" and does not infringe on constitutionally protected speech. *See*, *e.g.*, *Daniel Chapter One*, 2009 FTC LEXIS 157, at *273 (citations omitted) (stating that "[c]ourts have consistently held that an FTC cease and desist

[47] If the claim is inadequately qualified such that the net impression is that POM Products treat or prevent disease, then the claims are deemed to fall under and Part I of the Order attaches.

order prohibiting misrepresentations about performance of products without substantiation is not an unconstitutional 'prior restraint,' but a reasonable sanction, imposed after a hearing establishes a violation of the FTC Act"); *Bristol-Myers Co. v. FTC*, 738 F.2d 554, 562 (2d Cir. 1984) (stating that the prior substantiation doctrine as applied here does not violate the First Amendment); *Sears, Roebuck & Co. v. FTC*, 676 F.2d 385, 399 (9th Cir. 1982) (stating that "[t]he Commission may require prior reasonable substantiation of product performance claims after finding violations of the [FTC] Act, without offending the First Amendment"); *Jay Norris, Inc. v. FTC*, 598 F.2d 1244 (2d Cir. 1979) (holding that "because the FTC here imposes the requirements of prior substantiation as a reasonable remedy for past violations of the Act, there is no constitutional prior restraint"). Therefore, the Notice Order's substantiation requirement for future claims neither exceeds the FTC's authority nor violates the Constitution.

Finally, contrary to Respondents' assertion that a multi-product order is not warranted, it is proper here given the facts. Respondents sell a variety of foods and supplements that could be promoted using the kinds of health-related representations that were challenged in this matter. Respondents have made a variety of representations about the health benefits of other POM Products and have undertaken research on the health benefits of non-POM products, such as Fiji Water and pistachios. (*See* CC Br. at 61-62). The Commission has entered orders covering many of a company's products on the basis of violations as to a single product. *Litton Indus., Inc.*, 97 F.T.C. 1, 78-80 (1981), *aff'd as modified*, 676 F.2d 364 (9th Cir. 1982); *Sears Roebuck & Co.*, 95 F.T.C. 406, 515-22 (1980), *aff'd*, 676 F.2d 385 (9th Cir. 1982). Therefore, the multi-product order coverage is entirely appropriate in this matter.

VII. CONCLUSION

In marketing her brands, one of Lynda Resnick's stated goals has been to "break through the clutter" of competing messages. (L. Resnick, Tr. at 84). As she has eloquently and concisely stated, "sometimes you whisper to . . . break through the clutter, when everybody else is screaming." (CX1359 (L. Resnick, Dep. at 243)). Although we may not have achieved our initial goal of brevity (CC Reply Br. at 1), with this Reply, we hope to have succeeded in breaking through the clutter of Respondents' brief.

Based on the record evidence, and for the reasons stated in our Post-Trial Brief, Proposed Findings of Fact and Conclusions of Law, and this Reply, we respectfully request that the Court find for Complaint Counsel and direct the relief set forth in the Proposed Order attached to the Complaint.

Respectfully Submitted,

Date: February 7, 2012

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CERTIFICATE OF SERVICE

I certify that on February 7, 2012, I caused the filing and service of public and confidential versions of *Complaint Counsel's Post-Trial Reply Brief and Reply to Respondents' Proposed Findings of Fact* as set forth below:

One electronic copy of the redacted public filing via the FTC E-Filing System, and electronic and paper copies, including the paper original, of the confidential filing to:

Donald S. Clark, Secretary
Federal Trade Commission
600 Pennsylvania Ave., NW, Room H-159
Washington, DC 20580

Paper copies of the confidential and redacted public filings via hand delivery, and electronic copies via email to:

The Honorable D. Michael Chappell
Administrative Law Judge
600 Pennsylvania Ave., NW, Room H-110
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ATTACHMENT A

VIOLATIONS OF REQUIREMENTS IN ORDER ON POST-TRIAL BRIEFS

The proposed finding is unsupported because evidence cited is not in the record, in violation of the Court's Order on Post-Trial Briefs	**The proposed finding is not supported by any reference to the record, in violation of the Court's Order on Post-Trial Briefs**
Respondents' Findings of Fact ¶¶ 4, 358, 756 (p. 190), 761 (p. 192), 763-70, 775, 777-78, 1096, 1802-05, 1807-20, 2117-18, 2206, 2244-46, 2545, 2554, 2557, 2563 Total: 44	Respondents' Findings of Fact ¶¶ 17, 27-32, 34-37, 39, 40, 47-49, 108-09, 201-05, 248, 308, 354, 364, 608-09, 617, 687-89, 754 (p. 195), 779, 800, 804, 809-10, 829-30, 840, 844-45, 865, 868-69, 873, 909, 914, 942, 945, 949-51, 958, 990, 1120, 1211, 1931, 2205, 2211(c-d), 2212, 2214, 2219-22, 2236, 2248, 2261-62, 2266, 2270-71, 2272, 2274, 2286, 2289-90, 2293, 2297-99, 2308, 2313-14, 2317, 2319-21, 2338-39, 2342-43, 2354-56, 2370-73, 2376, 2378-80, 2383, 2392, 2396-99, 2402, 2404-06, 2430, 2433-34, 2436, 2449, 2451-52, 2459-62, 2476-77, 2515, 2547, 2555-56, 2564, 2566, 2570, 2574, 2578, 2580, 2585-86, 2592, 2594-95, 2612-14, 2617, 2620, 2621, 2799 Respondents' Appendix of Advertisements ¶¶ 4-5, 9, 21, 24-25, 45, 55, 74, 77, 83, 87, 89, 91, 104-05, 110, 120, 124, 134, 137-38, 141, 150, 153-54, 158, 167, 170-72, 174, 181, 199, 202, 205, 212, 215-16, 221, 232, 236, 239, 251, 254, 260, 264-65, 267, 279-80, 297, 303, 310, 314, 316, 325, 329, 332, 338, 342, 345, 352, 355-56, 369-70, 380, 383-85, 394, 398, 413, 416-17, 433-34, 450-51, 475, 478-79, 495-96, 510, 513-14, 532-34, 543, 556, 559-60, 571, 574-75, 593-94, 603, 607-08, 617 Total: 256