ORIGINAL

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

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

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"Too often, brands promise more than they can ever hope to deliver."

Lynda Resnick, Owner, POM Wonderful and Roll Global

in *Rubies in the Orchard, The POM Queen's Secrets to Marketing Just About Anything* (CX0001_00035).

I. INTRODUCTION AND STATEMENT OF FACTS

In an ironic twist, Corporate Respondents POM Wonderful LLC ("POM") and Roll Global LLC ("Roll"), and Individual Respondents Stewart A. Resnick, Lynda Rae Resnick, and Matthew Tupper (collectively "Respondents") violated Sections 5(a) and 12 of the Federal Trade Commission Act ("FTC Act") by failing to deliver on their promises that POM Wonderful 100% Pure Pomegranate Juice ("POM Juice"), and POMx Pills and POMx Liquid (collectively, the "POM Products") treat, prevent, and reduce the risk of heart disease, prostate cancer, and erectile dysfunction (the "Challenged Claims"). To distinguish the POM Products from those of competitors, Respondents focused their marketing campaigns on these specific purported health benefits of POM Juice and POMx that they emphasized were "backed" by millions of dollars in scientific research. (CCFF ¶¶ 66, 281-324, 372-373, 376, 380-381, 384, 386-388, 389, 398, 407, 411, 415-416, 425, 440, 444, 473, 496-498, 508, 517, 536-537, 572-573, 631, 1120). They represented in print, point-of-purchase, Internet, and other promotional materials that the POM Products are effective weapons against heart disease, prostate cancer, and erectile dysfunction (ED), punctuating these claims with hard-hitting headlines, selected quotes from published research, and powerful medical imagery. Respondents' advertising targeted professional, health-

conscious individuals, including persons concerned about heart disease and men who feared getting prostate cancer, promising them specific and "real results" for serious health conditions. (CCFF ¶¶ 299-308). For example, they repeatedly told consumers that the POM Products "minimize factors leading to atherosclerosis," reduce plaque in the arteries "up to 30%," significantly "delay[] PSA doubling times," decrease "stress-induced ischemia (restricted blood flow to the heart)," and demonstrate "17% improvement in blood flow." (CCFF ¶¶ 271, 326, 330, 336, 344, 368, 378-379, 410-411, 415, 419, 425, 432, 440, 446, 453-454, 463-464, 485, 515, 524, 556).

Respondents admit making specific health benefit claims for the POM Products. (CCFF ¶¶ 41, 154, 156-157, 284, 288, 347, 360, 365, 369, 373-374, 420, 433, 619, 674, 953-954). As the Individual Respondents have testified repeatedly, they *believe* POM Juice and POMx are effective against heart disease, prostate cancer, and ED and they know consumers believe it as well. (CCFF ¶¶ 155, 283-291, 616-620). Moreover, Respondents' documents and testimony demonstrate they intended to market the POM Products for these health conditions. (CCFF ¶¶ 155, 159-160, 208, 239-241, 246-248, 250-251, 260, 269, 271-273, 281-324, 334, 337, 617-620, 630, 632-634). However, neither Respondents' belief that the POM Products are effective for these health conditions nor Respondents' substantiation is sufficient to support their advertising claims to consumers of such benefits. Respondents know that the law requires them to possess "competent and reliable scientific evidence" to substantiate health efficacy claims and that the claims at issue require clinical studies designed and conducted in a manner to yield accurate, objective, and credible results. (CCFF ¶¶ 683, 662-674, 690-691, 1123, 1126).

The evidence demonstrates that Respondents lack the proper scientific support for their claims that the POM Products treat, prevent, or reduce the risk of heart disease, prostate cancer,

and ED, and that such benefits have been established. Although Respondents boast spending over $34 million in scientific research to back their claims, Complaint Counsel's experts revealed that the science Respondents rely upon is not adequate – in methodology or outcome – to substantiate the Challenged Claims. Most of Respondents' studies to date were exploratory, without proper study design controls (*e.g.*, blinding, randomization, and comparison to placebo) or validated measures necessary to determine whether the POM Products treat, prevent, or reduce the risk of heart disease, prostate cancer, or ED in humans.

Moreover, the evidence shows that Respondents knew that their scientific studies were insufficient to support their aggressive health efficacy and establishment claims. (CCFF ¶¶ 683, 902, 952-954, 966-972, 1010, 1045-1051, 1096-1098). Regarding their heart disease studies, they acknowledge that the "current body of [heart] research [was] only viewed as '3' on a scale of 1-10 by MDs[.]" (CCFF ¶¶ 971-972). As for the prostate cancer research, they acknowledge that it too has gaps. (CCFF ¶ 394). The only published study is an unblinded, uncontrolled trial of POM Juice using a study endpoint – prostate specific antigen doubling time ("PSADT") – that is inherently variable and is not generally predictive of prostate cancer mortality. (CCFF ¶¶ 1044-1051). Respondents admit their substantiation for their ED claims similarly rests on a study of POM Juice that has limitations due to the small number of participants and failure to yield statistically significant results. (CCFF ¶ 1096; *see also* CCFF ¶ 1078). Respondents also received signals from researchers, outside advertising bodies, consumers, and federal regulators that Respondents' advertising was out of step with Respondents' level of scientific support. (CCFF ¶¶ 662-693).

While Respondents early on may have been "naïve" about the rules of the road for health efficacy claims (S. Resnick, Tr. 1648-49), their documents and testimony reflect a well-

conceived, sophisticated strategy of marketing the POM Products as an antidote for specific disease conditions. Respondents intentionally differentiated their products from competitors by offering consumers not just a pure fruit juice or dietary supplement, but "health in a bottle," which they broadcast as antioxidant prowess paired with specific health benefits. (*See, e.g.*, CCFF ¶¶ 155, 281-283, 289-290, 292, 310, 326, 336-337, 341, 344, 349, 351, 357, 363, 372, 386, 400, 411, 415, 425, 430, 443-460, 488). They aggressively publicized to consumers the results of their clinical research on heart disease, prostate cancer, and ED. Instead of pursuing FDA authorized health claims of "reduced risk of heart disease" or "reduced risk of prostate cancer" for the POM Products, Respondents determined it was more advantageous either to do "targeted research for Marketing/PR/Medical Outreach purposes" or just "publicize what we already have." (CCFF ¶¶ 159, 683, 969-971). From a business standpoint, an FDA authorized health claim offered little return on the Resnicks' investment, as Mr. Tupper noted, because the resulting claim "would not be specific to POM, but rather it would be generic to all pomegranate products meeting a minimum level of polyphenol content," including their competitors' products. (CCFF ¶ 683).

A. Respondents Have Advertised and Sold the POM Products to the Public Since 2002

Corporate Respondents POM and Roll are Delaware limited liability companies with their principal place of business at 11444 West Olympic Boulevard, Los Angeles, California. (CCFF ¶¶ 16, 88, 92). POM began operating in 2001, and since that time has emerged as the self-described largest grower and distributor of pomegranates and pomegranate juice in the United States. (CCFF ¶¶ 87, 149). The company markets and sells "Wonderful" variety fresh

pomegranates and several derivative products, including POM Juice, POM Juice blends, POMx Pills and Liquid, POMx sports recovery drink, and POMx bars. (CCFF ¶¶ 122-123).

Roll is a $2 billion company that parents and services the Resnicks' affiliated businesses, including POM, Teleflora, Fiji Water, Paramount Citrus, Paramount Farms, Suterra, and Justin Vineyards and Wineries. (CCFF ¶ 12). Roll provides services such as advertising, public relations, consulting, accounting, and human resources to its family of companies. (CCFF ¶¶ 94-96). Roll's in-house advertising agency, dubbed "the Agency" and later "Fire Station," provides advertising services to POM and the other Roll companies. (CCFF ¶ 96; CX1359_0027). Over the years, POM and Roll have collaborated to create content for, and determine placement of print, outdoor, direct mail, and online advertisements, and public relations communications for the POM Products. (CCFF ¶¶ 99-102). Fire Station also monitors and reports on the effectiveness of POM's advertisements. (CCFF ¶ 99; PX0364 ¶ 2). Roll provides public relations and related services (*e.g.*, press releases, press kits, celebrity outreach, media relations) through its Corporate Communications department. (CCFF ¶ 103). Roll also has an in-house consulting group that has assisted POM with projects related to product development, juice processing, business expansion, consumer research, and sales and marketing. (CCFF ¶¶ 104-105).

At all pertinent times, Individual Respondents Stewart Resnick, Lynda Resnick, and Matthew Tupper have directed, controlled, and/or participated in the business activities of POM and Roll. (CCFF ¶¶ 9-86). High ranking executives of POM and Roll report directly or indirectly to the Resnicks and Mr. Tupper. (CCFF ¶¶ 17, 52-56). The Resnicks have complete control over POM and Roll, and over the last decade have served as officers and in positions of

final authority over the companies' business matters. (CCFF ¶¶ 13-15, 19-27, 36-37, 40-41, 45-46; CX1421_0002-3; PX0364 ¶¶ 3-4).

The Resnicks have actively participated in POM's business operations, including hiring POM personnel and agents, such as POM's president, Chief Financial Officer, medical director, current and past personnel responsible for handling POM sponsorship of medical research, and various senior marketing executives. (CCFF ¶¶ 37, 58, 161, 163, 166-167). The Resnicks also have directed POM's medical research program by, for example, providing funding, executing contracts, engaging scientific consultants, and hosting research summits. (CCFF ¶¶ 30, 119). Stewart Resnick holds regular meetings with POM's president Matthew Tupper and makes final decisions about the investments and expansion of the POM business. (CCFF ¶¶ 25, 48, 53, 83).

From the outset, Lynda Resnick has fashioned POM's marketing strategy and creative development. (CCFF ¶¶ 21-23, 38-43). Over the years, she regularly met with POM marketing and Roll advertising personnel, provided input on POM marketing materials, developed consumer market research, and participated in decisions about what studies to reference in product advertising. (CCFF ¶¶ 38-43, 187-191, 309, 331-333, 336-339, 372-373).

Matthew Tupper, the president and Chief Operating Officer of POM, has set the policies and practices of POM since 2003. (CCFF ¶¶ 41-54). Respondents admit in their Answer that "Mr. Tupper, as an officer of POM Wonderful LLC, together with others, formulates, directs, or controls the policies, acts, or practices of POM Wonderful, LLC." (CCFF ¶ 48). POM's heads of marketing and scientific affairs report to Mr. Tupper. (CCFF ¶¶ 54-56). Mr. Tupper has been intimately involved in the full spectrum of POM's operations, including management of juice processing and bottling, marketing and sale of the POM line of products, and expansion of the business. (CCFF ¶¶ 48, 51, 53). Throughout his tenure, he has collaborated with Lynda Resnick

on product marketing and advertising claims and has been responsible for the hiring and firing of POM employees. (CCFF ¶¶ 58-59, 61, 67-68, 72-73, 76). Mr. Tupper has worked closely with Stewart Resnick and POM's research advisors to determine the areas of scientific research the company will sponsor. (CCFF ¶¶ 80-86). Moreover, Matthew Tupper and Lynda Resnick have been the public faces of POM, explaining to the media and to consumers the purported health benefits of the POM Products for heart disease, prostate cancer, and ED. (CCFF ¶¶ 44, 75, 568-578).

POM began bottling, selling, and marketing POM Juice on a regional basis in the fall of 2002, and in national markets in 2003. (CCFF ¶ 151).

(CCFF ¶ 124, *in camera*). Prior to sale, POM reconstitutes and pasteurizes the concentrate to make "100 percent juice." (CCFF ¶ 125). The final juice product contains 85.4% water, 10.6% sugars, 1.4% pectin, 0.2-1.0% polyphenols, and organic acids. (CCFF ¶ 125). Approximately 2.5 pomegranates produce an eight-ounce serving of POM Juice. (CCFF ¶ 129). From the juice's launch in September 2002 through November 2010, POM made approximately $247 million in POM Juice sales. (CCFF ¶ 139). According to Mrs. Resnick, it became an "overnight sensation." (PX0370 at 1, 2). POM Juice is a [redacted] sold in the refrigerated produce section of supermarkets throughout the United States. (CCFF ¶¶ 136, *in camera*,142, 378). As of 2008, POM Juice cost approximately $2.93 for an 8-ounce bottle and $4.29 for a 16-ounce bottle. (CCFF ¶ 140).

Over the years, POM expanded its line of products to include pomegranate-based tea, coffee, bars, and supplements. (CCFF ¶ 123). In 2007, the company introduced POMx Pills and POMx Liquid. (CCFF ¶ 141). POMx is derived from the fruit mash that remains after the first

juice pressing. (CCFF ¶ 130). POM has sold POMx to consumers via POM's website, telephone sales, and through a few U.S. retail outlets (*e.g.*, GNC stores). (CCFF ¶¶ 142, 231).

(CCFF ¶ 145, *in camera*). From the products' launch in 2007 through November 2010, POM earned approximately $4 million in POMx Pill gross revenue and approximately $210,000 in POMx Liquid gross revenue. (CCFF ¶¶ 143-144).

B. Respondents' Marketing Strategy for the POM Products Has Been to Emphasize Specific Health and Disease Benefits

When the Resnicks formed POM in 2001, their fresh pomegranate crops' yield exceeded the expected sales of seasonal pomegranates, making it "essential to immediately begin a marketing program for the Pom Juice product." (CCFF ¶ 149-150; JX0003; PX0370 at 1-2). However, when Respondents went about creating a market for pomegranate juice, "only about one in ten Americans said they were familiar with pomegranates . . . ." (CCFF ¶ 152).

But, Lynda Resnick firmly believed that POM Juice had "the power to help heal people." (CCFF ¶¶ 155, 283). She was convinced that "[p]eople needed pomegranate juice in their lives (even if they didn't know it yet)" and that "they would pay what it was worth." (CCFF ¶ 155). The Resnicks had been funding research to explore the antioxidant properties and health benefits of pomegranate juice since the 1990s. Based on their research, they concluded that POM Juice and POMx derive specific health benefits from the products' polyphenol antioxidant content. (CCFF ¶¶ 160, 167, 473, 620, 790). As early as 2001, the scope of Respondents' research efforts was two-fold: "(A) for use in marketing (primarily circulation) and (B) 'home run' cure for cancer, etc." (CCFF ¶ 159). At that time, Respondents' then Medical Director acknowledged

the importance of conducting research on how the product works for purposes of substantiation "as we go to the FDA or the FTC for claims." (CCFF ¶ 683).

From a marketing standpoint, Mrs. Resnick saw value in ensuring "that the science was made public when the supply is available" and in "publish[ing] the findings in stages to keep the news new." (CCFF ¶ 160). Lynda Resnick's 2001 memo on marketing POM Juice outlined several purportedly "proven health benefits," such as lowering LDL cholesterol and guarding against heart disease, that she determined POM could "'talk about' at scientific meetings, public relations campaigns and consumer promotions." (CCFF ¶ 160). Over the years, Respondents' marketing teams have continued to focus on Mrs. Resnick's core message that POM Juice and POMx are "antioxidant superpowers," proven by scientific research to provide heart, prostate, and erectile function benefits. (CCFF ¶¶ 325, 341, 344, 349, 351, 357, 363, 372). Mrs. Resnick believed that "[POM had] new medical breakthroughs on a regular basis, so there is always something new and exciting to learn about POM." (PX0370 at 127; *see also* CCFF ¶ 568).

As early as 2004, Respondents began referencing in POM Juice advertising a study by Michael Aviram on the effect of POM Juice on arterial plaque (Aviram CIMT/BP Study (2004)), announcing to the general public that 8 ounces a day of POM Juice reduced plaque buildup in the arteries as much as "30%." (CCFF ¶¶ 170, 329, 336). In fact, the Aviram CIMT/BP Study (2004) was an unblinded, uncontrolled study of a handful of patients with severe heart disease, the results of which were not replicated in a larger well-designed, well-controlled study (Davidson CIMT Study (2009)) completed in early 2006. (CCFF ¶¶ 805-821, 879-911). Respondents continued to tout results of the Aviram CIMT/BP Study (2004) well into 2009 in both POM Juice and POMx ads. (CCFF ¶¶ 420, 821, 892). In or about 2008, Respondents also began referencing in their advertising the results of a heart study on the effect of POM Juice on

myocardial perfusion (blood flow to the heart) (Ornish MP Study (2005)), emphasizing improved blood flow to the heart based on one measure of blood flow, despite the fact that the study failed to show improvement on two other measures of blood flow and showed no significant changes in other cardiovascular risk measures. (CCFF ¶¶ 171, 407-411, 415, 419, 449, 824-854).

In 2006, after publication of a study by Dr. Allan Pantuck on the effect of POM Juice on PSA doubling time in 46 men previously treated for prostate cancer, Respondents began promoting POM Juice and POMx to consumers as preventing and treating prostate cancer. (CCFF ¶¶ 172, 368, 378, 397, 402-404, 410-411, 987, 1044-1053). In the advertising, Respondents touted a significant PSADT increase from a mean of 15 months at baseline to 54 months after treatment, despite the significant study design limitations emphasized by the authors of the publication – the study was unblinded, uncontrolled, and measured efficacy based solely on PSADT. (CCFF ¶¶ 378, 440, 996, 1002-1012). Despite Dr. Pantuck's concern that "the lay interpretation" of POM's ads will be that "[POM Juice] shows promise for the treatment of prostate cancer" (CCFF ¶ 402), Respondents have used the Pantuck Phase II Prostate Cancer Study (2006) as recently as 2010 to represent to consumers that POM Juice and POMx prevent, reduce the risk of, or treat prostate cancer. (CCFF ¶¶ 415, 419).

In 2007, Respondents began promoting POM Juice as beneficial for erectile dysfunction based on a published study by Christopher Forest (Forest Erectile Dysfunction Study (2007)). (CCFF ¶¶ 168, 173, 271, 389, 425). Despite the research showing no statistically significant difference between POM Juice and placebo based on two different erectile function questionnaires, Respondents used the study to advertise that POM Juice and later POMx treat, reduce risk, or prevent ED. (CCFF ¶¶ 1076-1078, 1101).

Many of the POM Juice advertisements and the entire POMx campaign conveyed Mrs. Resnick's core message in a serious, objective tone that offered substantial content about scientific findings. (CCFF ¶¶ 295, 303, 329-332). POM Juice ads also have embraced a lighthearted approach to convey the core health benefit message – for example the "Dressed Bottle" campaign, which cloaked the POM Juice bottle in various attire (*e.g.*, wrapped in a blood pressure cuff, hooked up to an EKG, or modeled as a hospital intravenous drip bag), and the "Super Hero" campaign, which portrayed the POM Juice bottle in a series of comic book style vignettes. (CCFF ¶¶ 73, 344-348, 372, 443). The overarching goal of each campaign was to communicate POM's health benefits by breaking through the clutter of competing advertising messages by connecting with consumers at a visceral level. (CCFF ¶¶ 295-297). So notes Mrs. Resnick, "if you make someone laugh or cry . . . if you can elicit an emotion from someone, their guard goes down a little and they listen to you. . . . [I]f you can be charming and funny or sad then your message will come through." (CCFF ¶ 297). Respondents' consumer research confirmed that Mrs. Resnick's marketing approach worked. *See infra*, Section II.B. Consumers cited health reasons more often than the other choices provided (*e.g.*, taste) as the reason for drinking POM Juice, and cited disease prevention (*e.g.*, "helps protect against prostate cancer") as a reason to purchase POM Juice. (CCFF ¶¶ 641-650).

As early as 2007, Respondents' ads emphasized, under headings like "Science, Not Fiction," that the POM Products' health benefits are supported by millions of dollars in medical research spent by the Resnicks. (CCFF ¶ 398). Over the years, the dollar figures have steadily increased from $20 million (2007), to $25 million (2008), to $32 million (2009), to most recently $34 million (2010). (CCFF ¶ 309; *see e.g.*, CX0101; CX0330). POM communicated to

consumers the amount of money invested in medical research to emphasize that POM does not "just say our product is great, we have clinical studies that prove its efficacy." (CCFF ¶ 311).

II. RESPONDENTS' DECEPTIVE ADVERTISING VIOLATES SECTIONS 5 AND 12 OF THE FTC ACT

A. Respondents' Ads Convey the Establishment and Efficacy Claims Alleged in the Complaint

The evidence shows that Respondents engaged in deceptive acts or practices and the making of false advertisements in violation of Sections 5 and 12 of the FTC Act. 15 U.S.C. §§ 45(a), 52 (2012); *Daniel Chapter One* (hereinafter *Daniel Chapter One Initial Decision*), Docket No. 9329, 2009 FTC LEXIS 157, at *134-35 (FTC Aug. 5, 2009) (stating that "the preponderance of the evidence standard governs FTC enforcement actions"). Section 5(a) of the Act declares unlawful "unfair or deceptive acts or practices in or affecting commerce . . . ." 15 U.S.C. § 45(a)(1). National advertising, marketing, or sales activity of the sort Respondents engaged in constitutes "commerce" under the FTC Act, and Respondents admit that the acts or practices alleged in the Complaint have been in or affecting commerce. *See, e.g.*, *P.F. Collier & Son Corp. v. FTC*, 427 F.2d 261, 272 (6th Cir. 1970); *Ford Motor Co. v. FTC*, 120 F.2d 175, 183 (6th Cir. 1941); (PX0364_0002).

In addition, Section 12 of the FTC Act prohibits the dissemination of "any false advertisement" in order to induce the purchase of "food, drugs, devices, services, or cosmetics." (15 U.S.C. § 52(a)(2)). A "false advertisement" under Section 12 is "an advertisement, other than labeling, which is misleading in a material respect[.]" 15 U.S.C. § 55(a)(1). Respondents admit that the POM Products are "foods" within the meaning of Sections 12 and 15 of the FTC Act. (PX0364_0002; 15 U.S.C. § 55(b)). Respondents specifically market POMx Pills as a dietary supplement (CCFF ¶¶ 142, 250, 504, 517, 523, 572; CX0115), and their experts consider

POMx Pills to be a dietary supplement (CCFF ¶ 929). The evidence also shows that the POM Products, based on their intended use and advertised claims, are "drug[s]" within the meaning of Section 12 of the FTC Act. 15 U.S.C. § 55(b) (defining "drug" as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man . . . ."); *Daniel Chapter One Initial Decision*, 2009 FTC LEXIS 157, at *81 ("There is no dispute that the Challenged Products are dietary supplements. . . . Such articles constitute 'food' and/or 'drug[s]' within the scope of Section 12 [of the FTC Act]."). (CCFF ¶¶ 281-324; *see* App. A, Tables 1 and 2). Respondents admit that they disseminated or caused to be disseminated advertising and promotional materials, including the materials attached to the Complaint. (CCFF ¶¶ 122, 578; PX0364_0002-03).

Neither Section 5 nor 12 limits the FTC's reach to a specific type of advertising or even to paid-for advertising. (*See* 15 U.S.C. § 55(a)(1) (defining "false advertisement" without requiring that the ad be paid for)). In fact, Respondents admit that public relations materials (CX1426 Exs. E-6, E-7, and Ex. F) are examples of "advertising and promotional materials" that they disseminated or caused to be disseminated. (CCFF ¶ 177; PX0364_0002-0003).

Respondents disseminated the challenged advertisements and promotional materials (*see* App. A, Tables 1 and 2) between 2003 and 2010 using a spectrum of media, including packaging and labeling, direct mail, print media, Internet (banner ads, paid search terms via Internet providers), and celebrity outreach and public relations venues (*e.g.*, press releases publicizing research milestones, press interviews) that would generate buzz about the POM Products. (CCFF ¶¶ 176-177; 261-280). This approach is consistent with Lynda Resnick's philosophy that product marketing is like a wheel with many spokes and, for the POM business, the marketing "spokes" included advertising, public relations, Internet marketing, event sponsorship, and

product placement. (CCFF ¶¶ 175-176). Consequently, all of Respondents' challenged advertising and marketing constitute "advertisements" within the scope of Section 12 of the FTC Act, 15 U.S.C. § 52, and alleged deceptive acts or practices within the scope of Section 5 of the FTC Act, 15 U.S.C. § 45. *Daniel Chapter One Initial Decision*, 2009 FTC LEXIS 157, at *168; *R.J. Reynolds Tobacco Co., Inc.*, 111 F.T.C. 539, 542 (1988) (citing *Thompson Med. Co. v. FTC*, 791 F.2d 189 (D.C. Cir. 1986); *Sears, Roebuck & Co. v. FTC*, 676 F.2d 385 (9th Cir. 1982); *Warner-Lambert Co. v. FTC*, 562 F.2d 749 (D.C. Cir. 1977); *Beneficial Corp. v. FTC*, 542 F.2d 611 (3d Cir. 1976)).

An "'advertisement is deceptive under the [FTC] Act if it is likely to mislead consumers, acting reasonably under the circumstances, in a material respect.'" *Daniel Chapter One Initial Decision*, 2009 FTC LEXIS 157, at *173 (quoting *Kraft, Inc. v. FTC*, 970 F.2d 311, 314 (7th Cir. 1992)); *see also FTC v. Direct Mktg. Concepts, Inc.*, 569 F. Supp. 2d 285, 297 (D. Mass. 2008), *aff'd*, 624 F.3d 1 (1st Cir. 2010); *Telebrands Corp.*, 140 F.T.C. 278, 290 (2005), *aff'd*, 457 F.3d 354 (4th Cir. 2006); *Thompson Med. Co.*, 104 F.T.C. 648, 788 (1984), *aff'd*, 791 F.2d 189 (D.C. Cir. 1986); *Cliffdale Assocs., Inc.*, 103 F.T.C. 110, 164-66, 175-76 (1984) (including as an appendix the *FTC Policy Statement on Deception* (hereinafter "*Deception Policy Statement*")). The evidence shows that Respondents made material representations about POM Juice and POMx that were likely to mislead reasonable consumers. (*See infra*, Sections II.B and II.C).

1. The Legal Standard for Determining Ad Meaning Is the Overall Net Impression Conveyed by the Ads

In implementing the "likely to mislead" standard, "the [FTC] examines the overall net impression of an ad and engages in a three-part inquiry: (1) what claims are conveyed in the advertisement; (2) are those claims false or misleading; and (3) are those claims material to prospective consumers." *Kraft*, 970 F.2d at 314.

"The primary evidence of the claims an advertisement conveys to reasonable consumers is the advertisement itself." *Daniel Chapter One Initial Decision*, 2009 FTC LEXIS 157, at *83 (citing *Telebrands Corp*., 140 F.T.C. at 290; *Novartis Corp*., 127 F.T.C. 580, 680 (1999), *aff'd*, 223 F.3d 783 (D.C. Cir. 2000); *Kraft, Inc*., 114 F.T.C. 40, 121 (1991), *aff'd*, 970 F.2d 311 (7th Cir. 1992). The Commission considers the "overall net impression created by the advertisement as a whole," by evaluating "the interaction of such elements as language and visual images." *Daniel Chapter One Initial Decision*, 2009 FTC LEXIS 157, at *176-77 (citing *Am. Home Prods. Corp. v. FTC*, 695 F.2d 681, 687 (3d Cir. 1982); *Kraft*, 114 F.T.C. at 122; *Thompson Med. Co.*, 104 F.T.C. at 793 n. 17 (1984)); *see also FTC v. Sterling Drug, Inc.*, 317 F.2d 669, 674 (2d Cir. 1963) ("The entire mosaic should be viewed rather than each tile separately. 'The buying public does not ordinarily carefully study or weigh each word in an advertisement'") (quoting *Aronberg v. FTC*, 132 F.2d 165, 167 (7th Cir. 1942)).

In considering the net impression of an advertisement, the Commission does "not require that all consumers reading or viewing it be sophisticated experts in interpreting the nuances of the English language." *Thompson Med. Co.*, 104 F.T.C. at 792 ("We look at how such individuals actually interpret advertisements in a real-life situation, not at how they would if they had sufficient time and incentives attentively to review the ads so as to come up with the most

semantically correct interpretation of them"). In addition, Commission law recognizes that advertisements may be susceptible to more than one reasonable interpretation. *Kraft, Inc.*, 114 F.T.C. at 120-21 n. 8; *Thompson Med. Co.*, 104 F.T.C. at 789 n. 7. "[S]tatements susceptible of both a misleading and a truthful interpretation will be construed against the advertiser." *FTC v. Bronson Partners, LLC*, 564 F. Supp. 2d 119, 127 n. 6 (D. Conn. 2008) (quoting *Country Tweeds, Inc. v. FTC*, 326 F.2d 144, 148 (2d Cir. 1964)). "An ad is misleading if at least a significant minority of reasonable consumers are likely to take away the misleading claim." *Telebrands Corp.*, 140 F.T.C. at 291.

Respondents were deliberate in the marketing messages they intended to convey (*see infra*, Section A.2.), and were acutely aware of the net impression consumers would likely take from the POM Product advertisements. (CCFF ¶¶ 281-297, 616-621, 632-634, 639-650). Lynda and Stewart Resnick are accomplished business people, and Lynda Resnick is an acclaimed marketer. (CCFF ¶¶ 11-12, 147-155, 176). Mrs. Resnick conveyed to her marketing people to use "baby talk," meaning keep the text simple so that a layperson could understand it. (CCFF ¶ 239). More broadly, she understood the importance of connecting with consumers to evoke interest in the POM Products, remarking that "[i]f we can make you chuckle, we have an opportunity to connect with a more serious message grounded in our brand's identity and extrinsic value." (CCFF ¶ 296; *see also* CCFF ¶ 297). The Resnicks' business protégé, Matt Tupper, likewise has extensive marketing experience based on his nearly ten years' tutelage by the Resnicks. (CCFF ¶¶ 45-47, 53, 68-77). Like Lynda Resnick, he understood how the "reasonable consumer" thinks. (CCFF ¶¶ 622, 624).

2. Respondents Intended to Convey Hard-Hitting Establishment and Efficacy Claims

There is ample evidence in the record that Respondents intended to communicate to consumers that the POM Products treat, prevent, or reduce the risk of heart disease, prostate cancer, and ED and that they have clinical proof of these benefits. (*See*, *e.g.*, CCFF ¶¶ 281-324). Although not required for finding liability under Section 5 of the FTC Act, "a showing of intent is powerful evidence that the alleged claim in fact was conveyed to consumers." *Telebrands Corp.*, 140 F.T.C. at 304; *see also Novartis Corp.*, 127 F.T.C. at 683.

Respondents view the claimed medical benefits of POM Juice, and its purported equivalent POMx, as the "unique selling proposition" to market the POM Products to consumers and to set the products apart from competitors. (CCFF ¶¶ 156, 281-283, 289, 292, 294). As previously noted (*see supra* I.B.), Lynda Resnick was eager to market POM Juice as protective against heart disease when the product initially launched and to publicize scientific findings on a continuing basis to keep the medical news about POM Juice fresh for consumers. (CCFF ¶¶ 153-160, 290). To this end, Respondents have highlighted medical research in POM Product advertising and marketing materials over the years because the research lends credibility to the claims and gives consumers a "reason to believe." (CCFF ¶ 306).

According to Lynda Resnick and Matt Tupper, the ads also stressed that Respondents' claims are backed by $20-34 million in scientific research to underscore to consumers the depth and rigor of their science, as compared to competitors. (CCFF ¶¶ 309-315). However, the studies cited in the challenged ads cost only a fraction (approx. $2.5 million) of the $34 million figure touted. (CCFF ¶¶ 168, 324). Instead, the amount is merely a running tab of science-related expenses, including meetings, competitor product testing, and animal feed research.

(CCFF ¶¶ 319-324). It is not limited to "real results" as touted. (*See, e.g.*, CCFF ¶¶ 319-322, 468).

Respondents' intent to make the challenged claims is evident by their various admissions in the record that the POM Product ads and marketing pieces convey serious health and medical messages. (*See, e.g.*, CCFF ¶¶ 281-290, 293, 295-297, 334, 337-338, 350-355, 359-360, 365, 369, 373-374, 383, 547, 616-617). This medical messaging mirrors Respondents' outspoken beliefs that pomegranate juice "can be very helpful as a natural disease prevention and curative," including "to ward off prostate cancer," to reduce arterial plaque and factors leading to atherosclerosis, and to treat some forms of impotence, and that POMx has been shown to possess the same health benefits as POM Juice. (CCFF ¶¶ 284-286, 406-412, 574, 576). Indeed, Stewart Resnick testified that Respondents publicize the results of their research because of a belief "that people should try to both prevent and cure diseases as naturally as they can." (CCFF ¶ 154).

In addition, Respondents targeted advertising of the POM Products to consumers concerned about preventing or reducing their risk of illness. (CCFF ¶¶ 299-308). *Telebrands Corp*., 140 F.T.C. at 290 (stating that "[i]f an ad is targeted at a particular audience, the Commission analyzes ads from the perspective of that audience") (citing *Deception Policy Statement*, 103 F.T.C. at 178-79). The creative briefs (standard industry tools in the ad development process) – prepared by POM marketing and relied on by Fire Station to execute specific ads and campaigns – reflect Respondents' intent to reach consumers who were educated, affluent, and "very health-conscious (hypochondriacs)" as well as "primarily men who are scared to get prostate cancer." (CX0409_0001; CX0409_0023; *see also* CCFF ¶¶ 192-200, 236, 302-305). Per Lynda Resnick's direction, the creative briefs had to be tight and instructive, so that "if the author were run over by a bus, anyone could pick up the project and complete it."

(CX0001_0011; *see also* CCFF ¶ 199). Respondents reached their target audience by, for example, placing advertisements for the POM Products in health and fitness magazines (*e.g.*, Men's Fitness, Prevention), in reception areas of urologists' offices, in health clubs, on prescription drug bags, and on medical-oriented websites (*e.g.*,WebMD). (CCFF ¶¶ 177, 225-226, 253).

3. A Facial Analysis Demonstrates That the Challenged Ads and Promotional Materials Convey the Establishment and Efficacy Claims

This Court has the authority to rule on the conveyed meaning of the challenged advertisements and promotional materials based on a facial analysis. *Auto. Breakthrough Scis., Inc*., Nos. 9275-77, 1996 FTC LEXIS 252, at *44 (May 22, 1996) (citing *Kroger Co.*, 98 F.T.C. 639, 726, 729 n.12 (1981); *Ford Motor Co.*, 87 F.T.C. 756, 794-97 (1976)). Courts have consistently held that the FTC may use its own reasoned analysis to determine what claims an advertisement conveys. *See, e.g., Kraft, Inc.*, 970 F.2d at 318; *FTC v. Colgate-Palmolive Co.*, 380 U.S. 374, 385 (1965). Thus, "[i]f the advertisement explicitly states or clearly and conspicuously implies a claim, the court need not look to extrinsic evidence to ascertain whether the advertisement made the claim." *FTC v. Nat'l Urological Group, Inc.*, 645 F. Supp. 2d 1167, 1189 (N.D. Ga. 2008), *aff'd*, 356 F. Appx 358 (11th Cir. 2009); *see also Colgate-Palmolive Co*., 380 U.S. at 391-92; *Kraft Inc.*, 970 F.2d at 320.

The FTC has challenged 43 of Respondents' ads and promotional pieces as violating Sections 5 and 12 of the FTC Act. (*See* App. A, Tables 1 and 2).[1] Twenty-six of the challenged ads and promotional pieces convey the health benefit claims at issue for POM Juice, and 17 of

[1] Respondents may also have disseminated other ads making the claims at issue. The fact that those ads have not been challenged by the Commission does not mean that they did not violate Sections 5 and 12 of the FTC Act.

the challenged ads and promotional pieces convey the health benefit claims at issue for both POMx and POM Juice. (*See* App. A, Tables 1 and 2). The advertising and promotional pieces are segregated by the two categories of claims challenged in the Complaint: (1) express or implied establishment claims touting a scientific level of substantiation that the POM Products treat, prevent, or reduce the risk of heart disease, prostate cancer, and ED (*see* App. A, Table 1); and (2) express or implied efficacy claims that POM Juice treats, prevents, or reduces the risk of heart disease or prostate cancer (*see* App. A, Table 2).[2] The advertisements containing establishment claims (App. A, Table 1) by virtue of their very nature also make the efficacy claims challenged as lacking a reasonable basis. A mere handful of ads and promotional materials made non-establishment efficacy claims only (App. A, Table 2).

a) False Establishment and Unsubstantiated Efficacy Claims

Thirty-eight of the 43 challenged ads and promotional materials – *i.e.*, most of the POM Juice ads and promotional materials, and all of the POMx ads and promotional materials – convey establishment claims – that is, claims that the disease-related representations are based on scientific proof. (*See* App. A, Table 1).[3] Through a combination of powerful language (*e.g.*,

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[2] Within each category, Complaint Counsel has further separated the ads based on each of the disease areas at issue (heart disease, prostate cancer, and ED).

[3] These 38 challenged pieces are: CX0016 ("Drink and Be Healthy" Ad); CX0029 ("10 out of 10 People" Ad); CX0031 ("Floss your arteries. Daily" Ad); CX0034 ("Amaze your cardiologist" Ad); CX0103 ("Decompress" Ad); CX0109 ("Heart Therapy" Ad); CX0192 ("What gets your heart pumping" Ad); CX0260/1426 Ex. B ("Drink to Prostate Health"); CX0274/1426 Ex. C ("I'm off to save prostates" Ad); CX0314 ("Drink to Prostate Health" Magazine Wrap); CX0372/CX0379/CX0380 ("Lucky I have super health powers" Magazine Wrap); CX0475/1426 Ex. A (Juice Bottle Hang Tag); CX0120 ("One Small Pill for Mankind" Ad); CX0122 ("Science, Not Fiction" Ad); CX0169/1426 Ex. L ("The power of POM" Ad); CX0180/1426 Ex. K ("Antioxidant Superpill" Ad); CX0279 ("Science, Not Fiction" Ad); CX0280 ("Live Long Enough" Ad); CX0328 ("Your New Health Care Plan" Ad); CX0331/1426

"Medical studies have shown" that POM Juice "minimizes factors that lead to atherosclerosis"; "significant reduction in IMT (thickness of arterial plaque) by up to 30% after one year"; "statistically significant prolongation of PSA doubling times"), strong medical imagery (*e.g.*, picture of POM Juice bottle hooked to an electrocardiogram; picture of POM Juice bottle enclosed in a blood pressure cuff), bold headlines (*e.g.*, "Real Studies. Real Results."; "Science, not fiction"), and statements touting their science (*e.g.*, "backed by $32 million in medical research"), the ads convey the net impression that the POM Products are scientifically proven to treat, prevent, or reduce the risk of disease. (*See*, *e.g.*, CCFF ¶¶ 326, 344, 357, 398, 415, 419, 425, 468); *Metagenics, Inc.*, No. 9267, 1996 FTC LEXIS 459, at *41 (Oct. 11, 1996) (Initial Decision) (finding an establishment claim from an ad representing that "MCHC has been reported to improve fracture healing and relieve back pain in women with post menopausal bone loss"); *Bristol-Myers Co.*, 102 F.T.C. 21, 321 (1983) (establishment claims "may also be made through the use of visual aids . . . which clearly suggest that the claim is based upon a foundation of scientific evidence"), *aff'd*, 783 F.2d 554 (2d Cir. 1984); *Thompson Med. Co.*, 104 F.T.C. at 813-14 (ads referring to tests by a medical specialist or to "clinical tests" convey to consumers

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Ex. J ("Healthy Wealthy" Ad); CX0337 ("The First Bottle You Should Open" Ad); CX0342/CX0353 ("Take Out A Life Ins" Ads); CX0348/CX0350 ("24 Scientific Studies" Ads); CX0351/CX0355 ("Only Antioxidant Supplement Rated X" Ads); CX1426 Ex. I ("Antioxidant Superpill" brochure); CX1426 Ex. M (POMx Heart Newsletter); CX1426 Ex. N (POMx Prostate Newsletter); CX0473(POMWonderful.com); CX0473 (POMWonderful.com Community site); CX0473 (Pomegranatetruth.com); CX0473 (POMPills.com); CX0013 (Jan. 2003 POM Juice press release); CX0044 (Sept. 2005 POM Juice press release); CX0065_0002 (July 2006 POMx press release); CX0128_0002 (June 2007 POM Juice press release); CX0473 (June 2008, Tupper on Fox Business show); CX0472 (Feb. 2009, Lynda Resnick on CBS *Early Show*); CX0473 (Mar. 2009, Lynda Resnick interview in Newsweek.com).

that the claims are scientifically proven in a manner acceptable to the medical/scientific community).[4]

In all of the challenged pieces listed on Table 1, Respondents emphasize their scientific research, either by detailing selected findings from clinical studies or by advertising that the millions of dollars Respondents invested in medical research have yielded positive results for heart, prostate, and erectile function or both. (CCFF ¶¶ 325-340, 344-348, 357-388, 397-441, 443-535, 541-567, 572-578). For example, several of the pieces reference the Aviram CIMT/BP Study (2004) and describe the findings as "resulting in a significant IMT reduction (thickness of arterial plaque) by up to 30% after one year," or similar language. (CCFF ¶¶ 330, 336, 344, 411, 415, 431, 437, 449, 453-454). Other ads and promotional materials cite to the Ornish MP Study (2005), and tout that consumption of POM Juice for three months resulted in a "17% improvement in blood flow." (CCFF ¶¶ 431, 437, 449, 551). POM's 2003 press release (CX0033) states that the Aviram ACE/BP Study (2001) showed that "[p]omegranate juice inhibited ACE by 36% after two weeks of juice consumption." (CCFF ¶ 544; *see also* CCFF ¶¶ 455-456). Respondents' prostate-focused ads and promotional materials repeatedly tout the Pantuck Phase II Prostate Cancer Study (2006) to convince consumers that the POM Products will prevent, reduce the risk of, or treat prostate cancer, stating that this study showed significant increase in PSA doubling time. (CCFF ¶¶ 485, 524, 556, 576). "[R]eferences to clinical testing, research and case studies are express claims that the respondents' representations are supported

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[4] These establishment claims likewise permeate Respondents' rhetoric in this action. *See*, *e.g.*, Resp. Pre-Trial Br. at 13 ("findings from the entire body of research **show** that POM products have many dynamic and positive effects on the human cardiovascular system"); Resp. Pre-Trial Br. at 13 ("consumption of pomegranate juice **has been found** to nearly triple the [PSA] doubling time in 50% of men following radical prostatectomy") (emphasis added).

by scientific evidence." *Removatron Int'l Corp.*, 111 F.T.C. 206, 298 (1988) (citing *Thompson Med. Co.*, 104 F.T.C. at 814), *aff'd*, 884 F.2d 1489 (1st Cir. 1989). Moreover, the POMx ads make bold statements that POMx has health benefits equivalent to POM Juice and to pomegranates, and in turn detail findings of medical research on POM Juice in the areas of heart disease, prostate cancer, and ED. (*See, e.g.*, CCFF ¶¶ 400-401, 407-412, 415-416, 419, 425). In so doing, the POMx ads make express claims that the health benefits of both POMx and POM Juice are supported by scientific evidence.

In several instances (*e.g.*, CX0029, CX0033, CX1426 Exs. I, M and N), Respondents heighten the impact of their claims of established scientific support by prefacing the claims with information about the relevant health threat (*e.g.,* free radicals that attack healthy cells and may cause cancer, heart disease, and other illnesses; information on heart disease and prostate cancer related deaths in the United States). (*See, e.g.*, CCFF ¶¶ 331, 341, 432, 440). This tactic is consistent with the approach outlined in Respondents' creative briefs that the scientific information provided the consumer with a "reason to believe." (CCFF ¶¶ 302-306; *see also* CCFF ¶ 630).

Respondents employ bold headlines and subheadings throughout their advertisements that are replete with hard-hitting declarations of scientific validity for their claims – for example, "Amaze your cardiologist" (CX0034), "Decompress" (CX0103), "Science, Not Fiction" (CX0279); and "Backed by Science" (CX0314). (CCFF ¶¶ 344, 357, 380, 398, 411). Combined with prominent, engaging images of the POM Products donning medical apparatuses (*e.g.*, CX0034) or staged in a medicine cabinet or on a doctor's couch (*e.g.*, CX0031, CX0109), these messages and visual cues hold consumers' attention. (CCFF ¶¶ 336, 344, 357, 363). The POMx ads and promotional materials have a decidedly medical tone and emphasis, and frequently

highlight positive results from clinical studies and favorable quotes from scientific researchers. (*See, e.g.*, CCFF ¶¶ 378, 410, 411, 415, 419, 425, 431, 456, 474, 525, 529, 557). The net impression of such advertisements is that "respondents' claims were based on competent scientific proof." *Removatron Int'l Corp.*, 111 F.T.C. at 298 (citing *Bristol-Myers Co.*, 102 F.T.C. at 321; *Porter & Dietsch, Inc.*, 90 F.T.C. 770, 865 (1977), *aff'd*, 605 F.2d 294 (7th Cir. 1979).

When used, qualifying terms such as "preliminary," "pilot," and "emerging" typically appear in smaller font and blend in with the rest of the body copy, and are inadequate to offset the overarching message conveyed by the advertisements. (*See*, *e.g.*, CCFF ¶¶ 330, 337, 345, 357, 363, 368, 379, 409, 415, 419, 431, 447, 449, 458, 460). *Daniel Chapter One Initial Decision*, 2009 FTC LEXIS 157, at *213 (stating that qualifiers are "'not adequate to avoid liability unless they are sufficiently prominent and unambiguous to change the apparent meaning of the claims and to leave an accurate impression'") (quoting *Removatron Int'l Corp.*, 884 F.2d at 1497). *See also FTC v. Medlab, Inc.*, 615 F. Supp. 2d 1068, 1077 (N.D. Cal. 2009); *Thompson Med. Co.*, 104 F.T.C. at 842-43.

As this Court has recognized, individual words of caution have little effect on the impression generated by "the entire mosaic" of an advertisement. *See Daniel Chapter One Initial Decision*, 2009 FTC LEXIS 157, at *204 ("Even though the language of the product description . . . attempts to relegate GDU's claimed effectiveness to a supporting role in 'helping' or 'aiding' the body, . . . the entire mosaic of the advertisement belies a merely 'supporting' role for GDU.").

By virtue of their very nature, the advertisements containing establishment claims (*see* App. A, Table 1) also make the efficacy claims challenged as unsubstantiated in the Complaint.

b) Unsubstantiated Efficacy Claims

Merely five of the challenged promotional materials convey only that POM Juice is effective for treating, preventing, or reducing the risk of heart disease or prostate cancer without stating directly the level of science that substantiates the claims.[5] (CCFF ¶¶ 341-343, 349, 356, 536-540, 570; *see also* App. A, Table 2). As with the ads that make establishment claims, these five pieces convey express or clearly implied efficacy claims through the use of strong visual imagery and dominating headlines and strong statements of efficacy. (CCFF ¶¶ 341-343, 349-356, 536-540). *See Kraft, Inc.*, 970 F.2d at 319 n.4 (describing express claims as directly stating the representation at issue, while implied claims making representations without direct statements); *FTC v. Febre*, No. 94 C 3625, 1996 U.S. Dist. LEXIS 9487, at *14 (N.D. Ill. July 3, 1996) ("The courts and the FTC have consistently recognized 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.").

For example, the "Life Support" print ad, "Cheat Death" print ad, "Heart Therapy" banner ad, and "Off to save prostates" banner ad (CX0033, CX0036/CX0188, CX0463, and CX0466/CX1426 Ex. H) employ captivating images – a POM Juice bottle dressed as an intravenous drip bag, a POM Juice bottle with a noose around the neck, a POM Juice bottle with a pulsating heart logo, a caped POM Juice bottle flying off to save prostates – in combination with dominating headlines to engage consumers and invite them to learn more about POM Juice's medical benefits. (CCFF ¶¶ 341, 349, 536, 539-540). The first two ads bring home the

[5] These five challenged pieces are: CX0033 ("Life Support" Print Ad); CX0036/CX0188 ("Cheat Death" Print Ad); CX0463 ("Heart Therapy" Banner Ad); CX0466/1426 Ex. H ("Off to save prostates" Banner Ad); CX0473 (Nov. 2008, Lynda Resnick on *Martha Stewart* Show).

message that POM Juice prevents or reduces the risk of heart disease (among other ailments) through body copy that emphasizes the juice's antioxidant power that can "fight hard against free radicals that can cause heart disease, premature aging, Alzheimer's, even cancer" or "can help prevent . . . heart disease, stroke, Alzheimer's, even cancer." (CCFF ¶¶ 341, 349). The "Off to save prostates" banner ad emphasizes that "prostates everywhere are in danger" and further suggests that POM Juice will "save" them from impending risk of prostate cancer. (CCFF ¶¶ 539-540). All four ads encourage consumers to visit the POM website for more detailed claims about the juice's health benefits. (CCFF ¶¶ 341, 349, 536, 539-540). On the Martha Stewart show, Mrs. Resnick directed viewers to make their male loved ones "drink eight ounces of pomegranate juice a day because what it does for prostate cancer is amazing." (CCFF ¶ 570).

B. Respondents' Claims Are Material

A "material" misrepresentation is one that involves information important to consumers and is therefore likely to affect the consumer's choice of, or conduct regarding, a product. *Deception Policy Statement*, 103 F.T.C. at 182; *Novartis Corp.*, 127 F.T.C. at 691 ("Materiality turns upon whether those consumers who have drawn the claim from the advertisement . . . are . . . likely to have their conduct affected by the [alleged] misrepresentation."). To be material, "a claim does not have to be the *only* factor or the *most* important factor likely to affect a consumer's purchase decision, it simply has to be *an* important factor." *Id*.

The challenged health-related efficacy claims for the POM Products are presumptively material. (CCFF ¶¶ 625-627). *Daniel Chapter One Initial Decision*, 2009 FTC LEXIS 157, at *245; *see also Kraft, Inc.*, 970 F.2d at 323 (noting that health-related efficacy claims involve information that is important to consumers); *Direct Mktg. Concepts, Inc.*, 569 F. Supp. 2d at 300 (disease health claims for dietary supplements were clearly material); *Nat'l Urological Group,*

645 F. Supp. 2d at 1190-91 (weight loss and sexual dysfunction claims for dietary supplements were presumptively material); *FTC v. QT, Inc.*, 448 F. Supp. 2d 908, 965-66 (N.D. Ill. 2006), *aff'd*, 512 F.3d 858 (7th Cir. 2008) (pain relief claims for Q-ray bracelet were material medical, health-related claims).

Likewise, Respondents' express representations are presumed material because "the willingness of a business to promote its products reflects a belief that consumers are interested in the advertising." *Deception Policy Statement*, 103 F.T.C. at 182 (express representations are presumed material because "the willingness of a business to promote its products reflects a belief that consumers are interested in the advertising") (quoting *Cent. Hudson Gas & Elec. Co. v. Pub. Serv. Comm'n*, 447 U.S. 557, 567 (1980)); *see Bronson Partners, LLC*, 564 F. Supp. 2d at 135 (implied claims that are made "by such strong implication that they are the functional equivalent of an express claim" are presumed material).

The health benefit claims relate to the "central characteristics" of the POM Products as advertised and are therefore presumptively material. (CCFF ¶ 626). *Telebrands Corp.*, 140 F.T.C. at 292 ("The Commission presumes that claims are material if . . . they pertain to the 'central characteristics of a product * * * such as those relating to its purpose * * * [or] efficacy . . . .'") (quoting *Thompson Med. Co.*, 104 F.T.C. at 816-17) (alteration in original); *see also Novartis Corp.*, 127 F.T.C. at 687 (agreeing with the ALJ that "the challenged superior efficacy claim relates to the central characteristic of the product, that is, Doan's ability to relieve back pain.").

As described previously, the record evidence shows that Respondents intended to make the Challenged Claims. (*See supra* Section II.A.2). The Commission has inferred materiality where the record shows that a respondent intended to make an implied claim. *Novartis Corp.*,

127 F.T.C. at 686-89 (explaining that the ALJ correctly presumed implied superior efficacy claims were material because Novartis had intended to make such claims) (citing *Deception Policy Statement*, 103 F.T.C. at 182); *see also FTC v. 1st Guar. Mortg. Corp.*, No. 09-cv-61840, 2011 U.S. Dist. LEXIS 38152, at *46 (S.D. Fla. Mar. 30, 2011) ("[D]eliberately-implied claims used to induce the purchase of a product or service are presumed to be material to consumers as a matter of law."); *Bronson Partners, LLC*, 564 F. Supp. 2d at 135 ("The underlying rationale for finding [an intended] claim to be presumptively material . . . is 'the assumption that the willingness of a business to promote its product reflects a belief that the consumers are interested in the advertising.'"); *Nat'l Urological Group*, 645 F. Supp. 2d at 1190 ("[D]eliberately made implied claims, used to induce the purchase of a particular product or service are presumptively material.").

Respondents' marketing surveys show that the health claims for the POM Products were material to consumers' purchasing decisions. (CCFF ¶¶ 639-650). In one survey "helps promote heart health" (57%), and "helps protect against prostate cancer" (47% of males) were the second and third ranked of nine or ten specific health benefits motivating drinkers of POM Juice. (CCFF ¶ 643). Heavy pomegranate juice drinkers in an online study ranked cardiovascular health and prostate health as the top two (out of six) health benefits of drinking pomegranate juice in importance to them. (CCFF ¶ 649). Among a larger sample population that included drinkers of other juices, 18% of males ranked erectile dysfunction as the first or second most important health benefit to them. (CCFF ¶ 650). The Commission has relied upon similar consumer survey results as evidence of materiality. *Kraft, Inc.*, 114 F.T.C. at 86, 135, 138 n. 30; *see also Novartis Corp.*, 127 F.T.C. at 690.

Moreover, Respondents' expert, Dr. Reibstein, testified that consumers in POM's target audience who were concerned about heart disease, prostate cancer, or erectile dysfunction would likely find the challenged claims to be important. (CCFF ¶ 638). Expert testimony that a challenged claim would motivate the target audience to purchase a product is a basis for finding materiality. *Novartis Corp.*, 127 F.T.C. at 689-90.

Respondents were given numerous warnings that their advertising claims were deceptive and yet persisted in making the claims. (CCFF ¶¶ 402, 662-685). In addition, Respondents pursued making disease treatment and prevention claims after assuring researchers and research institutions that they would not. (CCFF ¶¶ 686-693). Persistence in using claims in the face of warnings that a deceptive message is being conveyed is a basis for inferring materiality. *Kraft, Inc.*, 970 F.2d at 323; *Kraft, Inc.*, 114 F.T.C. at 137.

Respondents have failed to rebut the presumption of materiality. *Kraft, Inc. v. FTC*, 970 F.2d at 323. Their rebuttal evidence, the Reibstein Survey, did not expose consumers to the challenged ads or the challenged claims, so it did not provide a proper measure of materiality. (CCFF ¶¶ 651-657). The Reibstein survey should have, but did not, ask survey respondents to evaluate the importance of the challenged claims in terms of whether those claims were likely to have an effect on their decision to purchase or to use POM Juice. (CCFF ¶¶ 658-661). Moreover, the overwhelming evidence on this issue in the record supports a finding that the challenged claims are material. *Novartis Corp.*, 127 F.T.C. at 686-89.

C. Respondents' Representations that the POM Products Prevent, Reduce Risk, or Treat Disease and that These Benefits Are Established Are Deceptive and Violate Sections 5 and 12 of the FTC Act

Respondents' advertisements are deceptive as charged in the Complaint, because the health claims made or implied by the advertisements are both false and unsubstantiated

(Complaint ¶¶ 12-21). As established through the detailed analysis of Respondents' research in each relevant disease area, the science Respondents touted in their advertising and relied upon as the basis for their claims lacks the rigor, consistency, and evidence of efficacy necessary to support such claims. (*See* CCFF Sections VII.C.4, VII.D.4, and VII.E.4).

The vast majority of Respondents' challenged marketing contains express and implied representations that their health efficacy claims are proven through clinical research, tests, and studies. (*See* App. A, Table 1 (representing 38 of the 43 challenged ads and promotional materials); *see* Section II.A.3.a, *supra*). If advertisements make science-based establishment claims, the advertiser must possess a level of proof sufficient to satisfy the relevant scientific community of the claims' truth. *Removatron Int'l Corp.*, 111 F.T.C. at 297; *see id*. at 298-99 (noting the advertiser must possess "competent scientific proof"). In affirming the Commission's *Removatron* decision, the First Circuit stated that "a 'reasonable basis,' when one makes establishment claims, means well-controlled scientific studies. Without such a study, petitioners could not, as a matter of law, have a reasonable basis for their establishment claims." *Removatron Int'l Corp. v. FTC*, 884 F.2d 1489, 1498 (1st Cir. 1989).

No well-controlled clinical studies, research, or trials to date prove that the POM Products are effective for heart disease, prostate cancer, and ED. To the contrary, the studies Respondents herald in their ads were exploratory in nature (*i.e.*, designed to explore whether further research to determine product efficacy was warranted) and/or failed to test valid endpoints. These studies fail to demonstrate the products' efficacy for these serious health conditions. (CCFF ¶¶ 951-965 (heart science); 1037-1043 (prostate science); 1086-1095 (ED science)). Thus, Respondents' establishment claims are undeniably false.

By virtue of their very nature, the advertisements containing establishment claims also make the efficacy claims challenged as unsubstantiated in the Complaint. In addition, a few of the challenged ads and promotional materials make only non-establishment, efficacy claims. (*See* App. A, Table 2 (representing 5 of the 43 challenged ads and promotional materials); *see supra* Section II.A.3.b). For those advertisements, the Court must determine the appropriate level of substantiation.

"For non-establishment claims, what constitutes sufficient substantiation may depend on multiple factors, such as the type of claim, the type of product, the consequences of a false claim, the benefits of a truthful claim, the cost of developing substantiation for the claim, and the amount of substantiation that experts in the field believe is reasonable." *Daniel Chapter One Initial Decision*, 2009 FTC LEXIS 157, at *226-27 (citing *Direct Mktg. Concepts*, 569 F. Supp. 2d at 299); *see also Removatron Int'l Corp.*, 111 F.T.C. at 306-07 n. 20; *Thompson Med. Co.*, 104 F.T.C. at 821, 839-40 (including as an appendix the *FTC Policy Statement Regarding Advertising Substantiation*). Moreover, claims that are difficult or impossible for consumers to evaluate for themselves require a high level of substantiation, such as scientific tests.[6] *Removatron Int'l Corp.*, 111 F.T.C. at 306 n. 20; *Thompson Med. Co.*, 104 F.T.C. at 822-23. Likewise, claims referring to specific facts and figures of a product's capabilities require a high

[6] Moreover, the POM Products are expensive for consumers to purchase. [redacted] (*See* CCFF ¶¶ 127-28, *in camera*, 133, *in camera*, 135, *in camera*, 140, 145-46, *in camera*,). Spending money on an expensive and unproven preventative or treatment causes economic injury, which also weighs in favor of requiring a higher level of substantiation. *See Daniel Chapter One Initial Decision*, 2009 FTC LEXIS 157, at *234 (citing *Schering Corp.*, 118 F.T.C. at 1115 (Initial Decision); *Removatron Int'l Corp.*, 111 F.T.C. at 306 n. 20). Furthermore, the use of POM Products is not risk-free. (*See* CCFF ¶¶ 1021).

level of substantiation, such as scientific tests. *Removatron Int'l Corp.*, 111 F.T.C. at 306 n. 20; *Thompson Med. Co.*, 104 F.T.C. at 822. Applying these factors here leads to the conclusion that valid clinical trials are needed to substantiate Respondents' non-establishment efficacy claims as well.

Courts have consistently found or upheld that double-blind, randomized, placebo-controlled trials ("RCTs") are required to provide adequate substantiation for the truthfulness of health-related claims.[7] *See, e.g.*, *Direct Mktg. Concepts, Inc.*, 569 F. Supp. 2d at 303 (noting double-blind, placebo-controlled human studies to substantiate health-related efficacy claims); *Nat'l Urological Group*, 645 F. Supp. 2d at 1202-03 (accepting undisputed expert testimony that erectile dysfunction claims require well-designed, placebo-controlled, randomized, double-blind clinical trials for substantiation); *FTC v. Braswell*, CV 03-3700 DT, 2005 U.S. Dist. LEXIS 42976, at *35 (C.D. Cal. Sept. 26, 2005) (by offering unrefuted evidence that the standard to substantiate claims for various health-related products should be double-blind, placebo-controlled tests, Commission offered sufficient evidence to withstand summary judgment); *FTC v. SlimAmerica, Inc.*, 77 F. Supp. 2d 1263, 1274 (S.D. Fla. 1999) (requiring "a double blind study of the combination of ingredients used in" the defendants' weight loss product for claim substantiation); *FTC v. Pantron I Corp.*, 33 F.3d 1088, 1097-98 (9th Cir. 1994) (placebo-

[7] A well-conducted RCT requires: use of a patient population consistent with the condition being treated; randomization to equalize the chance of each patient being either in the treatment or the placebo group; blinding so that neither the study investigator nor the participants know who is receiving the placebo; use of a valid, reliable endpoint that is relevant to the disease and population; appropriate statistical analysis; and at the end of the trial, an outcome of statistically significant and clinically significant improvement in the treatment group relative to the control group. *QT*, 448 F. Supp. 2d at 938 (citing the *Federal Judicial Center Reference Guide on Statistics* and the *Federal Judicial Center Reference Manual on Scientific Evidence*).

controlled study needed for hair growth product); *Removatron*, 884 F.2d at 1498-1500 (double-blind clinical test needed for hair removal device performance claims); *FTC v. Sabal*, 32 F. Supp. 2d 1004, 1008-09 (N.D. Ill. 1998) (rejecting a study as inadequate substantiation, in part, because it was not blinded or placebo-controlled); *FTC v. Cal. Pac. Research, Inc*., No. CV-N-88-602, 1991 U.S. Dist. LEXIS 12967, at *12-13 (D. Nev. Aug. 27, 1991) (only placebo-controlled, double-blind clinical studies meet "the most fundamental requirements for scientific validity and reliability"); *Schering Corp*., 118 F.T.C. 1030, 1080, 1115-16 (1991) (Initial Decision) (weight-loss and generalized health benefit claims for a high fiber supplement required "substantiation by two well controlled clinical trials," which were described as double-blind, placebo controlled); *Thompson Med. Co.*, 104 F.T.C. at 822 (requiring "two well-controlled clinical tests" for pain relief claims for a skin cream).

The need for RCTs as substantiation is particularly evident when the advertisements tout medical studies purporting to demonstrate specific benefits. *See QT*, 448 F. Supp. 2d at 962 ("[W]ith medical, health-related claims, a well-conducted, placebo-controlled, randomized, double-blind study, the gold standard, should have been conducted. . . . Defendants would not be required to have a gold-standard study to substantiate the Q-Ray bracelet if they did not make such a strong, medical claim"). Here, Respondents themselves have asserted that one does not know that an antioxidant product is efficacious until one finds "measurements that are medically meaningful" through clinical testing on humans. (*See* CCFF ¶¶ 491, 1122).

With respect to the type of products at issue, the Commission also has made clear that health claims about the efficacy of foods require the level of scientific evidence experts in the field find necessary to substantiate the claims. *See FTC Enforcement Policy Statement on Food Advertising* at CX0002_0018 (noting also that "[t]he Commission's standard for substantiation

of health claims in food advertising shares many elements with FDA's approach to such claims in labeling. Like FDA, the Commission imposes a rigorous substantiation standard for claims relating to the health or safety of a product, including health claims for food products."). *See also Dietary Supplements: An Advertising Guide for Industry*, CX1014_0014 ("The FTC typically requires claims about the efficacy or safety of dietary supplements to be supported with 'competent and reliable scientific evidence,' . . . This is the same standard the FTC applies to any industry making health-related claims").

"The Court can look to what experts in the relevant area of study would consider to be adequate in determining the amount of and type of evidence that is sufficient" to substantiate the advertisers' claims. *Braswell*, 2005 U.S. Dist. LEXIS 42976, at *31 (citing *Thompson Med. Co.*, 104 F.T.C. at 821). Complaint Counsel's experts in the fields of antioxidants and epidemiology (Dr. Meir Stampfer), heart disease (Dr. Frank Sacks), prostate cancer (Dr. James Eastham), and ED (Dr. Arnold Melman) independently opined on the level of substantiation they would expect, as experts in their respective fields, to support Respondents' claims that the POM Products prevent, reduce the risk of, and treat heart disease, prostate cancer, and erectile dysfunction and claims that Respondents' clinical research proves such benefits. These experts all agree that well-designed, well-conducted RCTs showing statistically and clinically significant improvements in valid endpoints are necessary to test the efficacy of the POM Products. (CCFF ¶ 1102). In no instance does Respondents' evidence meet that standard.

Contrary to Respondents' arguments that RCTs are not a scientifically effective model for nutrients and are not economically feasible, the record makes clear that foods and supplements can be, should be, and have been the subject of well-designed RCTs to evaluate

whether a causal relationship exists between nutrients in a food or supplement and a certain disease or health-related condition.[8] (CCFF ¶ 1102).

Respondents acknowledge these requirements (CCFF ¶¶ 1122-1126), and have themselves commissioned nine RCTs on endpoints related to the three diseases at issue (CCFF ¶ 1127), albeit often with either disappointing or inconclusive results.[9] (CCFF ¶¶ 822-824 (Ornish 17-person CIMT); 855 (Ornish CIMT study); 879 (Davidson CIMT Study (2009)); 912 (Davidson BART/FMD study); 921, 929-930 (San Diego Study); 1079 (Pantuck Phase III Study); 946 (Heber Diabetes and Hill Diabetes studies); 1063-1064 (Forest Erectile Dysfunction Study (2007))). Respondents also commissioned additional RCTs related to other diseases and areas of health. (CCFF ¶ 1128). Moreover, Respondents' own experts have solicited for, participated in, and conducted some of Respondents' sponsored RCTs on POM products. (CCFF

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[8] Respondents' health claims are founded in part on the premise that antioxidant supplementation can play an important role in the prevention or treatment of disease. (CCFF ¶ 1103). As Complaint Counsel's expert Dr. Meir J. Stampfer, M.D. explains, "there is conflicting scientific evidence on the benefits of specific nutrients with antioxidant activity in preventing or treating diseases." (CX1293 (Stampfer, Report at 0011); *see also* CCFF ¶ 1105). Dr. Stampfer states that "[a]lthough observational and laboratory studies suggest that these nutrients have beneficial effects, several randomized controlled clinical trials have found no consistent benefit for specific nutrient antioxidants." (CX1293 (Stampfer, Report at 0011-12); *see also* CCFF ¶ 1105 (citing, *e.g.*, RCTs of vitamin E, vitamin C, selenium, and beta carotene)). Indeed, an RCT on beta carotene and vitamin E showed an *increase* in mortality due to supplementation. (CX1293 (Stampfer, Report at 0014)). Dr. Stampfer concluded that "this demonstrates the importance of performing randomized, double blind, placebo controlled trials before drawing conclusions regarding causality." (CX1293 (Stampfer, Report at 0015)).

[9] Through their use of RCTs, Respondents also demonstrated their ability to fund a scientific research program to ascertain the health benefits of their products. Indeed, Respondents told consumers they spent $34 million in medical research regarding the POM Products. (*See* CCFF ¶ 309). However, this total actually represents a running tab of all sorts of related expenses, not just the direct cost of appropriate research. (CCFF ¶ 322). For example, the cost of the two well-conducted, placebo-controlled, randomized, double-blind clinical trials commissioned by Respondents to determine any benefits of POM Juice in treating and preventing cardiovascular disease (the Davidson studies) was approximately $3 million. (*See* CCFF ¶ 878).

¶¶ 1110 (Heber); 822-824,855, CX1198 (Ornish)). Their experts never told Respondents that it was not necessary to conduct RCTs to determine the efficacy of the POM Products and, in fact, Dr. Ornish encouraged the Resnicks to conduct such research. (CCFF ¶¶ 1110, 1118).

Ultimately, Respondents' disease benefit claims must be judged by the quality of the research, not by the quantity of money spent on research or sound bites about the studies as touted in their advertising. Millions of research dollars and numerous published studies do not constitute a reasonable basis, if: (1) the studies are not designed and executed in a manner that experts in the field conclude is needed to yield accurate and reliable results for disease treatment and prevention claims, or (2) the studies are properly designed and executed and the results are negative or inconclusive. *See infra*, Sections II.C.2 through II.C.4.

1. Respondents' Heart Disease Claims Are False and Unsubstantiated

Two of Complaint Counsel's experts reviewed Respondents' heart science: (1) Frank M. Sacks, M.D., an expert in nutrition, cardiovascular disease ("CVD"), coronary heart disease ("CHD"), cholesterol disorders, hypertension, and interpretation of clinical studies; and (2) Dr. Stampfer, an expert in epidemiology, nutrition (including its relation to the prevention and treatment of CVD and prostate cancer), and clinical testing related to the prevention of prostate cancer and CVD. (CCFF ¶¶ 707, 699). Dr. Sacks and Dr. Stampfer both concluded that Respondents' scientific evidence is not sufficient to support claims that the POM Products prevent, reduce the risk of, or treat heart disease. (CCFF ¶¶ 963-964).

According to Drs. Sacks and Stampfer, to substantiate a claim that a product, including a conventional food or dietary supplement, can prevent, reduce the risk of, or treat heart disease, one must rely on appropriately analyzed results of well-designed, well-conducted RCTs (*infra* Section B.3). (CCFF ¶ 784; Stampfer, Tr. 706, 716-718). In addition, the findings of the RCTs

must be statistically significant (*i.e.*, have strong "p" values). (CCFF ¶ 779). The results of the RCTs must demonstrate significant changes in valid surrogate markers of cardiovascular health, such as blood pressure and LDL cholesterol (two surrogate markers recognized by the FDA) or C-reactive protein, HDL cholesterol, and triglycerides (three surrogate markers recognized by many experts in the field). (CCFF ¶ 785). Regarding use of carotid intima media thickness (CIMT) as a surrogate marker, Dr. Sacks states CIMT is usually relevant to cardiovascular health, but such measures alone are not conclusive evidence that an intervention treats existing heart disease. (CCFF ¶ 786).

In Dr. Sacks' opinion, the same level of evidence is needed to show that clinical studies, research, or trials prove that a product prevents, reduces the risk of, or treats heart disease as is needed to substantiate a heart disease efficacy claim. (CX1291 (Sacks, Report at 0010-11); *see also* CCFF ¶ 784).

a) Respondents did not possess a reasonable basis to substantiate their efficacy claims that the POM Products prevent, reduce the risk of, or treat heart disease.

Eleven of the Respondents' sponsored human studies relating to heart disease are discussed in the record. (CCFF ¶ 787; *see also infra*, Section II.C.1.b, Table 3). None of these, however, alone or in combination are adequate to support the challenged heart disease claims. (CCFF ¶¶ 950-965).

To support claims that POM Juice and POMx can prevent or treat heart disease, including by reducing blood pressure, Respondents rely on the Aviram ACE/BP Study (2001) and the Aviram CIMT/BP Study (2004) of pomegranate juice, each of which evaluated a small sample of patients and was unblinded and uncontrolled. (CCFF ¶ 955). As a result, Dr. Sacks and Dr. Stampfer state that it is not possible to tell whether the purported changes in blood pressure were

due to drinking pomegranate juice or to some other factor. (CCFF ¶¶ 802-803). Moreover, one cannot extrapolate the results of the two Aviram studies of pomegranate juice to the POMx products. (CCFF ¶ 965). The remainder of Respondents' clinical studies on potential heart benefits showed no change in blood pressure as a result of consuming POM Juice or POMx. (CCFF ¶ 956). Accordingly, considered as a whole, Respondents' evidence does not support the conclusion that POM Juice or POMx prevents or treats heart disease, including through blood pressure reduction. (CCFF ¶¶ 955-958). Indeed, Mr. Resnick has admitted that Respondents do not have enough evidence to support a blood pressure claim. (CCFF ¶ 958).

To support claims that the POM Products can prevent or treat heart disease, including by reducing arterial plaque, Respondents rely on the small, unblinded, uncontrolled Aviram CIMT/BP Study (2004) and on cherry-picked observations from the Davidson CIMT Study (2009). (*See* CCFF ¶¶ 805-821; 879-911). Regarding the Davidson CIMT study, Respondents give import to a trend noted six months before completion of the study that ultimately did not bear out and to unconfirmed results of an exploratory sub-group analysis performed *post hoc*. (*See* CCFF ¶¶ 885-887). Respondents discount the primary outcome of the 289-patient Davidson CIMT Study and the 73-patient Ornish CIMT Study, both of which were blinded, well-controlled, and showed no benefit from consuming POM Juice. (CCFF ¶¶ 882; 855-868). In contrast, the Aviram CIMT/BP Study (2004) was unblinded and uncontrolled, and thus it is not possible to determine what caused the change in CIMT results over the course of the study. (CX1291 (Sacks, Report at 0018-19); *see also* CCFF ¶ 814). Neither these studies nor Respondents' other heart studies substantiate the claim that POM Juice or POMx prevents or treats heart disease, including by reducing arterial plaque. (CCFF ¶ 951). Mrs. Resnick has

admitted that Respondents did not possess sufficient evidence to support a plaque reduction claim. (CCFF ¶ 954).

The Ornish MP Study (2005) is inadequate to support Respondents' claims that the POM Products can prevent or treat heart disease, including by increasing blood flow. (CCFF ¶ 959). First, change in myocardial perfusion (*i.e.*, blood flow to the heart) is not a recognized surrogate marker of therapeutic effects on CHD, because improved blood flow will not necessarily result in improved cardiovascular health, such as reductions in heart attack and stroke. (CCFF ¶ 844). Second, the Ornish MP Study (2005) report indicates significant changes in only one of three measures of blood flow – in summed difference score (SDS), but not summed rest score (SRS) or summed stress score (SSS). (CCFF ¶ 827). It is not clear that the change in SDS would be clinically meaningful, because the authors did not show that the patients experienced improvement in their clinical symptoms. (CCFF ¶ 849). There also was a large discrepancy between the pomegranate juice and the control groups in the baseline values of SRS and SSS, the two components of the SDS. (CCFF ¶ 850). The control group's baseline values were worse than those of the pomegranate group, and thus "[i]t could be predicted that the control group, having worse coronary perfusion than the pomegranate group at baseline, would have a more accelerated form of the disease and show worsening on follow-up." (CX1291 (Sacks, Report at 0022); *see also* CCFF ¶ 851). Finally, the 12 month study was cut short by Dr. Ornish and the Resnicks, when the three month data came in favorably and Dr. Ornish faced cost overruns that the Resnicks would not reimburse. (CCFF ¶¶ 834-839). The 12 month study period required by the study protocol was not disclosed in the published report. (CCFF ¶ 834). In addition, the study showed no improvement in other measures, such as blood pressure, cholesterol, inflammatory biomarkers, and oxidative stress. (CCFF ¶¶ 825, 829). In light of these problems

in the design and conduct of the trial, the Ornish MP Study (2005) does not support a conclusion that POM Juice has a beneficial effect on coronary perfusion. (CCFF ¶ 854). As Dr. Sacks concluded, "the interpretation of [Ornish MP] study that is most consistent with the principles of clinical study design and conduct is that the treatment had no effect on any measure of cardiac health." (CX1291 (Sacks, Report at 0024)). Respondents were aware of the many flaws in the Ornish MP Study (2005) study. (CCFF ¶ 959).

Respondents also rely on the results of two unblinded, uncontrolled studies for the proposition that the POM Products increase antioxidant levels and reduce oxidative stress – the Denver Study and the Rock Diabetes Study. (CCFF ¶¶ 726-727, 735 (Denver), 744-745 (Rock)). Three RCTs (the San Diego Study, the Heber Diabetes Study, and the Hill Diabetes Study), however, showed no such improvements. (CCFF ¶¶ 929-943 (San Diego Study); 946-949 (Heber/Hill Diabetes studies)). Similarly, there were no changes in antioxidant and inflammation markers in the Davidson CIMT Study (2009). (CCFF ¶ 884).

In Dr. Sacks' opinion, only three of Respondents' studies have sufficient evidence of reliability to warrant serious consideration: the Davidson CIMT Study (2009); the Ornish CIMT Study; and the Davidson BART/FMD Study – all well-conducted RCTs. (CX1291 (Sacks, Report at 0038)). These three studies showed that, in the populations identified in the protocols, the consumption of pomegranate juice provided no statistically or clinically significant benefit for heart disease prevention or treatment, either in direct endpoints related to heart disease or in appropriate surrogate markers of heart disease. (CX1291 (Sacks, Report at 0038)). Consequently, Dr. Sacks concludes that there is "strong evidence that, at the present time, there is no competent and reliable evidence to support the conclusion that consumption of POM Juice will prevent or reduce the risk of heart disease, or treat heart disease." (CX1291 (Sacks, Report

at 0038)). Similarly, he concludes that these studies provide no evidence that POMx Pills or POMx Liquid provides any such benefit. (CX1291 (Sacks, Report at 0038)).

b) Clinical studies, research, and/or trials do not prove Respondents' establishment claims that the POM Products prevent, reduce the risk of, or treat heart disease.

Based on the analysis set forth above, Dr. Sacks and Dr. Stampfer opined that "clinical studies, research, and /or trials do not prove that drinking eight ounces of POM Juice or taking one POMx Pill or one teaspoon of POMx Liquid, daily, prevents or reduces the risk of or treats heart disease including by, decreasing arterial plaque, lowering blood pressure and/or improving blood flow to the heart." (CX1291 (Sacks, Report at 0010); CX1293 (Stampfer, Report at 0017); *see also* CCFF ¶¶ 963-964). Moreover, Respondents recognize that they lack proof that the POM Products prevent or treat CVD. According to a 2009 Medical Research Portfolio prepared by Respondents, with regard to their heart disease evidence, their "current body of research [is] only viewed as '3' on a scale of 1-10 by MDs." (CCFF ¶ 971).

Table 3: Summary of Respondents' Human Heart Studies

Study	Product	Design	Participants	Duration	Results
Aviram ACE/BP (2001) [CCFF ¶¶ 796-804]	Pomegranate Juice concentrate/ no placebo	Unblinded, uncontrolled	10	2 weeks	7 of 10 had statistically significant 36% reduction in ACE activity; 10 had statistically significant 5% reduction in systolic BP (within group analysis).
Aviram CIMT/BP (2004) [CCFF ¶¶ 805-819]	Pomegranate Juice concentrate/ no placebo	Unblinded, uncontrolled	10 drank juice; (additional 9 received no beverage)	1 year	In juice group, 35% decrease in mean CIMT compared to baseline and 12% decrease in systolic BP (within group analysis). In no beverage group, 9% increase in CIMT and no change in BP.
Ornish MP (2005) [CCFF ¶¶ 824-854]					At 3 months, significant ($p = 0.05$) improvement in one measure (SDS score) of blood flow as compared to the placebo group, but no significant changes in the other two blood flow measures (SRS and SSS scores). No significant changes in lipids, blood

		Double blind RCT	17	3 months	pressure, or markers of oxidative stress and inflammation. No change in CIMT.
Ornish CIMT [CCFF ¶¶ 855-871]	Pomegranate Juice/placebo juice	Double blind RCT	73	12 months	No significant changes between juice and placebo groups for CIMT or elastic properties, systolic and diastolic BP, cholesterol, LDL, HDL, or triglycerides.
Davidson CIMT (2009) [CCFF ¶¶ 879-911]	Pomegranate Juice/placebo juice	Double blind RCT	289	18 months	No significant differences in CIMT between juice and placebo groups. No significant differences between groups in anterior wall and posterior wall values and progression rates, and no statistically significant changes in the measured indicators of inflammation, or oxidative stress (incl. C-reactive protein, PON, and TBARS), or blood pressure.
Davidson BART/FMD [CCFF ¶¶ 912-919]	Pomegranate Juice/placebo juice	Double blind RCT	45	13 weeks	No statistically significant differences between juice and placebo groups in flow mediated dilation, blood pressure, ACE, PON, cholesterol, or TBARS.
Denver [CCFF ¶¶ 922-926; 940-941]	POMx capsules/ no placebo	Unblinded, uncontrolled	50	28 days	Weight increased and TBARS levels (test of lipid peroxidation in the blood) decreased, but no changes in diastolic and systolic BP or in antioxidant, oxidative, and inflammatory markers (within group analysis).
San Diego [CCFF ¶¶ 929-943]	POMx capsules/ placebo capsules	Double-blind RCT	64	4 weeks	No statistically significant changes between juice and placebo groups in blood pressure or any of the antioxidant or inflammation markers, including C-reactive protein and nitric oxide.
Rock Diabetes [CCFF ¶¶ 944-945]	POMx Liquid and POM Juice/ no placebo	Unblinded, uncontrolled	30	4-6 weeks	Improved PON
Heber/Hill Diabetes (2 studies) [CCFF ¶¶ 946-949]	POM Juice/ placebo juice POMx capsules/ placebo	RCTs	70	12 weeks	No change in PON or malondialdehyde (TBARS)

Over seventy percent (31 of 43) of the challenged ads and promotional materials contain false or unsubstantiated heart disease efficacy claims.[10] (*See* App. A, Tables 1 and 2). The vast majority of these pieces (28 of 43) represent, either expressly or implicitly, that clinical studies prove that the POM Products treat, prevent, or reduce the risk of heart disease.[11] (*See* App. A, Table 1). The establishment claims are false, as charged in Paragraphs 12 and 13 of the Complaint, and the attendant efficacy claims are unsubstantiated as charged in Paragraphs 19-21

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[10] These 31 challenged pieces are: CX0016 ("Drink and Be Healthy" Ad); CX0029 ("10 out of 10 People" Ad); CX0031 ("Floss your arteries. Daily" Ad); CX0034 ("Amaze your cardiologist" Ad); CX0103 ("Decompress" Ad); CX0109 ("Heart Therapy" Ad); CX0192 ("What gets your heart pumping" Ad); CX0475/1426 Ex. A (Juice Bottle Hang Tag); CX0169/1426 Ex. L ("The power of POM" Ad); CX0180/1426 Ex. K ("Antioxidant Superpill" Ad); CX0279 ("Science, Not Fiction" Ad); CX0280 ("Live Long Enough" Ad); CX0328 ("Your New Health Care Plan" Ad); CX0331/1426 Ex. J ("Healthy Wealthy" Ad); CX0337 ("The First Bottle You Should Open" Ad); CX0342/CX0353 ("Take Out A Life Ins" Ads); CX0348/CX0350 ("24 Scientific Studies" Ads); CX0351/CX0355 ("Only Antioxidant Supplement Rated X" Ads); CX1426 Ex. I ("Antioxidant Superpill" brochure); CX1426 Ex. M (POMx Heart Newsletter); CX0473(POMWonderful.com); CX0473 (POMWonderful.com Community site); CX473 (Pomegranatetruth.com); CX0473 (POMPills.com); CX0013 (Jan. 2003 POM Juice press release); CX0044 (Sept. 2005 POM Juice press release); CX0065_0002 (July 2006 POMx press release); CX0473 (June 2008, Tupper on Fox Business show); CX0033 ("Life Support" Print Ad); CX0036/CX0188 ("Cheat Death" Print Ad); CX0463 ("Heart Therapy" Banner Ad).

[11] These 28 challenged pieces are: CX0016 ("Drink and Be Healthy" Ad); CX0029 ("10 out of 10 People" Ad); CX0031 ("Floss your arteries. Daily" Ad); CX0034 ("Amaze your cardiologist" Ad); CX0103 ("Decompress" Ad); CX0109 ("Heart Therapy" Ad); CX0192 ("What gets your heart pumping" Ad); CX0475/1426 Ex. A (Juice Bottle Hang Tag); CX0169/1426 Ex. L ("The power of POM" Ad); CX0180/1426 Ex. K ("Antioxidant Superpill" Ad); CX0279 ("Science, Not Fiction" Ad); CX0280 ("Live Long Enough" Ad); CX0328 ("Your New Health Care Plan" Ad); CX0331/1426 Ex. J ("Healthy Wealthy" Ad); CX0337 ("The First Bottle You Should Open" Ad); CX0342/CX0353 ("Take Out A Life Ins" Ads); CX0348/CX0350 ("24 Scientific Studies" Ads); CX0351/CX0355 ("Only Antioxidant Supplement Rated X" Ads); CX1426 Ex. I ("Antioxidant Superpill" brochure); CX1426 Ex. M (POMx Heart Newsletter); CX0473(POMWonderful.com); CX0473 (POMWonderful.com Community site); CX473 (Pomegranatetruth.com); CX0473 (POMPills.com); CX0013 (Jan. 2003 POM Juice press release); CX0044 (Sept. 2005 POM Juice press release); CX0065_0002 (July 2006 POMx press release); CX0473 (June 2008, Tupper on Fox Business show).

of the Complaint. (CX1426_0017-20). In addition, three challenged ads represent that POM Juice is effective for treating, preventing, or reducing the risk of heart disease, without stating directly the specific level of science that substantiates the claims. (*See* App. A, Table 2). Respondents did not possess a reasonable basis to substantiate these heart disease claims as charged in Paragraphs 19-21 of the Complaint. (CX1426_0019-20).

2. Respondents' Prostate Cancer Claims Are False and Unsubstantiated

a) Respondents did not possess or rely upon a reasonable basis to substantiate their efficacy claims that the POM Products prevent, or reduce the risk of, or treat prostate cancer

Complaint Counsel has submitted the expert report and testimony of James A. Eastham, M.D., Chief of Urology, Department of Surgery, and Director of Clinical Research, Urology Department at Memorial Sloan Kettering Cancer Center. (CCFF ¶ 710). He is an expert in the fields of urology, including the prevention and treatment of prostate cancer, as well as clinical testing related to the prevention and treatment of prostate cancer. (CCFF ¶ 714). Dr. Stampfer also reviewed Respondents' prostate cancer research and provided his independent opinion. (CCFF ¶¶ 700-01).

Dr. Eastham and Dr. Stampfer state that experts in the field of prostate cancer would require at least one well-designed, randomized, double-blind, placebo-controlled clinical trial involving an appropriate sample population and endpoint to support claims that the POM Products prevent prostate cancer. (CX1287 (Eastham, Report at 0012); CX1293 (Stampfer, Report at 0009-10); *see also* CCFF ¶ 974). The appropriate sample population for a cancer prevention trial "would involve more than 10,000 healthy men, ages 50 to 65, having no sign of prostate cancer." (CX1287 (Eastham, Report at 0012); *see also* CCFF ¶ 975). Dr. Eastham notes that "[a] prostate cancer prevention study must be conducted over a long enough period of

time to see an effect over time." (CX1287 (Eastham, Report at 0014)). Dr. Eastham states that "[t]he primary endpoint in a prostate cancer prevention trial for measuring whether a product has been effective is the prevalence or incidence of prostate cancer between the treatment and placebo groups at the conclusion of the study." (CX1287 (Eastham, Report at 0014); *see also* CCFF ¶ 975).

To date, the POM Products have not been studied in healthy men. The clinical studies examining the effect of the POM Products on prostate cancer have been conducted on men who either have prostate cancer, or have been treated for prostate cancer and have experienced a biochemical recurrence. (CCFF ¶¶ 992, 1017, 1026, 1030). Therefore, Dr. Eastham and Dr. Stampfer opine that there is no competent and reliable scientific evidence supporting a claim that the POM Products prevent prostate cancer. (CX1287 (Eastham, Report at 0016); CX1293 (Stampfer, Report at 0029); *see also* CCFF ¶ 1037). The principal investigators of both the Pantuck Phase II Prostate Cancer Study (2006) and Carducci Dose Study, and Respondents' own documents support the views of Complaint Counsel's experts. (CCFF ¶¶ 1000, 1010, 1018). Drs. Pantuck and Carducci testified that the results of their clinical trials do not demonstrate that POM Juice or POMx Pills prevents prostate cancer. (CCFF ¶¶ 1000, 1018). More importantly, Respondents have admitted in their own documents that "POM currently has a research gap: no data on prostate cancer prevention, prior to radiation or prostatectomy." (CX1029_0004; *see also* CCFF ¶ 1010).

To support claims that POM Juice, POMx Pills and POMx Liquid treat prostate cancer, Dr. Eastham and Dr. Stampfer state that experts in the field would require a randomized, placebo-controlled, double-blind clinical trial with an appropriate sample population and endpoint. (CX1287 (Eastham, Report at 0015); CX1293 (Stampfer, Report at 0009-10); *see also*

CCFF ¶ 977). The Pantuck Phase II Prostate Cancer Study (2006) – an unblinded, uncontrolled clinical trial evaluating the effect of drinking eight ounces of POM Juice daily on 46 men who previously underwent radiation or surgery for prostate cancer – is the only published clinical trial examining the effectiveness of POM Juice on prostate cancer. (CCFF ¶ 992). The study participants' PSA levels were measured every three months, and those measurements were used to calculate the participants' PSA doubling time (*i.e.*, the time it takes for PSA levels to double). (CCFF ¶ 993). As the study investigators note, "it remains controversial" whether modulation of PSA levels is a valid clinical endpoint, equal to slowing the growth of a tumor or preventing disease progression to a metastatic state. (CCFF ¶ 994). While PSADT significantly increased from a mean of 15 months at baseline to 54 months after treatment, the study investigators acknowledged that further research was needed to address the limitations of their study, namely the lack of a blinded control group. (CCFF ¶¶ 993, 995-998).

Both Dr. Eastham and Dr. Stampfer state that this study fails to provide reliable scientific evidence. (CX1287 (Eastham, Report at 0018); CX1293 (Stampfer, Report at 24); *see also* CCFF ¶ 1002). First, the study lacked a placebo-control group and "[w]ithout a control group, it is not possible to conclude that POM Juice alone had an effect on the patients' PSA." (CX1287 (Eastham, Report at 0018); CX1293 (Stampfer, Report at 24); *see also* CCFF ¶¶ 1003-1004). At his deposition, Dr. Pantuck testified that the lack of a "blinded control" group was the "greatest limitation" of his study. (CX1341 (Pantuck, Dep. at 110); *see also* CCFF ¶ 996). Dr. Pantuck noted in the study report that his currently ongoing Phase III study would address "several limitations of [his] study, with the inclusion of . . . a placebo control." (CX0815_0008; *see also* CCFF ¶ 1026).

Second, the primary endpoint for measuring efficacy was PSADT which "is not recognized by experts in the field as a surrogate endpoint in prostate cancer clinical trials." (CX1287 (Eastham, Report at 0019); *see also* CX1293 (Stampfer, Report at 25); CCFF ¶ 978). According to Dr. Eastham, "[a] surrogate endpoint is a measurement or sign used as a substitute for a clinically meaningful endpoint which measures directly how a patient feels, functions, or survives." (CX1287 (Eastham, Report at 0010); *see also* CCFF ¶ 781). "PSADT is not recognized by experts in the field as a surrogate endpoint in prostate cancer clinical trials." (CX1287 (Eastham, Report at 0019); *see also* CX1293 (Stampfer, Report at 25); CCFF ¶ 978). Moreover, "[a]ltering PSADT has not been shown to change the natural history of the disease by delaying the development of metastases or death from prostate cancer." (CX1287 (Eastham, Report at 0019); *see also* CCFF ¶ 983). Respondents' prostate cancer expert Dr. Jean deKernion also confirmed Dr. Eastham's view. In his report, Dr. deKernion wrote, "there are no studies that have been performed for sufficient length to determine an impact [of PSADT] on survival[.]" (PX0161 (deKernion, Report at 0004); *see also* CCFF ¶ 983). Indeed, Dr. Pantuck, the principal investigator of the study, acknowledged these issues in his study report, stating that "further research is needed . . . to determine whether improvements in such biomarkers (including PSADT) are likely to serve as surrogates for clinical benefit." (CCFF ¶ 995).

Therefore, "[e]ven if POM Juice prolonged PSADT, it is unclear whether that outcome is truly clinically significant." (CX1287 (Eastham, Report at 0019); *see also* CCFF ¶ 1009). The average pretreatment PSADT for the study participants was 15 months. (CCFF ¶ 1009). Patients with a PSADT of 15 months are considered to have the lowest risk of dying from prostate cancer. (CCFF ¶ 982). According to Dr. Eastham, "[t]here is no evidence that

prolonging the PSADT in a group already considered to be 'most favorable' is beneficial." (CX1287 (Eastham, Report at 0019); *see also* CCFF ¶ 1009).

Finally, the results from the Pantuck Phase II Prostate Cancer Study (2006) cannot be used to support claims for POMx Pills and POMx Liquid. (CCFF ¶ 1011). POM Juice is not identical to POMx Pills and POMx Liquid. (CCFF ¶¶ 964-65). According to Dr. Eastham, "[e]ven if the active ingredient is known, the alternate compound may contain some other as yet unknown compound that might counter-act the benefit of the active agent." (CX1287 (Eastham, Report at 0020); *see also* CCFF ¶ 1011). Therefore, Dr. Eastham states that "an expert in prostate cancer would not rely upon the clinical testing of one product to support the efficacy of a non-identical product." (CX1287 (Eastham, Report at 0020); *see also* CCFF ¶ 1011). More importantly, Respondents' own internal documents recognize that research on POM Juice cannot be used to support claims for POMx. (CCFF ¶ 965).

b) Clinical studies, research, and/or trials do not prove Respondents' establishment claims that the POM Products prevent, reduce the risk of, or treat prostate cancer.

The same level of evidence discussed above is needed to show that clinical studies, research, or trials prove that a product prevents, reduces the risk of, or treats prostate cancer. (CCFF ¶¶ 974, 977). Dr. Eastham states that to his knowledge, there are no randomized, double-blind, placebo-controlled trials studying the effect of the POM Products on prostate cancer using accepted, clinically meaningful outcomes as a primary endpoint. (CX1287 (Eastham, Report at 0025); *see also* CCFF ¶ 1037). Likewise, Respondents' prostate cancer expert Dr. Jean deKernion acknowledges in his expert report that "[n]o Phase III randomized trial has been completed to absolutely prove that POM products prolong the life of patients . . . ." (PX0161, (deKernion, Report at 0011); *see also* CCFF ¶ 1038). Therefore, the clinical studies, research,

and/or trials conducted thus far on the POM Products do not prove that drinking eight ounces of POM Juice, or taking one POMx Pill or one teaspoon of POMx Liquid, daily prevents, reduces the risk of, or treats prostate cancer. (CX1287 (Eastham, Report at 0025-26); CX1293 (Stampfer, Report at 29); *see also* CCFF ¶ 1037). In their 2009 medical research summary, Respondents acknowledge that this evidence does not exist, noting that to make such claims they need further studies with endpoints of death or cancer progression monitored through biopsy. (CX1029_0004; CCFF ¶¶ 1045-1046).

Respondents have always known that PSADT is not an acceptable endpoint to support claims that their products will prevent, treat, or reduce the risk of prostate cancer. Dr. Liker, POM's Medical Director, testified that he became aware that PSADT is not an accepted biomarker for drug approval as early as 2002 or 2003. (CCFF ¶ 1044). The Pantuck Phase II Prostate Cancer Study (2006) published report clearly stated that PSADT is not an accepted clinical endpoint for prostate cancer treatment trials. (CCFF ¶ 1044). Yet, Respondents continued to promote the POM Products as a prevention or treatment for prostate cancer relying on PSADT.

Over sixty-five percent (29 of 43) of the challenged ads and promotional materials contain false or unsubstantiated prostate cancer efficacy claims.[12] (*See* App. A, Tables 1 and 2).

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[12] These 29 challenged pieces are: CX0260/1426 Ex. B ("Drink to Prostate Health"); CX0274/1426 Ex. C ("I'm off to save prostates" Ad); CX0314 ("Drink to Prostate Health" Magazine Wrap); CX0372/CX0379/CX0380 ("Lucky I have super health powers" Magazine Wrap); CX0475/1426 Ex. A (Juice Bottle Hang Tag); CX0120 ("One Small Pill for Mankind" Ad); CX0122 ("Science, Not Fiction" Ad); CX0169/1426 Ex. L ("The power of POM" Ad); CX0180/1426 Ex. K ("Antioxidant Superpill" Ad); CX0279 ("Science, Not Fiction" Ad); CX0280 ("Live Long Enough" Ad); CX0328 ("Your New Health Care Plan" Ad); CX0331/1426 Ex. J ("Healthy Wealthy" Ad); CX0337 ("The First Bottle You Should Open" Ad); CX0342/CX0353 ("Take Out A Life Ins" Ads); CX0348/CX0350 ("24 Scientific Studies" Ads);

Twenty-seven of the 29 pieces making prostate cancer efficacy claims represent, either expressly or implicitly, that clinical studies prove that the POM Products treat, prevent, or reduce the risk of prostate cancer.[13] (*See* App. A, Table 1). The establishment claims are false, as charged in Paragraphs 14 and 15 of the Complaint, and the attendant efficacy claims are unsubstantiated as charged in Paragraphs 19-21 of the Complaint. (CX1426_00018-20). In addition, two challenged ads and promotional pieces represent that POM Juice is effective for treating, preventing, or reducing the risk of prostate cancer, without stating directly the specific level of science that substantiates the claims. (*See* App. A, Table 2). Respondents did not possess a reasonable basis to substantiate these prostate cancer claims as charged in Paragraphs 19-21 of the Complaint. (CX1426_00019-20).

3. Respondents' Erectile Dysfunction Claims Are False and Unsubstantiated

a) Respondents did not possess or rely upon a reasonable basis to substantiate their efficacy claims that the POM Products prevent, reduce the risk of, or treat erectile dysfunction.

Complaint Counsel has submitted the Expert Report and testimony of Arnold Melman, M.D., a Professor and Chairman of the Department of Urology at the Albert Einstein

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CX0351/CX0355 ("Only Antioxidant Supplement Rated X" Ads); CX1426 Ex. I ("Antioxidant Superpill" brochure); CX1426 Ex. N (POMx Prostate Newsletter); CX0473 (POMWonderful.com);CX0473 (POMWonderful.com Community site); CX473 (Pomegranatetruth.com); CX0473 (POMPills.com); CX0065_0002 (July 2006 POMx press release); CX0473 (June 2008, Tupper on Fox Business show); CX0472 (Feb. 2009, Lynda Resnick on CBS *Early Show*); CX0473 (Mar. 2009, Lynda Resnick interview in Newsweek.com); CX0466/CX1426 Ex. H ("Off to save prostates" Banner Ad); CX0473 (Nov. 2008, Lynda Resnick on *Martha Stewart* Show).

[13] All but two (CX0466/CX1426 Ex. H ("Off to save prostates" Banner Ad) and CX0473 (Nov. 2008, Lynda Resnick on *Martha Stewart Show*) of the 29 challenged pieces referenced above (*supra* n. 12) make claims of clinical proof.

College/Montefiore Medical Center in New York. (CCFF ¶ 717). Dr. Melman is an expert in the evaluation of whether a product prevents, reduces the risk of, or treats erectile dysfunction, and in the design and conduct of clinical trials involving erectile dysfunction. (CCFF ¶¶ 717-720).

To constitute a reasonable basis for the claims that the POM Products prevent, reduce the risk of, or treat erectile dysfunction, at least one well-designed, human RCT involving several investigatory sites is required. (CCFF ¶¶ 773-775, 777, 1055). A well-designed, human RCT must use a validated tool for measuring treatment outcomes. (CCFF ¶¶ 781, 1057). This is essential for obtaining meaningful data that can be compared with research outcomes obtained by different investigators. (CCFF ¶ 783). The International Index of Erectile Function ("IIEF") is the widely used validated questionnaire that evaluates change in erectile function. (CCFF ¶ 1058-1059). In addition, a clinical trial must have a total sample population "large enough to produce clinically significant results and a statistical significance of $p<0.05$." (CCFF ¶¶ 779, 782, 1055).

The Forest Erectile Dysfunction Study (2007) was a double-blinded, placebo-controlled study of the effect of POM Juice on 53 subjects with mild to moderate erectile dysfunction. (CCFF ¶ 1064). Patients were randomized into two groups for a four-week study period, during which they consumed either POM Juice or a placebo beverage. (CCFF ¶ 1065). After the first treatment period, the groups were provided with the opposite study beverage for another four-week treatment period. (CCFF ¶ 1065). Efficacy was assessed using two questionnaires: 1) the Global Assessment Questionnaire (GAQ), an unvalidated questionnaire based on a respondent's self-evaluation of whether the treatment had an effect; and 2) the erectile function domain of the IIEF. (CCFF ¶ 1060, 1066-1068).

Dr. Melman opines that the Forest Erectile Dysfunction Study (2007) does not provide scientific support for claims that POM Juice prevents, reduces the risk of, or treats erectile dysfunction because it failed to achieve statistical significance on both the validated instrument (IIEF) and the unvalidated instrument (GAQ). (CCFF ¶¶ 1076-1077, 1086).

Dr. Harin Padma-Nathan and Mr. Forest, authors of the Forest Erectile Dysfunction Study (2007), support Dr. Melman's opinion. Dr. Padma-Nathan said that the GAQ was not a validated measure for measuring erectile function. (CCFF ¶ 1067). He also testified that the Forest Erectile Dysfunction Study (2007) was a "pilot study" or a "proof of concept" study designed to determine whether there is any evidence of a treatment effect and was underpowered. (CCFF ¶¶ 1064, 1071). Dr. Padma-Nathan and Mr. Forest testified that the Forest Erectile Dysfunction Study (2007) did not have statistically significant results for the GAQ or IIEF, and therefore did not demonstrate that POM Juice prevents, reduces the risk of, or treats erectile dysfunction. (CCFF ¶¶ 1069, 1074). As such, the Forest Erectile Dysfunction Study (2007) concluded that further studies were needed to confirm any potential benefit for erectile dysfunction. (CCFF ¶ 1074).

Dr. Melman also reviewed the *in vitro* and animal studies Respondents submitted in support for their claims. (CCFF ¶¶ 763-764, 1084-1085). Dr. Melman notes that neither *in vitro* nor animal studies provide support that a product works in humans. (CCFF ¶¶ 763-764, 1084-1085). Although nitric oxide has a role in erectile function, studies on the relationship between nitric oxide and antioxidants do not directly involve erectile function in humans, and cannot alone prove that POM Juice, or any other pomegranate product treats, reduces the risk, or prevents erectile dysfunction in humans. (CCFF ¶ 1085).

In addition, Respondents' erectile dysfunction and nitric oxide experts fail to opine that POM Juice prevents, reduces the risk of, or treats erectile dysfunction. (CCFF ¶¶ 1088-1089). Respondents' erectile dysfunction expert, Dr. Irwin Goldstein, opines that the Forest Erectile Dysfunction Study (2007) is "suggestive evidence that the use of pomegranate juice would benefit the patient with erectile dysfunction," but does not recommend POM Juice as a treatment for erectile dysfunction." (CCFF ¶¶ 1090, 1093). Similarly, Respondents' nitric oxide expert, Arthur Burnett, M.D., would be concerned about relying on the Forest Erectile Dysfunction Study (2007) to conclude that POM Juice is efficacious in treating erectile dysfunction. (CCFF ¶ 1088).

Respondents' experts limit their recommendation of POM Juice to promoting erectile health only, not erectile dysfunction. (CCFF ¶¶ 1091-1095). Moreover, Respondents' expert Dr. Goldstein stated that the use of POM Juice to promote erectile health "requires dialogue with a healthcare provider. This isn't somebody who just goes to . . . a supermarket and just drinks pomegranate juice for no reason. This would be done in a context of a dialogue with the patient and a physician who understood the sexual issues of that person." (CCFF ¶ 1095).

b) Clinical studies, research, and/or trials do not prove Respondents' establishment claims that the POM Products prevent, reduce the risk of, or treat erectile dysfunction.

The same level of evidence discussed above is needed to show that clinical studies, research, or trials prove that a product prevents, reduces the risk of, or treats erectile dysfunction. (CCFF ¶ 1086). Other than the Forest Erectile Dysfunction Study (2007), Dr. Melman states, to his knowledge, there are no other clinical trials of POM Juice, or any other pomegranate product, demonstrating efficacy on erectile dysfunction. (CCFF ¶ 1087). Therefore, there is no competent and reliable evidence to support claims that clinical studies, research, and/or trials

prove that drinking eight ounces of POM Juice daily prevents, reduces the risk of, or treats erectile dysfunction. (CCFF ¶¶ 1086-1087). Again, neither Dr. Goldstein nor Dr. Burnett offers an opinion to the contrary. (CCFF ¶¶ 1088-1090).

Eight of the challenged ads and promotional materials contain false or unsubstantiated ED efficacy claims.[14] (*See* App. A, Tables 1 and 2). All eight ads and promotional materials represent, either expressly or implicitly, that clinical studies prove that the POM Juice treat, prevent, or reduce the risk of erectile dysfunction. (*See* App. A, Table 1). The establishment claims are false, as charged in Paragraphs 17 and 18 of the Complaint. In addition, Respondents did not possess a "reasonable basis" to substantiate the attendant efficacy claims as charged in Paragraphs 19-21 of the Complaint. (CX1426_00019-20).

III. COMPLAINT COUNSEL IS ENTITLED TO THE PROPOSED ORDER AGAINST RESPONDENTS

A. Corporate Respondents POM Wonderful and Roll Global Are Liable for Violating Sections 5 and 12 of the FTC Act

POM and Roll are each liable for their involvement in making the false and unsubstantiated health claims discussed in Section II.A. POM is liable for claims made in its advertisements for its products. Roll is liable because it fully participated in POM's business activities by sponsoring scientific studies on POM products, creating content for advertisements for POM products through its internal advertising agency, providing public relations and related services for POM products through its Corporate Communications department, and providing

[14] These eight challenged pieces are: CX0475/1426 Ex. A (Juice Bottle Hang Tag); CX0351/CX0355 ("Only Antioxidant Supplement Rated X" Ads); CX0473(POMWonderful.com); CX0473 (POMWonderful.com Community site); CX0473 (Pomegranatetruth.com); CX0473 (POMPills.com); CX0128_0002 (June 2007 POM Juice press release); CX0473 (Mar. 2009, Lynda Resnick interview in Newsweek.com).

business consulting services through the Roll Consulting Group. (CCFF ¶¶ 94, 99, 103-04, 107). Additionally, Roll and POM are jointly liable under the common enterprise theory.

The common enterprise theory exists for situations where corporations are entwined so that a judgment of no liability against one defendant would provide another defendant "with a clear mechanism for avoiding the terms of the order . . . ." *Nat'l Urological Group*, 645 F. Supp. 2d at 1182 (internal quotation marks omitted). "'Where one or more corporate entities operate in a common enterprise, each may be held liable for the deceptive acts and practices of the others.'" *FTC v. Bay Area Bus. Council, Inc.*, No. 02 C 5762, 2004 WL 769388, at *33-34 (N.D. Ill. Apr. 9, 2004); *see also Telebrands Corp.*, 140 F.T.C. at 451 (Initial Decision) (stating that "[c]orporate respondents acting in concert to further a common enterprise are each liable for the acts and practices of the others in furtherance of the enterprise"). "It is not necessary that the FTC prove any particular number of entity connections and any specific connection." *FTC v. Kennedy*, 574 F. Supp. 2d 714, 722 (S.D. Tex. 2008).

The record evidence demonstrates that Roll and POM engaged in interrelated business transactions while sharing common ownership, officers, office locations, and commingled funds. (CCFF ¶¶ 108-120). It is undisputed that Stewart and Lynda Resnick own and control their closely held affiliated corporations, Roll and POM. (CCFF ¶¶ 9-16, 110-111). Serving as "the umbrella company," Roll provides advertising and other marketing services to POM, which have been only partially reimbursed, and risk management, human resources, and consulting to POM without any reimbursement. (CCFF ¶¶ 108, 115-117). [redacted]

(CCFF ¶ 112, *in camera*).

Perhaps most telling is Mrs. Resnick's role, as best exemplified by her email address lresnick@pomqueen.com. (CCFF ¶ 19). She had no title or position in POM LLC, yet she participated in POM's business on almost a daily basis in the company's early years, and on a weekly or biweekly basis thereafter and through 2010. (CCFF ¶¶ 18, 22, 34; *see also* CCFF ¶¶ 35-44). Major branding, marketing, creative, and advertising decisions made in the POM business are done in consultation with Mrs. Resnick. (CCFF ¶ 20-23). Her only official position is Vice-Chairman of Roll, however. (CCFF ¶¶ 14-15). It is undisputed that the Resnicks had ultimate say over all business functions of POM and Roll (CCFF ¶ 111) and, most critically, that all of the money comes out of the Resnicks' pockets. (CCFF ¶¶ 29, 119). Thus, Roll and POM operated as a common enterprise. *See Telebrands Corp.*, 140 F.T.C. at 451 (Initial Decision).

B. The Resnicks and Matt Tupper Are Individually Liable for Violating the FTC Act

"When both a corporation and an individual are named in the complaint, to obtain a cease and desist order against the individual, Complaint Counsel must prove violations of the FTC Act by the corporation and that the individual either directly participated in the acts at issue or had authority to control them." *Daniel Chapter One Initial Decision*, 2009 FTC LEXIS 157, at * 276 (citing *FTC v. Standard Educ. Soc'y*, 302 U.S. 112, 119-20 (1937). The evidence demonstrates that the Resnicks possessed the authority to control both Roll's and POM's corporate practices and actively participated in their business operations as they related to the complaint allegations. (CCFF ¶¶ 9-44). Mr. Resnick made decisions about finances, investments, the expansion of POM, hiring, funding scientific studies, and whether and how to publish study results. (CCFF ¶¶ 25-28, 30, 894-896). In addition, Mr. Resnick has been intimately involved in the development of POM's scientific research program, frequently meeting with POM and its scientific advisors

about POM-sponsored research. (CCFF ¶¶ 30-32). From POM's inception, Mrs. Resnick has directed the creative development of the company and the vision for the POM Juice and POMx advertising campaigns and she has been deeply involved on a day-to-day basis in marketing and advertising. (CCFF ¶¶ 20-23, 34-35). Mrs. Resnick was the chief marketing person at POM reviewing and providing input on POM's marketing materials and POM's media plans, participating in decisions as to which studies to reference in product advertising, participating in the hiring and firing of the heads of marketing at POM, and providing final approval of advertising content. (CCFF ¶¶ 36-43).

Mr. Tupper, President and Chief Operating Officer of POM, formulated, directed, and controlled the policies, acts, or practices of POM. (CCFF ¶¶ 46-48). Mr. Tupper has been intimately involved in POM's operations, the marketing and sales of POM's products, decisions involving research, the review and approval of POM advertising, decisions on how to describe POM's research in ad copy, and decisions for the hiring and firing of key marketing and science executives. (CCFF ¶¶ 49-86).

As discussed in Section II, POM and Roll have violated the FTC Act by disseminating false and unsubstantiated health claims. By virtue of their control and participation in the challenged conduct relating to Roll and POM, the Resnicks and Mr. Tupper are individually liable.

C. The Scope of the Proposed Order Is Appropriate to Address Respondents' Violations

As the Supreme Court described in the *Ruberoid* case, the Commission has "wide discretion" in crafting an appropriate remedy against FTC Act violators. *FTC v. Ruberoid Co.*, 343 U.S. 470, 473, 475 (1952); *see also Jacob Siegel Co. v. FTC*, 327 U.S. 608, 611-13 (1946).

Whether the case involves consumer protection or competition violations, the "wide discretion" described in *Ruberoid* is subject only to two constraints: the order must bear a "reasonable relation" to the unlawful practices, *Jacob Siegel Co.*, 327 U.S. at 613, and it must be sufficiently clear and precise that its requirements can be understood, *Colgate-Palmolive Co.*, 380 U.S. at 392. Pursuant to this authority, the courts have affirmed Commission orders requiring remedies in diverse factual scenarios. *FTC v. Nat'l Lead Co.*, 352 U.S. 419, 431 (1957) (limiting individual use of zone pricing); *N. Tex. Specialty Physicians v. FTC*, 528 F.3d 346 (5th Cir. 2008) (requiring cancellation of existing contracts); *Chicago Bridge & Iron Co. N.V. v. FTC*, 534 F.3d 410, 441 (5th Cir. 2008) (mandating divestiture of assets to create a competitor); *Sears, Roebuck & Co.*, 676 F.2d at 389 n.10 (requiring competent and reliable evidence for future performance claims for major household appliances); *Thompson Med. Co.*, 791 F.2d at 189, 192 (requiring at least two adequate and well-controlled, double-blinded clinical studies for future efficacy claims for a topical analgesic); *Porter & Dietsch, Inc. v. FTC*, 605 F.2d 294, 306-307 (7th Cir. 1979) (mandating disclosure requirements); *Cont'l Wax Co. v. FTC*, 330 F.2d 475, 480 (2d Cir. 1964) (requiring trade name excision). In each instance, the underlying inquiry has been the same: what remedy is needed to ensure that respondents do not again violate the FTC Act. *See Colgate-Palmolive Co.*, 380 U.S. at 394-95 (noting that the Commission may frame its order broadly enough to prevent respondents from engaging in similar illegal practices).

In determining the appropriate scope of relief, the Commission considers the seriousness and deliberateness of the violations; the ease with which the unlawful conduct can be transferred to other products; and whether the respondents have a history of past violations. *Thompson Med.*

Co., 104 F.T.C. at 832-833 (1984).[15] The seriousness of these violations is apparent from the fact that the claims related to significant diseases (s*ee supra* Section.II.A) and the fact that consumers could not readily judge the truth or falsity of those claims. Respondents engaged in a calculated, years-long effort to promote POM Juice and POMx as products that were not only efficacious, but also validated by rigorous human clinical medical research. (*See* CCFF ¶¶ 328, 335, 340, 348, 361, 367, 371, 376, 384, 388, 405, 414, 418, 424, 429, 434, 441, 471, 494, 500, 535, 548, 555, 562, 567, 573, 575, 577). Although their data consisted largely of either unblinded, uncontrolled studies on questionable endpoints (including the prostate studies and the Aviram studies), or controlled, blinded data with negative results (such as the Davidson CIMT, Davidson BART/FMD, and the Ornish CIMT studies),[16] they described their research to consumers as "real studies, real results." (*See, e.g.*, CCFF ¶¶ 468, 471).[17] Consumers apparently responded to Respondents' message by purchasing more than $200 million of POM Products and taking them to prevent or treat disease. (CCFF ¶¶ 139, 143, 144, 616-617).

The deliberateness of the violations is evidenced by Respondents' "ready willingness to flout the law[.]" *See Sears, Roebuck & Co.*, 676 F.2d at 392. Despite concerns expressed by the

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[15] The more egregious the facts with respect to a particular element, the less important it is that another negative factor be present. *See Sears, Roebuck & Co.*, 676 F.2d at 392; *Thompson Med. Co.*, 104 F.T.C. at 648.

[16] The sole exception is the RCT Ornish MP Study (2005) that achieved one positive result on an intermediate heart marker. Respondents were aware, however, that this study was deeply flawed, having been cut short at 3 months with numerous design and conduct errors. (CCFF ¶¶ 824-39).

[17] Violations have been found also to be "serious" where "claims were consciously made despite flaws in the studies relied upon by [the respondent], and because consumers who were not able to assess the validity of those claims relied on the misrepresentation that the [product] had been proven to be effective." *See Schering Corp.*, 118 F.T.C. at 1121 (Initial Decision).

New York State Attorney General's Office, the Council for Better Business Bureaus' National Advertising Division ("NAD"), NBC television, Dr. Pantuck, several IRBs, the FTC, and the FDA that POM's advertising claims misled consumers, POM continued to make the same or similar claims. (CCFF ¶¶ 402, 662-684, 686-688). For example, after the NAD challenged POM's 30% reduction in arterial plaque claim in 2005, Respondents continued to cite to the Aviram CIMT/BP Study (2004) and specifically its 30% reduction finding until at least 2009. (*See, e.g.*, CCFF ¶¶ 453-54). As of 2009, Respondents' website also continued to tout blood pressure reduction results from the unblinded, uncontrolled 2001 and 2004 Aviram studies, despite the fact that at least five subsequent controlled studies completed between 2004 and 2007 consistently showed *no* reduction in blood pressure from use of POM Juice or POMx. (CCFF ¶¶ 829, 858, 883, 915, 932, 957). Respondents' own internal assessments recognized that their research was not sufficient to substantiate POM's claims. (CX1029_0003-04, 0013). In particular, Respondents noted that they lacked sufficient research to make treatment, prevention or reduction of risk claims for heart disease, prostate cancer, and treatment claims for erectile dysfunction. (*See, e.g.*, CCFF ¶¶ 968-71, 1010, 1045-47, 1051, 1096-1098).

Yet, Respondents have expressed no remorse for the misleading impressions that their advertisements left on consumers. Mr. Resnick testified that if consumers are interpreting from Respondents' "Decompress" ad that POM Juice lowers blood pressure, '[i]t's not my problem ... it's their problem." (CX1376 (S. Resnick OS Dep. at 310); *see also* CCFF ¶ 618). In fact, Respondents testified at trial that they will continue making the same claims. Mr. Tupper testified that POM feels comfortable continuing to advertise the results of the Aviram CIMT/BP Study (2004) (*i.e.*, 30% reduction in plaque) despite the null results of the Davidson CIMT Study (2009). (CCFF ¶ 953). Mr. Resnick testified that if POM's "ads communicate to consumers that

POM can prevent or delay the onset of prostate cancer," he is very comfortable with that claim. (CX1376 (S. Resnick, OS Dep. at 156; *see also* CCFF ¶ 619). Rather than heed Dr. Pantuck's concern about POM's misuse of his prostate cancer study in their advertising, Mrs. Resnick testified that if she had heard his concern she would have disregarded it because "Dr. Pantuck is not a marketing person." (CCFF ¶ 691). Mr. Tupper testified that he still thinks Respondents' science on heart disease, prostate cancer, and erectile dysfunction is an 8 out of 10, despite the facts that: 1) doctors' view the cardiovascular research as only a 3 out of 10; 2) Dr. Pantuck has told Respondents that the likelihood of obtaining a drug treatment claim with a PSA endpoint is remote; and 3) Respondents' own scientific director, Dr. Gillespie, stated it will be difficult to further publicize the erectile dysfunction research because the science is weak. (CCFF ¶¶ 971-972, 1050, 1054, 1098, 1100). Respondents' blatant willingness to make advertising claims not supported by adequate substantiation demonstrates the need for strong, clear, and precise injunctive relief.

Finally, the violations at issue – misrepresentations of health benefits – are readily transferrable to the other foods or dietary supplements sold by Respondents. For example, Respondents sell other pomegranate-based products, such as POMx Coffee, POMx Tea, POMx Bars, and a POM sports recovery drink, and other food products, such as Wonderful Pistachios, Wonderful Almonds, and Fiji Water. (CCFF ¶¶ 12, 123). In addition, Respondents have made a variety of health representations – which are not challenged by the Commission's Complaint – about the potential benefits of POM products for other health conditions, including but not limited to Alzheimer's, stroke, premature aging, and sports recovery. (*See e.g.*, CCFF ¶¶ 241, 308, 326, 341, 349, 495, 570, 668). Respondents also have begun researching the health benefits

of their other food products, such as the effect of pistachios and Fiji Water on triglycerides and bone health, respectively. (CCFF ¶ 725).

Thus, fencing-in relief is not only appropriate, but is essential, in this case where the violations are serious, deliberate, and readily transferable. *See*, *e.g.*, *Brake Guard Prods., Inc.*,125 F.T.C. 138, 253-254 (1998) (misrepresentations related to motor vehicle safety were serious); *Schering Corp*., 118 F.T.C 1030, 1121 (1994) (Initial Decision) (violations were serious where claims consciously made despite flaws in the studies respondent relied on and because consumers were not able to assess the validity of the claims); *Thompson Med. Co.*, 104 F.T.C at 834, 837 (long-term, deliberate, transferrable violations warrant fencing-in relief).[18]

Therefore, Complaint Counsel respectfully requests that the Court enter the proposed Notice Order accompanying the Complaint. The Notice Order issued by the Commission contains three provisions designed to prevent future violations by Respondents. Parts I and III are substantiation provisions. Part I addresses disease claims made for any POM Product (defined as any food, drug or dietary supplement containing pomegranate or its components). It provides that the necessary substantiation for future claims that any POM Product is effective in the diagnosis, cure, mitigation, treatment, or prevention of any disease[19] – including heart disease, prostate cancer, or erectile dysfunction – is FDA approval, which may be provided in the form of a tentative final or final over-the-counter ("OTC") drug monograph, a new drug

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[18] In advertising cases, the term "fencing-in" typically describes order terms that cover products or claims not challenged in the complaint. The term also describes prophylactic order provisions in general, however. *See, e.g., FTC v. Nat'l Lead Co.*, 352 U.S. 419, 431 (1957).

[19] These claims parallel the definition of "drug" in Section 15 of the FTC Act, 15 U.S.C. § 55(c) ("articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man").

application, or labeling approval under regulations promulgated pursuant to the Nutrition Labeling and Education Act of 1990 ("NLEA").

For example, a claim that POM Juice reduces the risk of heart disease would need to be supported by an FDA regulation authorizing such a claim in labeling; such regulations may be adopted by the FDA when there is, "based on the totality of publicly available scientific evidence . . . significant scientific agreement[] among experts qualified by scientific training and experience to evaluate such claims" that the claim is supported. NLEA, 21 U.S.C. § 343(r)(3)(B)(i) (2010). *Accord*, FTC, *Enforcement Policy Statement on Food Advertising*, CX0002_0006 (citing the "significant scientific agreement" standard). Similarly, the evidence required for FDA approval of a new drug application consists of "substantial evidence," consisting of "adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have[.]" Federal Food, Drug, and Cosmetic Act, Section 505(d), 21 U.S.C. § 355(d) (2010). This standard is similar to the FTC's substantiation standard for health benefit claims. *See, e.g.*, *Daniel Chapter One Initial Decision*, 2009 FTC LEXIS 157, at *109-10 (competent and reliable scientific evidence, consisting of controlled clinical studies, are required to support disease claims); *Dietary Supplements: An Advertising Guide for Industry*, CX1014_0014 (requiring competent and reliable scientific evidence).

The FDA standards on the level of evidence required to support disease claims are similar to the FTC's, and thus the requirement contained in Part I is "reasonably related to the challenged practice." Deference to the FDA's standards and its evaluation of scientific evidence

is consistent with prior Commission practice. In *Thompson Medical*, the Commission determined, under a *Pfizer* analysis, that the proper level of substantiation for the company's advertising claims for the topical analgesic Aspercreme was two well-controlled clinical tests. It went on to note:

> [w]e are additionally persuaded to use this level of substantiation because . . .this is the standard currently being required. . .by the [FDA]. We believe that advertisers of drug products subject to the joint jurisdiction of the FTC and the FDA will benefit from greater regulatory certainty if they can act with reasonable assurance that the two agencies will accept the same evidence to demonstrate the safety and efficacy of a particular ingredient.

104 F.T.C. at 826. The Part I relief proposed here also is consistent with the relief approved in recent Commission settlements. *See The Dannon Co., Inc.*, 151 F.T.C. 62 (2011) (consent order); *Nestle HealthCare Nutrition, Inc*., 151 F.T.C. 1, 12-13 (2011) (consent order); *FTC v. Iovate Health Sciences U.S.A., Inc.*, No. 10-CV-587 (W.D.N.Y., July 29, 2010) (stipulated final judgment and order).

More importantly, the requirement of FDA pre-approval before Respondents make further diet-disease claims for POM Products will result in an order that is "clear and precise," as required under *Colgate-Palmolive*, and thus significantly increase its enforceability. Given the body of research presented by Respondents which, while facially impressive, does not support their advertising claims, the staff anticipates that a requirement merely stating that disease claims must be substantiated by "competent and reliable scientific evidence" would not be sufficiently clear as to Respondents' obligations for proper substantiation. Rather, one could expect that the

parties would be back in litigation in short order. This order instead sets forth a bright line standard – FDA authorization – for substantiating future disease-related claims.[20]

The requirement of FDA pre-approval as the substantiation standard for any disease claims is particularly warranted in this matter where the Respondents have shown a willingness to flout the law. Respondents have always known the "rules of the road" but chose to ignore them. For example, POM could have sought FDA approval for a qualified health benefit claim for pomegranate juice with a certain level of polyphenols. In a 2003 proposal to POM, a consultant noted that a qualified health claim "allow[s] food and dietary supplement manufacturers to communicate emerging scientific information about the health benefits of their products, as long as it is truthful and not misleading." (CX0017_0002; *see also* CCFF ¶ 683). Respondents chose not to go through this process because it would have provided no benefit to POM against its competitors. (CCFF ¶ 683). In another example, the Institutional Review Boards (IRBs) for at least five research institutions have questioned whether POM's prostate cancer studies were intended to support a significant change in advertising in the product, or whether POM intended to market its tested product for the treatment, cure, or prevention of disease, which would require an Investigational New Drug application (IND) on file with the FDA. (CCFF ¶ 686). Instead of complying with FDA rules, Respondents repeatedly argued against filing an IND and told the institutions they did not advertise their products a a treatment or preventative for prostate cancer. (CCFF ¶¶ 686-693). Respondents were finally forced to file an IND when Johns Hopkins threatened to shut down their studies. (CCFF ¶ 1034).

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[20] This is the law for claims made in labeling as set forth by Congress under both the FDCA and the NLEA and creates no additional burdens for Respondents. In fact, it simply harmonizes their obligations to both agencies.

Respondents' past conduct of failing to heed warnings from law enforcement agencies is especially troubling. In January 2008, the FTC sent POM a letter alerting the company to its concerns about the advertising claims for POMx. (CCFF ¶ 678). In response, POM stated that its scientific findings

and that there was

(CCFF ¶ 679, *in camera*). As the record makes clear, however, POM was aware of inconsistent study results at the time. (CCFF ¶ 679, *in camera*). Also, in February 2010, the FDA issued a warning letter to POM, finding POM made therapeutic claims on its website about POM Juice and that it was intended for use in the cure, mitigation, treatment, or prevention of diseases, such as prostate cancer, erectile dysfunction, and heart disease. (CCFF ¶ 681).

At trial, Mr. Tupper testified that POM did not make any specific changes to its marketing in response to receiving letters from the FTC and the FDA. (CCFF ¶ 684). Mr. Tupper noted during a deposition in a competitor action that FDA was "off [its] rocker." (CCFF ¶ 682). In fact, Mr. Resnick testified that Respondents are "hitting my standard . . . " and that he believes his standard is "an adequate standard . . . [o]r more than adequate," when asked if he had stated in prior testimony that he did not refer to any standards promulgated by the FTC or FDA in considering how much evidence is enough to make a claim. (CCFF ¶ 684). Thus, Respondents have made it clear that they do not intend to comply with the law voluntarily. Moreover, Mr. Resnick also testified that "[w]ell, 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." (CCFF ¶ 684). The Part I relief will assist in eliminating any confusion or ambiguities over the appropriate standard that Respondents must have to make disease claims.

The Notice Order's Part I relief establishing a bright-line substantiation standard is necessary in this matter to ensure Respondents' compliance. Given Respondents' past conduct, the complexity of the scientific issues, the unquestioned expertise of the FDA to evaluate scientific evidence relating to disease claims, and the Commission's interest in harmonizing with the FDA, a requirement for FDA approval of future disease prevention and treatment claims as the level of substantiation required for such claims is not only reasonably related to the violations alleged, but provides necessary clarity and precision, and therefore is an appropriate remedy.

Part III of the Notice Order addresses health benefit claims for Covered Products (defined as any food, drug, or dietary supplement, including the POM Products). It provides that representations, *other than representations covered by Part I*, about the health benefits, performance, or efficacy of any Covered Product must be non-misleading and supported by "competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted in the relevant scientific fields, when considered in light of the entire body of relevant and reliable evidence, to substantiate that the representation is true." For example, if Respondents disseminate advertising – characterizing the limited scientific evidence supporting the relationship between a POM product and reductions in disease risk in a carefully qualified manner – that creates a net impression other than that the product is effective for the treatment or prevention of disease, that claim would be covered by Part III.

The remaining Order provisions are standard. Part II of the Notice Order prohibits, in connection with the marketing of any Covered Product, misrepresentations about the existence,

content, validity, results, conclusions or interpretations of any test, study, or research. Part IV contains safe harbors, permitting respondents to make representations approved by FDA. Part V is a record-keeping requirement. Part VI sets forth Order distribution requirements. Part VI and VII require the corporate and individual respondents, respectively, to file notifications about changes in structure and employment. Part IX sets forth compliance reporting requirements. Finally, Part X is a sunsetting provision.

IV. CONCLUSION

The record evidence demonstrates that Respondents have violated Sections 5 and 12 of the FTC Act through their dissemination of false and unsubstantiated claims that: 1) clinical studies, research, or trials prove that POM Juice, POMx Pills, and POMx Liquid treat, prevent, or reduce the risk of heart disease, prostate cancer, and erectile dysfunction; and 2) that POM Juice, POMx Pills, and POMx Liquid treat, prevent, or reduce the risk of heart disease, prostate cancer, and erectile dysfunction. Accordingly, Complaint Counsel respectfully requests that this Court enter the proposed order attached to the Complaint in this case.

Respectfully Submitted,

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I certify that on January 11, 2012, I caused the filing and service of public and confidential versions of *Complaint Counsel's Post-Trial Brief and Proposed Findings of Fact and Conclusions of Law* 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
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Paper copies of the confidential and redacted public filings via hand delivery, and electronic copies via email to:

The Honorable D. Michael Chappell
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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

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RECORD REFERENCES

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CX – Complaint Counsel exhibit

PX – Respondents exhibit

Tr. – Trial testimony

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

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

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

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

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

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

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

CCFF ¶ – Complaint Counsel's Proposed Findings of Fact

CCCL ¶ – Complaint Counsel's Proposed Conclusions of Law

I. EXECUTIVE SUMMARY

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

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

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

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

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

b. Unsubstantiated efficacy claims related to heart disease. The complaint further alleges that Respondents represented without an adequate basis, expressly or by implication, through advertising and promotional materials, that drinking eight ounces of POM Juice daily, or taking one POMx Pill or one teaspoon of POMx Liquid daily, treats, prevents or reduces the risk of heart disease, including by (1) decreasing arterial plaque, (2) lowering blood pressure, and/or (3) improving blood flow to the heart. (CX1426_00019-20).

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

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

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

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

4. Evidentiary Hearings. Complaint Counsel presented its case-in-chief on May 24-27, June 6-9, June 13, and June 15, 2011. Respondents presented their case on August 30-September 2, and October 11-12, 2011. Complaint Counsel presented rebuttal testimony on September 14, October 14, and November 4, 2011. Twenty-four witnesses testified:

10 fact witnesses[2] (including one rebuttal fact witness) and 14 expert witnesses (including two rebuttal experts). The transcripts of hearings consist of more than1,400 pages and approximately 1,875 exhibits were admitted into evidence. The evidentiary record closed on November 18, 2011.

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

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

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

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

II. RESPONDENTS

A. Individual Respondents

1. Stewart and Lynda Resnick

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

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

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

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

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

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

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

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

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

17. Michael Perdigao ("Mr. Perdigao"), the president of Roll's advertising agency, Fire Station, and Roll's Corporate Communications department, reports to the Resnicks.

(CX1376 (S. Resnick, OS Dep. at 145); JX0001 ¶ 18; Perdigao, Tr. 590, 594).

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

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

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

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

22. From POM's inception, Mrs. Resnick has directed the creative development of the company and the vision of the POM Juice and POMx advertising campaigns. (CX0001_0006-07; 0013-14; *see also* CCFF ¶¶ 187, 197-209, 237-40, 280).

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

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

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

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

(S. Resnick, Welch Dep. at 55)).

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

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

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

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

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

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

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

34. Mrs. Resnick participated in POM's business on almost a daily basis in the company's early years, and on a weekly or biweekly basis thereafter and through 2010. (L. Resnick,

Tr. 93, 157-58; *see also* CX1375 (L. Resnick, Trop. Dep. at 19-22, 78); CX1359 (L. Resnick, Dep. at 108)).

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

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

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

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

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

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

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

particular study in POM advertising likely are joint decisions made by Mr. Resnick, Mr. Tupper, and other advisors at POM)).

42. Mrs. Resnick developed, implemented, and relied on consumer and marketing research. (CX1359 (L. Resnick, Dep. at 76-78); CCFF ¶ 596).

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

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

2. Matthew Tupper

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

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

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

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

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

50. POM's former Senior Vice President of Marketing testified that she "would never do

something [Mr. Tupper] wasn't involved in. He was [her] boss." (CX1357 (Kuyoomjian, Dep. at 51)).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

67. Mr. Tupper has reviewed work on each of POM's large advertising campaigns at the

concept stage before they were shown to Lynda Resnick. (Leow, Tr. 459-60).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

B. Corporate Respondents

1. POM Wonderful LLC

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

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

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

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

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

2. Roll Global LLC

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- Dr. Liker signing a protocol agreement for pomegranate research as a Medical Consultant for Roll (CX0739_0003);
- Mr. Resnick signing an agreement on behalf of Roll for Dr. Liker to work as POM's Medical Director (CX0548_0001; CX0706_0001);
- Karen Edwards, a Roll employee, providing the study beverages and assisting the researchers in writing the journal article for a POM-sponsored erectile dysfunction study

(CX1337 (Forest, Dep. at 60-61, 181-87)); and

- Roll's Chief Financial Officer signing an agreement on behalf of POM and Roll with the Prostate Cancer Foundation. (CX0710_0004).

107. Roll has sponsored and/or funded studies on POM products. (CX0588_0001 (showing Roll as the sponsor on a letter of intent for a POM study); CX1065_0001 (listing Roll as funding a cardiovascular study on pomegranate juice); CX0665_0005 (showing Roll as the point of contact for the Resnick Trust, the listed sponsor in the clinical study agreement for an erectile dysfunction study); CX0785_0009, 0013, *in camera*

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

3. Roll and POM Operate as a Common Enterprise

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

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

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

111. The Resnicks have had ultimate say over all business functions of Roll and POM. They have set policy and supervised the senior executives of both companies, disregarding corporate formalities. For example, Mrs. Resnick has had complete oversight over POM's business, despite lacking any formal position with the company. (CX1368 (L. Resnick, Welch Dep. at 8-9); CX1362 (L. Resnick, TCCC Dep. at 45-46); CX1374 (Tupper, OS Dep. at 18-19); *see also* CX0001_0037 (characterizing Mrs. Resnick's involvement at POM as a partnership with Mr. Tupper since 2003); S. Resnick, Tr. 1631

(stating that Mrs. Resnick is very involved in setting POM's marketing and advertising budget); L. Resnick, Tr. 184 (stating that she has interviewed candidates for the chief marketing officer or other senior vice president positions at POM); JX0001 ¶ 18; CX276_0003; Posell, Tr. 321, 325 (stating that while Vice President of Corporate Communications, Ms. Posell reported to Mr. Tupper and Mrs. Resnick)).

112.

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

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

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

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

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

117. Roll also interacts with POM for the purposes of joint cash management, as noted by

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

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

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

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

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

III. THE POM PRODUCTS

A. Description of the POM Products

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

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

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

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

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

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

128. According to Respondents, (CX1379_0008, *in camera*).

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

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

131. Mrs. Resnick stated "[m]y marketing team and I were eager to learn if we could produce a pomegranate extract that could deliver the power of eight ounces of POM juice in a

capsule. . . . [P]roduction of a pomegranate extract would necessitate a whole new round of science to determine whether it was safe and effective." (CX0001_00013).

132.

(CX0967_0014, *in camera*).

133.

(CX1379_0008-09, *in camera*).

134.

(CX0967_0014, *in camera*).

135.

(CX1379_0008, *in camera*).

B. Respondents' Sales in Commerce

136. (CX0967_0014, *in camera*).

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

138. According to Mrs. Resnick, the "lion's share of the business is a hundred percent pomegranate juice." (L. Resnick, Tr. 278-79).

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

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

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

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

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

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

145.

(CX1379_0009-10, *in camera*).

146. [redacted] (CX1379_0010-11, *in camera*).

IV. HISTORY OF POM AND FORAY INTO SCIENTIFIC RESEARCH

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

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

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

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

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

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

153.

(CX0967_0009, *in camera*).

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

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

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

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

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

159. In notes about a March 2001 meeting with Mrs. Resnick, Dr. Dornfeld described POM's

"scope of research" as having "two directions. (A) for use in marketing (primarily circulation) and (B) 'home run' cure for cancer, etc." (CX0003_0001).

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

161. In 2001, Respondents hired Dr. Liker, a physician at UCLA, to assist Dr. Dornfeld. (Liker, Tr. 1873, 1877; CX1350 (Liker, Dep. at 27-28)). Dr. Liker also became the Resnicks' personal physician and company wellness coordinator and wellness director in 2001. (Liker, Tr. 1876-77). Dr. Liker became POM's medical director in 2002. (Liker, Tr. 1877). He has been paid approximately for his work. (CX1379_0037, *in camera*).

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

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

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

165. Dr. Dreher reported to Mr. Tupper. He would also report to a certain extent to Dr. Liker, to help him manage the logistics associated with some of the larger studies. (Dreher, Tr.

529). Dr. Dreher and Dr. Liker met weekly for the first two-and-a-half to three years at POM, and then less frequently in the last year of his employment. (Dreher, Tr. 530).

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

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

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

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

170. The second Aviram study, published in 2004, was *Pomegranate Juice Consumption for 3 Years by Patients with Carotid Artery Stenosis Reduces Common Carotid Intima-Media Thickness, Blood Pressure and LDL Oxidation* ("**Aviram CIMT/BP Study (2004)**"). (CX0611). The Aviram CIMT/BP Study (2004), conducted on 19 patients, examined the effect of POM Juice consumption on carotid intima-media thickness ("CIMT"), which is an indirect measure of arterial plaque, and blood pressure. (CX0611).

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

172. Dr. Pantuck's study, published in 2006, was *Phase II Study of Pomegranate Juice for*

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

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

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

V. RESPONDENTS' MARKETING AND ADVERTISING OF THE POM PRODUCTS

A. Overview of Marketing Techniques

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

176. Mrs. Resnick believes she created a market for pomegranate juice through "public relations, advertising events, product placement, et cetera, all the arms of marketing." POM itself stated that the millions of dollars it has spent promoting pomegranate juice for health in fact created the market for the juice: "Through its investment of millions of dollars to research and promote the nutritional qualities and health benefits associated with pomegranate juice, [POM] largely created the burgeoning market for genuine

pomegranate juice that exists today." (CX1362 (L. Resnick, TCCC Dep. at 120); CX1395_0004; CX1396_0004; CX1397_0004; CX1398_0004;CX1399_0004).

177. Information about the POM Products has been disseminated to the public through a variety of media, including print advertisements in magazines, freestanding inserts ("FSIs") in newspapers, out of home media such as billboards and bus shelters, posters in health clubs and doctors' offices, advertising on prescription drug bags, Internet websites, online banner advertisements, medical outreach, radio, television, press releases and press interviews. (L. Resnick, Tr. 81-82 (radio), 186 (FSIs); Leow, Tr. 426-428, 457 (out of home, health clubs, banner ads, television); Perdigao, Tr. 597-98 (press releases), 608 (prescription drug bags); Tupper, Tr. 927 (magazine wraps); CX1375 (L. Resnick, Trop. Dep. at 167) (medical outreach); CX1357 (Kuyoomjian, Dep. at 85-86 (posters in doctors' offices), 122 (radio); PX0364-0002, Answer ¶¶ 9-10 (press interviews); *see also* CX1426_0002, Compl. ¶¶ 9-10; PX0364-0002, Answer ¶¶ 9-10 (admitting advertising and promotional materials attached to Complaint were disseminated)).

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

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

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

B. Process of Creating and Disseminating POM Product Advertising

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

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

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

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

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

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

1. "LRR Meetings"

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

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

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

190. The purpose of the LRR Meetings, and notes and recaps following the meetings, was to

aid staff in following through on the next steps of the creative projects. (L. Resnick, Tr. 106).

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

2. Creative Briefs and Advertising Concepts

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

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

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

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

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

- Fresh juice (CX0409_0123-33, 0142-43, 0172; PX0520);
- POMx Pills (CX0409_0015-21, 0023-25, 0027-34, 0044-50, 0055-66, 0073-74, 0088-89, 0091-92, 0095-102, 0147; CX0129-0131);

- POMx Liquid (CX0409_0038-43, 0051-54, 0067-72, 0075-76; PX0516);
- Internet sites and emails (CX0409_0085-87, 0110-113, 0117-120, 0122, 0134-41, 0148-51; PX0517; PX0519; PX0521);
- Package inserts and newsletters (CX0409_0079-84, 0121);
- Postcards and direct mail (CX0409_090, 0105-09);
- Physical promotions like shelf banners, hang tags (CX0409_0001-09, 0022, 0026, 0144-46, 0156, 0164-67);
- Concepts like "Women's Lifestyle Print/Outdoor," and "Bikini" (CX0409_0010-11, 0014);
- Commuter train posters (CX0409_0103-04);
- Retail packaging (CX0409_0093-94, 0115-16);
- POM Tea (CX0409_0035-37, 0173-76);
- New York marketing campaign (CX0409_0153-55);
- Television (CX0409_0157-58; PX0522);
- Trade or trade show materials (CX0409_0012-13, 0159-60, 0168-70; PX0523); and
- Recipe cards or booklets (CX0409_0152, 0161-63, 0171).

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

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

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

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

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

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

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

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

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

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

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

(CX0247_0002; CX0248_0002); and suggested and reviewed concepts for new advertisements (CX0266_0002-03; CX0320_0002).

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

- "Wanna give prostate cancer the finger?"
- "Want to avoid the cardiologist? Gulp."
- "I'm off to save prostates"
- "Up, up and away with erectile dysfunction"
- "Uh Oh! That heart is under attack"
- "Holy Health! $25 million in medical research"
- "Risk your health in this economy? Never."

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

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

3. Body Copy and Advertising Executions

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

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

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

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

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

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

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

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

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

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

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

221. After proofreading by Fire Station personnel, POM's advertisement would be sent to Fire Station's production department to create the "mechanical" – the completed

advertisement in final electronic form that's ready to be sent to publications. (Leow, Tr. 466-67).

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

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

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

4. Dissemination of Print Advertising

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

226. POM also disseminated a "magazine wrap" or "cover wrap" advertisement, which was placed around issues of *Time* magazine distributed in urologists' offices. (CX0314; Leow, Tr. 426; Tupper, Tr. 927; L. Resnick, Tr. 122). A "cover wrap" is a type of advertisement that covers the actual magazine cover, essentially replacing it. (CX1357 (Kuyoomjian, Dep. at 86)).

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

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

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

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

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

5. Strategy for Internet Advertising

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

253. POM has purchased online banner advertisements on websites, including specific websites with audiences interested in personal health, fitness, and physical well-being such as *Men's Health*, *ESPN*, *Livestrong*, and *WebMD*. (Rushton, Tr. 1397-98; CX0463; CX0466; CX0468; Leow, Tr. 428-29).

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

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

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

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

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

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

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

6. Strategy for Public Relations Communications

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

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

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

264. For POM, Ms. Posell was responsible for the strategic and tactical execution of all activities pertaining to corporate relations, public relations, crisis management, reputation

management, customer service, and celebrity outreach. At POM, Ms. Posell reported to Mrs. Resnick and Mr. Tupper. (Posell, Tr. 325; CX1436_0002).

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

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

267. Respondents' public relations staff would also pitch to the media information about company-sponsored scientific studies of pomegranate. (CX1375 (L. Resnick, Trop. Dep. at 145-46); *see also* CX1375 (L. Resnick, Trop. Dep. at 161) (acknowledging reference to "needing a PR push promoting the results" of two studies)).

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

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

270. Corporate Communications worked with Roll and POM personnel (*e.g.,* Mrs. Resnick, Mr. Tupper, POM Marketing, POM scientific affairs, Fire Station, and Roll Consulting) on the press releases, interactions with media regarding the health benefits of POM products, and website content, among other things. (CX0012; CX0013; CX0024; CX0028; CX0038; CX0041; CX0043; CX0044; CX0127; CX0238_0001).

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

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

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

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

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

- "[Pomegranate juice is] [b]eneficial for heart disease, prostate cancer and erectile dysfunction. -- these benefits are based on clinical (ie, human) research, not just test tube theories." (CX0182_0001).

- "Compared to other 'superfruits,' the pomegranate is the only one that has medically proven health benefits in the human body. -- This is a key point. Everybody else can brag about how great their product 'scores' in a test tube (and we of course can brag louder than anyone else!), but it really comes down to what happens in the human body." (CX0182_0001).

- "And, not all pomegranate juices are created equal. Of the other pomegranate juices, POM is the only one guaranteed to be 100% authentic, and the only one with proven health benefits." (CX0182_0001).

- "POM is the only pomegranate juice – and any other commercially available beverage, for that matter – backed by $23 million in medical research. Actually, POM is the only pomegranate juice backed by any medical research at all." (CX0182_0002).

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

> Positive effects on heart health that have been seen in humans include protection against LDL oxidation, a key factor in the build-up of plaque in the arteries. Pomegranate juice also blocked the ACE enzyme. Blocking ACE has been shown to lead to fewer heart attacks in patients with heart disease. In addition, drinking [POM Juice] lowered systolic blood pressure in people with high blood pressure. High blood pressure is a known risk factor for atherosclerosis.
>
> Additionally, studies in mice have revealed exciting results. In mice, P♥M Wonderful pomegranate juice was shown to prevent the formation of plaque in the arteries. In a subsequent study it was shown that pomegranate juice could actually halt the build-up of plaque even in advanced disease after two months of pomegranate juice consumption.

(CX0605_0002).

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

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

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

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

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

279. In 2006, the advertising equivalency for the articles that mentioned pomegranate juice

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

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

C. Respondents' Intent to Advertise Health Claims

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

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

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

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

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

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

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

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

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

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

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

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

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

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

294. Meeting notes from June 2006 described some of the "Unique Properties of POM" as "Anti-aging," and "Heart disease – aging of heart muscles, joints, etc [*sic*] heart plaque." One of POM's objectives at the time was to "ensure that all POM products stand for

building your immune system and keeping you healthy." Moreover, under a heading, "Who Are We??" the minutes stated, "Convince people of preventative medicine & effects," "Atnioxidants [*sic*] → Healthy buzz word (people accepted and believed)," and "PILLS – POMx – health – not about taste." (CX0058_0001, 0003, 0004).

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

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

297. Mrs. Resnick elaborated that "if you make someone laugh or cry . . . if you can elicit an emotion from someone, their guard goes down a little and they listen to you . . . . [I]f you can be charming and funny or sad then your message will come through." (CX1359 (L. Resnick, Dep. at 242-43)).

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

2. POM Targeted Health-Conscious Consumers Concerned About Illness

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

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

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

302. Numerous creative briefs dating from January 2004 to at least July 2006 described the POM target audience as "likely to be affluent, professional, college grads who are very health-conscious (hypochondriacs) and live in urban areas." (CX409_0001; *see also* CX0409_0003, 0005-6, 0008, 0010, and 0022). Similarly, in 2008, POM and Roll noted that the primary target consumer for a juice campaign "should be the 30-something health conscious (hypochondriac?) who is educated and affluent." (CX0211_0002).

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

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

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

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

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

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

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

309. Mrs. Resnick testified that POM wanted consumers to know about the investment that it has made in science and emphasized the scientific research in its marketing. (L. Resnick, Tr. 78-79, 277). Thus, POM's advertisements in various media claimed that its products were "supported" or "backed" by tens of millions of dollars in medical and scientific research at the world's leading universities. The specific amounts ranged from $20 million to $34 million, depending on the time frame of the advertisement. (*See, e.g.*, CCFF ¶¶ 357, 363, 364, 372, 379, 380, 385, 397, 409, 415, 421, 425, 426, 444, 473, 508).

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

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

312. Dr. Butters, Respondents' linguist, wrote in a previous article that the words "medical," "research," and "study" have highly positive connotations for consumers. He also wrote that as a modifier, "medical" seems to be strongly associated with treatment. (Butters, Tr. 2879-81).

313. One of the reasons POM moved away from the "Dressed Bottle" campaign was that it feared the campaign was selling the overall benefits of pomegranate juice regardless of brand, when only POM had conducted a significant amount of medical research to

confirm the health benefits of its product. (CX0286_0002).

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

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

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

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

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

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

320. Mr. Resnick knows that some studies POM conducted or is conducting will never be published, despite including the costs of those studies in the millions of dollars of

medical research funding "supporting" or "backing" POM's claims in its advertising. (S. Resnick, Tr. 1781). He feels that whether studies are published, not published, good results, bad results, or incomplete, all are still appropriately included in the "backed by $32 million" claims in POM's advertisements. (S. Resnick, Tr. 1711-12, 1764, 1776-77).

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

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

- Ongoing studies, which have not been completed and have no results (Tupper, Tr. 1017-18, 3028; CX1353 (Tupper, Dep. at 172, 192);
- Studies that did not show a statistically significant effect, showed "no effect," or were inconclusive (Tupper, Tr. 1018-19; S. Resnick, Tr. 1762-64; CX1376 (S. Resnick, OS Dep. at 316));
- Studies where no publication resulted (Tupper, Tr. 936);
- Studies on areas such as "Joint/Bone Health," "Urinary Tract Infection," "Cattle Health," "Weight loss," "Neuro/Brain," "Alsheimers" [*sic*], "Authenticity," "Cold/Flu," "Dairy/Cattle Health," "Fertility," "Organic Candy Test Run," "Osteoporosis, Lymphoma, Bone Density," and "Skincare," which were not related to the products or health conditions described in POM's advertisements (CX1276_0003-05);
- Meeting expenses, including "Brochure Printing," "Conference Fee," "Medical Exhibition Fees and Rental Space," "Member Contribution," "Membership fee," "Photo Shoot & Tapes," "Research Summit Expenses," and "Trade Shows." (Tupper, Tr. 1026; CX1276_0004-05); and
- Membership fees and member contributions to organizations such as the American Herbal Products Association and American Society for Nutrition. (Tupper, Tr. 1026-27).

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

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

D. Health Claims in Print Advertising

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

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

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

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

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

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

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

329. In 2004 and 2005, POM disseminated a POM Juice advertisement with the headline,

"**STUDIES SHOW THAT 10 OUT OF 10 PEOPLE DON'T WANT TO DIE.**" It appeared in *Prevention* magazine in November 2004 and January 2005, and *Martha Stewart Living* magazine in May 2005. (CX0029_0003).

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

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

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

(CX0029_0002).

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

333. Mrs. Resnick was involved in the approval of this specific advertisement. (CX0471_0007-08; L. Resnick, Tr. 158).

334. John Regal, POM's head of marketing at the time, stated that POM's intent in its *Prevention* advertorial was to convey "how POM is particularly good for clean & healthy arteries. We also wanted to highlight the new Aviram study regarding plaque reduction in humans." (CX0667_0001).

335. The specific reference to 30% reduction in plaque as well as the citation to a published study, the statistics regarding the role of arterial plaque in heart attacks and heart disease, and the recommendation to "drink 8 ounces" of POM Juice a day for heart health, along with the images in the advertisement, convey the net impression that drinking eight ounces of POM Juice daily treats, prevents, or reduces the risk of heart disease, including by reducing arterial plaque, and that this benefit is clinically proven. (CCFF ¶¶ 329-32, 334).

c. "Floss your arteries. Daily." Print Ad (CX0031)

336. In December 2004, POM disseminated in *Details* magazine and *Fitness* magazine a POM Juice advertisement with the bold headline "**Floss your arteries. Daily**." The advertisement contained an image of a POM bottle with logo on a medicine cabinet shelf along with items such as a toothbrush, toothpaste, and soap. The advertisement's body copy stated:

> Clogged arteries lead to heart trouble. It's that simple. That's where we come in. Delicious P♥M Wonderful P♥megranate Juice has more naturally occurring antioxidants than any other drink. These antioxidants fight free radicals – molecules that are the cause of sticky, artery clogging plaque. Just eight ounces a day can reduce plaque by up to 30%!* So every day: wash your face, brush your teeth, and drink your P♥M Wonderful. **P♥M Wonderful P♥megranate Juice. The Antioxidant Superpower.**

In very small type after the asterisk, the advertisement cited to one of the studies conducted by Dr. Aviram: "Aviram, M. *Clinical Nutrition,* 2004. Based on a clinical pilot study." (CX0031 (referring to the Aviram CIMT/BP Study (2004))).

337. Monique McLaws, former brand manager for POM Juice, testified that the message POM intended to convey with this advertisement and headline was "cleaning out your arteries." (CX1351 (McLaws, Dep. at 123-24)).

338. A 2005 creative brief about print and outdoor advertising aimed at women's lifestyles also indicates that POM Marketing believed the phrase "Floss Your Arteries Daily" communicated the benefit that "*If you drink POM Wonderful DAILY, you will have clean and healthy arteries[.]*" (CX0409_0010).

339. Mrs. Resnick approved this specific advertisement. (CX0471_0010; L. Resnick, Tr. 158-

59).

340. The imagery and text of this advertisement, for example, placing the POM Juice bottle in a medicine cabinet, referring to "floss[ing]" one's arteries, and referring to a specific percentage reduction in plaque with a study citation, convey the net impression that drinking eight ounces of POM Juice daily treats, prevents, or reduces the risk of heart disease, including by reducing arterial plaque, and that this benefit is clinically proven. (CCFF ¶¶ 336-38).

d. "Life Support" Print Ad (CX0033)

341. As early as 2004, POM disseminated a POM Juice advertisement with the headline "**Life Support.**" The advertisement ran in *Rolling Stone* magazine in December 2004 and in *Details* magazine in February 2005. (CX0033_0002). The page was dominated by an image of a bottle of POM Juice with logo, hanging upside down on a pole, with the juice running through a tube at the bottom of the bottle, in the manner of a hospital intravenous line. The advertisement's body copy stated:

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

The advertisement also directed consumers to POM's website, pomwonderful.com, directly under the POM logo. (CX0033).

342. Respondents' expert, Dr. Butters, testified that in the proper context, a visual of an intravenous drip bottle could be a symbol for drugs and medicine. (Butters, Tr. 2947).

343. The copy and images in this advertisement, particularly the image of the POM bottle "dressed" as an intravenous line, which is frequently used in medical treatment, along with the references to specific diseases juxtaposed with the recommendation to drink eight ounces a day for "life support," convey the net impression that drinking eight ounces of POM Juice daily prevents or reduces the risk of heart disease, among other diseases. (CCFF ¶¶ 341-42).

e. "Amaze your cardiologist" Print Ad (CX0034)

344. In February 2005, POM disseminated in *Prevention* magazine a POM Juice advertisement with the headline "**Amaze your cardiologist**." The advertisement featured an image of a bottle of POM Juice with electrocardiogram (EKG) leads attached to it. The advertisement's body copy stated:

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

(CX0034).

345. In very small type after the asterisk, the advertisement cited to one of the studies conducted by Michael Aviram: "Aviram, M., *Clinical Nutrition,* 2004. Based on a clinical pilot study." The advertisement also directed consumers to POM's website, pomwonderful.com, directly under the POM logo. (CX0034).

346. Dr. Butters testified that the phrase "amaze your cardiologist" makes explicit the theme of the importance of heart health. (Butters, Tr. 2911).

347. Mr. Resnick testified that he is comfortable with the "Amaze your cardiologist" claim given the company's "very positive results around heart health," citing, for example, the clinical study by Dr. Ornish on blood flow to the heart, and the study of "patients that had serious carotid artery problems [showing] it did reduce the plaque by up to 40 percent." (CX1376 (S. Resnick, OS Dep. at 159-60)).

348. The copy and images in this advertisement draw a clear association with cardiovascular disease diagnosis and treatment, particularly the bottle "dressed" as an EKG patient, references to a cardiologist and "ac[ing] your EKG," and specific citations to a study purportedly showing 30% reduction of arterial plaque. This advertisement conveys the net impression that drinking eight ounces of POM Juice daily treats, prevents, or reduces the risk of heart disease, including by reducing arterial plaque, and that this benefit is clinically proven. (CCFF ¶¶ 344-47).

f. "Cheat Death" Print Ad (CX0036)

349. In 2005 and 2006, POM disseminated a POM Juice advertisement with the headline, "**Cheat Death**." The advertisement ran in *Rolling Stone* magazine in March, June, and July 2005; in *Prevention* magazine in May 2005; and in *Fitness* magazine in January 2006. (CX0036_0002). The advertisement featured an image of the POM Juice bottle with logo with a rope noose around the neck of the bottle. The advertisement's body copy stated:

> Dying is so dead. Drink to life with P♥M Wonderful P♥megranate Juice, the world's most powerful antioxidant. It has more antioxidants than any other drink and can help prevent premature aging, heart disease, stroke, Alzheimer's, even cancer. Eight ounces a day is all you need. The sooner you drink it, the longer you will enjoy it. **P♥M Wonderful P♥megranate Juice. The Antioxidant Superpower.**

The advertisement also directed consumers to POM's website, pomwonderful.com, directly under the POM logo. (CX0036; *see also* CX0188 (similar advertisement disseminated in June 2008)).

350. Ms. McLaws testified that the "Cheat Death" advertisement's message was that one could avoid or prevent the diseases mentioned (heart disease, stroke, Alzheimer's) and therefore live longer. (CX1351 (McLaws, Dep. at 134-35).

351. In her book, Mrs. Resnick says the "Cheat Death" advertisement's imagery was intended to symbolically endow the juice with heroic powers: "When you see that brave little bottle with a noose around its neck – a noose broken by the antioxidant power of POM – you identify with it just as you identify with a hero's triumph or last-minute escape from danger on the movie screen." (CX0001_0019-0020).

352. Ms. Leow testified that the intent of the "Dressed Bottle" campaign, which included the "Cheat Death" and other similar juice advertisements (described in CCFF ¶¶ 336, 341, 344, and 357), was to "personify" the product. (Leow, Tr. 475, 487).

353. POM considered the "Cheat Death" advertisements to be a "hard-hitting execution," and after a period of little or no advertising, the company, with Mrs. Resnick's approval, decided to revive these and similar prior advertisements in 2008 in order to create some attention among consumers. (Perdigao, Tr. 627; CX0185_0003; CX1368 (L. Resnick,

Welch Dep. at 100-01)).

354. POM kept a log of consumer complaints. (CX1357 (Kuyoomjian, Dep. at 203)). In response to November 2009 and March 2010 consumer complaints about a billboard version of the "Cheat Death" advertisement, which contained the same headline and image, POM's consumer affairs representative told those consumers:

> The intention of "Cheat Death" is the recognition that disease of the heart and circularity [*sic*] system (cardiovascular disease or CVD) are some of the main causes of death in the US. There are preventative actions that can be taken to decrease this risk and finding healthy options that could potentially increase one's heart health, such as drinking POM, increases one's chances to live longer and healthier, to "cheat death."

(CX0454_0006-07; CX0456_0005).

355. In response to additional complaints about the "Cheat Death" billboard advertisement, POM's consumer affairs representative also repeatedly told consumers (***e.g.***, in November 2008, January 2009, and again in April 2010) that POM's advertising was created with the intent of using imagery that irreverently and boldly conveys to consumers that drinking POM Juice "may help prevent disease" or is "incredibly healthy." (CX0456_0002-03; CX0454_0009-10).

356. The copy and images in these "Cheat Death" advertisements, particularly the references to prevention of heart disease, stroke, and cancer, convey the net impression that drinking eight ounces of POM Juice daily prevents or reduces the risk of heart disease. (CCFF ¶¶ 349-52, 354-55).

g. "Decompress" Print Ad (CX0103)

357. In 2007, POM disseminated a juice advertisement with the headline "**Decompress**," which depicted the POM Juice bottle with logo wrapped in a blood pressure cuff. One version of the advertisement, disseminated in 2007 in *Health* magazine, *Prevention* magazine, and *New York* magazine, stated in the body copy:

> Amaze your cardiologist. Drink P♥M Wonderful Pomegranate Juice. It helps guard your body against free radicals, unstable molecules that emerging science suggests aggressively destroy and weaken healthy cells in your body and contribute to disease. P♥M

> Wonderful Pomegranate Juice is supported by $20 million of initial scientific research from leading universities, which has uncovered encouraging results in prostate and cardiovascular health. Keep your ticker ticking and drink 8 ounces a day. **P♥M Wonderful Pomegranate Juice. The Antioxidant Superpower.**

The advertisement also directed consumers to POM's website, pomwonderful.com, directly under the POM logo. (CX0103).

358. POM repeatedly disseminated advertisements with the headline "Decompress" and the blood pressure cuff imagery, including in 2007, 2008, and 2009. (Tupper, Tr. 976).

359. Ms. Leow testified that the purpose of dressing the POM Juice bottle in a blood pressure cuff for the "Decompress" advertisement was to show or suggest that POM may be healthy for the heart and the arteries. (Leow, Tr. 489).

360. Mr. Tupper, in testifying about a POM advertisement depicting a blood pressure cuff at the trial in *POM Wonderful, LLC vs. Tropicana Products, Inc.*, stated that the advertisement is "*talking about . . . the fairly vast body of published medical research. Many of those studies are, in fact, on various elements of the cardiovascular system, including blood pressure, but many others as well.*" He further acknowledged there was a strong association between the image of the blood pressure cuff and receiving medical care: "[I]t's very obviously a blood pressure cuff, and that's typically the first thing that your doctor will do when you go in for a physical is check your blood pressure as a means of getting an overall picture on your health." (CX1406 (Tupper, Trop. Tr. at 0179) (emphasis added)).

361. The copy and images in the "Decompress" advertisement, including the easily-recognizable blood pressure cuff and reference to cardiologists, as well as the statement that POM Juice would "[k]eep your ticker ticking," convey the net impression that drinking 8 ounces of POM Juice daily treats, prevents, or reduces the risk of heart disease, including by lowering blood pressure. In addition, by expressly stating that "[POM Juice] is supported by $20 million of initial scientific research," the advertisement further conveys the net impression that these benefits regarding heart disease are clinically proven. (CCFF ¶¶ 357, 359-60).

362. Consumer research confirms that the headline and imagery alone of this advertisement created a net impression to consumers that POM Juice treats, prevents, or reduces the risk

of heart disease, including by reducing blood pressure. (CCFF ¶¶ 585-591).

h. "Heart therapy" and "What gets your heart pumping?" Print Ads (CX0109) and (CX0192)

363. In April 2007, POM disseminated in *InStyle* and *Town and Country* magazines an advertisement with the headline "Heart therapy." The advertisement depicted a bottle of POM Juice with logo reclining on a couch, as in a therapist's office. The body copy of the advertisement stated:

> Seek professional help for your heart. Drink P♥M Wonderful Pomegranate Juice. It helps guard your body against free radicals, unstable molecules that emerging science suggests aggressively destroy and weaken healthy cells in your body and contribute to disease. P♥M Wonderful Pomegranate Juice is supported by $20 million of initial scientific research from leading universities, which has uncovered encouraging results in prostate and cardiovascular health. Keep your heart healthy and drink 8 ounces a day. **P♥M Wonderful Pomegranate Juice. The Antioxidant Superpower.**

The advertisement also directed consumers to POM's website, pomwonderful.com, directly under the POM logo. (CX0109).

364. In May 2008, POM disseminated an advertisement headlined "What gets your heart pumping?" and featuring an image of a POM bottle sideways, in a bikini top on a clothesline. The body copy read, "Supermodels or beaches? 36-24-36? Or perhaps healthy arteries . . . . P♥M Wonderful 100% Pomegranate Juice is supported by $23 million of initial scientific research from leading universities, which has uncovered encouraging results in prostate and cardiovascular health. Eight ounces a day is enough to keep your heart pumping, even if you're not dating a supermodel." (CX0192 (disseminated in *Men's Health* magazine)).

365. When shown the bikini top advertisement in a prior litigation, Mr. Tupper testified that "[t]here's been quite a lot of published medical science around the cardiovascular benefits associated with pomegranate juice, so heart pumping obviously refers to that research." (CX1364 (Tupper, TCCC Dep. at 293-94)).

366. The "Heart Therapy" and "Heart Pumping" advertisements have almost identical body copy to the "Decompress" advertisement. As Mr. Tupper described with respect to the

"Decompress" advertisement, POM considers the "scientific research" referred to in these advertisements to be the "fairly vast body of published medical research . . . on various elements of the cardiovascular system[.]" (CX1406 (Tupper, Trop. Tr. at 0179)).

367. The copy and images in the advertisements, including the bold headlines "Heart therapy," and "What gets your heart pumping" and text advising consumers to "[k]eep your heart healthy and drink 8 ounces a day," or "[e]ight ounces a day is enough to keep your heart pumping," convey the net impression that drinking eight ounces of [POM Juice] daily prevents or reduces the risk of heart disease. In addition, by expressly stating that POM Juice is supported by $20 [or $23] million of scientific research, the advertisements further convey the net impression that this benefit regarding heart disease is clinically proven. (CCFF ¶¶ 363-66).

2. POM Juice Print Ads Made Establishment Claims Regarding Prostate Cancer

a. "Drink to Prostate Health" Print Ad (CX0260)

368. An advertisement for POM Juice, disseminated in December 2008 in *Men's Health* and *Prevention* magazines with the headline, "**Drink to prostate health,**" featured a stark image of a POM Juice bottle with logo against a bright red background (the same color as the juice). (CX0260_0002). The advertisement's body copy stated:

> Sometimes, good medicine can taste great. Case in point: P♥m Wonderful. A recently published preliminary medical study followed 46 men previously treated for prostate cancer, either with surgery or radiation. After drinking 8 ounces of P♥M Wonderful 100% Pomegranate Juice daily for at least two years, these men experienced significantly longer PSA doubling times. Want to learn more about this study? Visit pomwonderful.com/prostate. **Trust in P♥M.**

(CX0260; *see also* CX1426_00028).

369. In testifying about this advertisement in the *POM vs. Tropicana* lawsuit, Mr. Tupper noted that although POM tries "to have a pleasant, humorous, cute, funny voice, [in this advertisement] we're talking about some very serious published research on pomegranate juice and, in this particular case, it was a study looking at men with advanced prostate cancer. So, it's clearly a very serious topic." (CX1406 (Tupper, Trop. Tr. at 0178)).

370. Dr. Butters testified that the inference from this advertisement is that POM Juice may be beneficial for people who have had prostate cancer. (Butters, Tr. 2943-44).

371. This advertisement, with a description of a study on prostate cancer patients and a bold headline advising consumers to "drink to prostate health," conveys the net impression that drinking eight ounces of POM Juice daily treats prostate cancer, including by slowing PSA doubling-time. Moreover, the advertisement's reference to a specific medical study conveys the net impression that POM's benefits for prostate cancer have been proven by clinical testing. (CCFF ¶¶ 368-70).

b. "I'm Off to Save Prostates" Print Ad (CX0274)

372. POM disseminated, in February 2009 in *Men's Fitness* magazine, a POM Juice advertisement with the headline, "**I'm off to save PROSTATES!**". The advertisement also appeared in March 2009 in *Advocate* magazine and *Men's Journal*. (CX0274_0002). It depicted a POM Juice bottle shooting off into the sky like a super hero. The advertisement's body copy stated:

> Man by man, gland by gland, The Antioxidant Superpower is 100% committed to defending healthy prostates. Powered by pure pomegranate juice . . . backed by $25 million in vigilant medical research* . . . there's no telling just how far it will go to improve prostate health in the future. *Prostate study details at http://www.pomwonderful.com/health_benefits.html.

(CX0274; *see also* CX1426_00029).

373. Mrs. Resnick testified that this advertisement intended to convey the message that POM was good for prostates and was backed by research to improve prostate health. She also testified that the prostate health benefits in the advertisement referred to the Pantuck Phase II Prostate Cancer Study (2006) and the basic science that had been done. (L. Resnick, Tr. 218); *see* CCFF ¶ 172).

374. Mrs. Resnick has testified that "prostate health" means "keeping you safe from prostate cancer." (CX1362 (L. Resnick, TCCC Dep. at 10)).

375. Dr. Butters testified that "defend" could mean "resist an attack made on (someone or something) and protect from harm or danger" and that it is possible this advertisement

communicates to viewers that POM Juice is protecting or defending prostates from disease. (Butters, Tr. 2899-2901).

376. This advertisement, with its references to "sav[ing]" and "defending" prostates, as well as "improve[ing] prostate health," conveys the net impression that drinking eight ounces of POM Juice daily prevents or reduces the risk of prostate cancer. Moreover, the advertisement's claim that POM Juice is "backed by $25 million in vigilant medical research," as well as a footnote referencing a "prostate study" under a URL entitled "health benefits" conveys the overall net impression that POM's benefits for prostate cancer have been proven by clinical testing. (CCFF ¶¶ 372-75).

c. "Magazine Wrap" Print Ads (CX0314; CX0372; CX0379; CX0380)

377. POM disseminated a "magazine wrap" advertisement in Fall 2008, which included the bold headline, "**Drink to prostate health**." with an image of the POM Juice bottle with logo on the cover. (CX0314_0003).

378. Although the advertisement's body copy was titled "**P♥M Wonderful and Prostate Health**," the detailed claims below the title made clear that POM's purported benefits for prostate "health" actually referred to benefits for prostate *cancer*. The advertisement discussed only studies related to prostate cancer (rather than any other prostate health condition). The advertisement stated:

> **A recently published medical study involving P♥M Wonderful 100% Pomegranate Juice followed 46 men previously treated for prostate cancer either with surgery or radiation.** After drinking eight ounces of P♥M Wonderful 100% Pomegranate Juice daily for at least two years, these men experienced significantly slower PSA doubling times. PSA (Prostate-Specific Antigen) is a biomarker that indicates the presence of prostate cancer. "PSA doubling time" is a measure of how long it takes for PSA levels to double. A longer doubling time may indicate slower progression of the disease.
>
> At the beginning of the study, PSA levels doubled on average every 15 months. By the end of the study, doubling time had slowed to 54 months – nearly a four-fold improvement.

> "*This is a big increase. I was surprised when I saw such an improvement in PSA numbers," said Dr. Allan Pantuck, lead author of the UCLA Study.*
>
> In addition, in-vitro testing using blood serum from the patients who drank pomegranate juice showed a 17% increase in prostate cancer cell death and a 12% decrease in cancer cell growth.
>
> *One important note:* All patients drank the same P♥M Wonderful 100% Pomegranate Juice which is available in your supermarket produce section.

(CX0314_0004).

379. The magazine wrap also emphasized the danger of prostate cancer, stating: "Prostate Cancer is the most commonly diagnosed cancer in men in the United States. After lung cancer, it's the second leading cause of cancer death in men. However, emerging science suggests that diet and lifestyle may be able to significantly improve prostate health." It went on to say: "**The Research Continues.** Results from this study were so promising that many of the original patients continued to drink pomegranate juice daily, and their PSA doubling times remained suppressed. Three more clinical studies are now underway to further investigate the effects of P♥M on prostate health." (CX0314_0004).

380. The magazine wrap further bolstered the efficacy claims by stating that they were "**Backed by Science.** Only P♥M is backed by $25 million in medical research conducted at the world's leading universities. Clinical studies have documented the benefits of drinking P♥M Wonderful 100% Pomegranate Juice, including improved cardiovascular and prostate health." The page on which these claims appeared was titled, "**The proof is in the P♥M**." (CX0314_0005).

381. Another magazine wrap dated October 2009 depicted a POM Juice bottle with a "speech" balloon above it saying, "**Lucky I have super HEALTH POWERS!**" The inside page showed a bottle "saying" "**HOLY HEALTH! $32 million in medical research.**" Other than increasing the "**Backed by Science**" figure to $32 million, the body copy of this magazine wrap contained the very same claims regarding prostate cancer as the "Drink to prostate health" wrap. (CX0379_0002-03; *see also* CX0380; CX0372 (additional copies of similar *Time* magazine wraps dated Nov. 2009 and Dec. 2009)).

382. Ms. Kuyoomjian testified that in drafting the *Time* magazine cover wrap with Mr. Tupper, she did not do any independent investigation of her own as to whether the statements about the research cited in the cover wrap were true. (CX1378 (Kuyoomjian, OS Dep. at 90, 93-94)).

383. According to Mr. Resnick, POM's advertising did convey, through reference to the prostate research, that "the taking of pomegranate juice would affect the growth or the advance of PSA in men with prostate problems." (CX1363 (S. Resnick, TCCC Dep. at 85)).

384. These magazine wraps, with their detailed descriptions of studies on prostate cancer, explanation of PSADT as an indication of disease progression, and emphasis on "[d]rink[ing] to prostate health," convey the net impression that drinking eight ounces of POM Juice daily treats, prevents, or reduces the risk of prostate cancer, including by slowing PSADT. Moreover, the magazine wraps' claims that POM Juice is "backed by science," has tens of millions of dollars in medical research behind it, and has been documented by "clinical studies," convey the overall net impression that POM's benefits for prostate cancer have been proven by clinical testing. (CCFF ¶¶ 377-81).

3. POM Juice Bottle Hang Tag Made Establishment Claims Regarding Heart Disease, Prostate Cancer, and Erectile Dysfunction (CX0475 / CX1426_00027 [Compl. Ex. A])

385. POM disseminated "hang tags," which were hard paper stock tags hung around the neck of POM Juice bottles, in order to promote the product or make announcements to consumers. (L. Resnick, Tr. 264).

386. One hang tag, which was disseminated on POM Juice bottles since at least September 2009, contained the bold headline "**SUPER HEALTH POWERS!**" on the outside of the tag. Inside, the hang tag stated:

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

The back of the hang tag contained a chart purporting to show that POM Juice has the most antioxidants, as compared to other beverages, and directed consumers to a page on POM's website, pomwonderful.com/compare. (CX0475; *see also* CX1426_00027).

387. Dr. Butters testified that a reasonable reader could infer from the phrase "backed by $25 million in medical research" on the hang tag that the research has been completed and has results. (Butters, Tr. 2878).

388. The hang tag's reference to "[p]roven to fight for cardiovascular, prostate and erectile health" and that the juice is "[b]acked by $25 million in medical research," combined with the POM Juice bottle and logo, convey the net impression that POM Juice treats, prevents, or reduces the risk of cardiovascular disease, prostate cancer, and erectile dysfunction, and that these health benefits are clinically proven. (*See* CCFF ¶¶ 386-87).

4. POMx Pill Print Ads Made Establishment Claims Regarding Heart Disease, Prostate Cancer, and Erectile Dysfunction

389. POM disseminated numerous print advertisements for POMx Pills in 2007 through 2010. In many advertisements, the headlines differed, but the body copy was substantially similar in describing POMx's purported benefits for prostate cancer, cardiovascular disease, and erectile dysfunction, using specific clinical studies of POM Juice, purported quotes from researchers, and statements that the claims were backed by tens of millions of dollars in medical research. (*See* CCFF ¶¶ 397-441).

390. POMx print advertisements frequently included a graphic showing a POMx Pill capsule next to a POM Juice bottle, with an equal sign between them, along with statements indicating equivalence of the two products, such as "The antioxidant power of our 8 oz. juice." (*See, e.g.,* CCFF ¶¶ 407-10, 430).

391. Mrs. Resnick was aware as early as 2006 that the Dietary Supplement Health and Education Act did not allow dietary supplement marketers to make disease claims to consumers, including through advertisements, websites, or product labels. (CX0054_0001).

392. Charlene Rainey, a regulatory consultant who assisted POM in submitting a new dietary ingredient application to FDA, reviewed a draft brochure for POMx in 2007. (Dreher, Tr. 541-42). In a January 2007 email providing her feedback on the brochure, Rainey cautioned, "Mentions of diseases: In labeling (which includes supporting materials such

as the brochure), FDA does not allow statements that *claim or imply that the product may help to diagnose, treat, cure or prevent any disease*, unless the statement is authorized by FDA." (CX0094_0001 (emphasis added)). Further emphasizing this point, Rainey wrote, "[l]abeling claims need to be limited to what are called 'structure/function claims,' which are statements about the ability of a product to maintain a healthy structure or function of the body, *without implying disease prevention or treatment*." (CX0094_0001 (emphasis added)). Rainey specifically warned:

> Therefore, the brochure and other supporting materials should be limited to statements such as "cardiovascular support," "helps maintain prostate health," etc.
>
> Examples of words or phrases that FDA would object to:
> - Inflammatory stress
> - Cardiovascular disease, heart disease, atherosclerosis, etc.
> - Hypertension, high blood pressure, etc.
> - Cancer
> - Plaque build-up
> - Thickening of artery walls
> - Ischemia

(CX0094_0001).

393. POM's internal documents show that when POM introduced POMx Pills, the company was concerned about using studies that were done on POM Juice to support claims for POMx Pills. (CX0073_0002 ("Please note that juice claims cannot simply be transferred to POMx claims. Please see the attached . . . starter list of claims. Note that all claims are based on clinical studies for the POMx material.")). Nonetheless, a 2007 press release for POMx Pills described the product as a supplement that "[j]ust like [POM Juice] . . . promote[s] heart and prostate health." (CX0115_0001).

394. POM's internal research assessments in February and July 2007 also noted "research gaps" in assessing the potency and efficacy of POMx Pills or Liquid versus POM Juice for cardiovascular disease and prostate cancer in humans. One document noted a "key question" for human studies in both diseases was whether POMx was as effective as POM Juice. (CX0100_0001; CX0132_0001).

395. As late as January 2009, Dr. Aviram stated that "I feel that it is important to learn more about the relationships between POM (PJ, and the pill, which, unlike PJ, we know very

little on it from a mechanistical point of view[.])" (CX1060_0001; CX1358 (Aviram, Dep. at 48)). At his deposition in March 2011, Dr. Aviram admitted that "very little was done with POMx" and that he could not confidently say POMx would work the same as POM Juice before testing it. (CX1358 (Aviram, Dep. at 48).

396. POMx print advertisements also frequently included a graphic showing a POMx Pill bottle next to a pomegranate fruit. Finally, POMx print advertisements frequently included a graphic of a caduceus, a symbol often associated with medicine or medical treatment. (*See*, *e.g.*, CCFF ¶¶ 397-98, 407-10; *see also* Butters, Tr. 2944).

a. "One small pill for mankind" / "Science, not fiction" Print Ads (CX0120 / CX0122)

397. As early as 2007, POM disseminated print advertisements introducing POMx Pills. One such advertisement, which ran in *Fortune* magazine in May 2007, included an image of a POMx Pill bottle over a bold headline, "**One small pill for mankind.**" Directly underneath the headline, in smaller but still bold font, the advertisement included a quote from a *New York Times* article dated July 4, 2006: "**Findings from a small study suggest that pomegranate juice may one day prove an effective weapon against prostate cancer.**" (CX0120).

398. POM disseminated a very similar POMx advertisement in June 2007 in *Discover* and *Scientific American* magazines. (CX0122_0002). This advertisement included the same images of the POMx Pill bottle, POM Juice bottle, and caduceus. The headline of this advertisement read, "**Science, not fiction.**" and the subheadline read, "**Made from the only pomegranates backed by $20 million in medical research.**" (CX0122).

399. The body copy of the "Science, not fiction" advertisement was otherwise almost identical to the "One small pill for mankind" advertisement.

400. Both advertisements expressly stated that taking one POMx Pill was the equivalent of drinking eight ounces of POM Juice: "Introducing P♥Mx – a highly concentrated, incredibly powerful blend of all-natural polyphenol antioxidants made from the very same pomegranates in **P♥M Wonderful 100% Pomegranate Juice**. . . . So now you can get all the antioxidant power of an 8oz glass of juice in the convenience of a calorie-free capsule." This paragraph appeared next to an image of a POM Juice bottle. The advertisements also included the tag line "**P♥M IN A PILL**" in bold font near the bottom of the page. (CX0120; CX0122).

401. The advertisements went on to state:

> Ready to take on free radicals? Put up your P♥Mx and fight them with a mighty 1000 mg capsule – that's more concentrated pomegranate polyphenol antioxidants than any other 100% pomegranate supplement. An initial UCLA medical study on P♥M Wonderful 100% Pomegranate Juice showed hopeful results for men with prostate cancer. And preliminary human research suggests that our California-grown pomegranate juice also promotes heart health. Take your antioxidants into your own hands.

Footnotes in the advertisements, which appeared next to a caduceus, referred consumers to two of POM's web pages, **pomwonderful.com/cancer.html** and **pomwonderful.com/heart_health.html**. (CX0120).

402. In August 2006, shortly after the Pantuck Phase II Prostate Cancer Study (2006) was published, Dr. Pantuck complained to Respondents that the information they intended to disseminate about his study, including information on POM's website, was "marketing" and that the claims troubled him. Dr. Pantuck told Dr. Liker in an email, which was forwarded to Mr. Tupper and Mrs. Resnick, that "I am not sure what it means to say PJ [POM juice] shows 'promise for prostate cancer.' I think the lay interpretation will be that it shows promise for the treatment of prostate cancer. I am very concerned that my legitimacy will be affected by displaying my name in such a manner[.]" (CX0072_0001; *see also* CCFF ¶ 691).

403. POM was also aware of Dr. Pantuck's view, expressed in an interview in October 2006 after the study was published, that he was "not at the point where [he] would say that everyone who has prostate cancer or who is at risk for prostate cancer should be drinking pomegranate juice." The article, in the Center for Science in the Public Interest's *Nutrition Action Newsletter*, was forwarded to Mr. Tupper and Mrs. Resnick. (CX0087_0001, 0004).

404. Nevertheless, even though POM was aware of Dr. Pantuck's concerns about overselling the scope of his study, POM continued to cite his study and claim it provided "hopeful results for men with prostate cancer" in advertisements in 2007, and made references to a website with the URL "pomwonderful.com/cancer.html." (CCFF ¶¶ 397-401; Tupper, Tr. 1004-05).

405. The imagery and text of these POMx advertisements, particularly in light of POM's stated intention to target consumers who sought to prevent diseases, including prostate cancer, *see* CCFF ¶¶ 304, 307, convey the net impression that taking one POMx Pill daily treats, prevents, or reduces the risk of prostate cancer and that those health benefits are clinically proven. Because the advertisements specifically note that the study was done on the POM Juice, and that one POMx Pill is equivalent to eight ounces of POM Juice, they also convey the net impression that drinking eight ounces of POM Juice daily treats, prevents, or reduces the risk of prostate cancer and that those health benefits are clinically proven. (CCFF ¶¶ 397-401).

b. "The power of P♥M, in one little pill"/ "The Antioxidant Superpill"/ "Science, not fiction" Print Ads (CX0169 / CX0180 / CX0279)

406. In 2008 and 2009, POM continued to disseminate POMx advertisements, with additional, detailed copy describing the POMx Pill's purported health benefits, usually citing scientific journal articles to bolster the claims. (*See* CCFF ¶¶ 407-11).

407. For example, one advertisement disseminated in January 2008 in the *New York Times* with the headline, "**The power of P♥M, in one little pill.**" included several different bold subheadlines, "**Antioxidant Superpill**," "**Peace of Mind in a Pill**," "**Safe and Natural**," "**Backed by Science**," and "**One a Day, For Life**." The advertisement also included images of a POMx Pills bottle next to a POM Juice bottle with an equal sign in between, a caduceus, and a POMx Pills bottle next to a pomegranate fruit. (CX0169).

408. As another example, in February 2008, POM disseminated in the *Los Angeles Times* a similar print advertisement for POMx Pills headlined, "**The antioxidant superpill.**" (CX0180).

409. A POMx Pills print advertisement with the headline, "**Science, not fiction.**" and with similar claims was disseminated in *Popular Science* magazine in March 2009. (CX0279).

410. The body copy for the "The Power of POM" advertisement described the purported effects of POM Juice in prostate cancer and coronary heart patients:

> POMx is made from the only pomegranates supported by $23 million in medical research. . . . An initial UCLA MEDICAL

> STUDY on POM Wonderful 100% Pomegranate Juice found *hopeful results for prostate health*. "Pomegranate juice delays PSA doubling time in humans," according to AJ Pantuck, et al, in Clinical Cancer Research, 2006. Two additional preliminary studies on our juice showed *promising results for heart health*. "Pomegranate juice improves myocardial perfusion in coronary heart patients," per D. Ornish, et al, in the American Journal of Cardiology, 2005. "Pomegranate juice pilot research suggests anti-atherosclerosis benefits," according to M. Aviram, et al, in Clinical Nutrition, 2004.

(CX0169).

411. Similarly, "The Antioxidant Superpill" print advertisement stated:

> POMx is made from the only pomegranates backed by $23 million in medical research, the same pomegranates we use to make our POM Wonderful 100% Pomegranate Juice. An initial UCLA MEDICAL STUDY on POM Wonderful 100% Pomegranate Juice found *hopeful results for prostate health*. The study reports "statistically significant prolongation of PSA doubling times," according to Dr. Allen [*sic*] J. Pantuck in Clinical Cancer Research, 2006. Two additional preliminary studies on our juice showed *promising results for heart health*. "Stress-induced ischemia decreased in the pomegranate group," Dr. Dean Ornish reported in the American Journal of Cardiology, 2005. "Pomegranate juice consumption resulted in a significant IMT reduction by up to 30% after one year," said Dr. Michael Aviram, referring to reduced arterial plaque in Clinical Nutrition, 2004.

(CX0180; *see also* CX0279 (similar body copy but stating "backed by $25 million in medical research")).

412. The clear implication of these claims, along with the images and text indicating equivalence between POMx Pills and POM Juice, is that the studies on POM Juice also support the same health benefits of POMx Pills. (CCFF ¶¶ 406-11).

413. Moreover, although Respondents did not use the specific terms "heart disease" or "prostate cancer," Dr. Butters testified that speakers of American English would interpret the phrases "heart health" and "prostate health" that were used in the advertisements to

mean a condition of not being diseased. (Butters, Tr. 2851).

414. These advertisements (CX0169, CX0180, and CX0279) convey the net impression that taking one POMx Pill daily treats, prevents, or reduces the risk of cardiovascular disease and prostate cancer, and that those health benefits are clinically proven. Because the advertisements specifically note that the studies were done on POM Juice, and that one POMx Pill is equivalent to eight ounces of POM Juice, they also convey the net impression that drinking eight ounces of POM Juice daily treats, prevents, or reduces the risk of cardiovascular disease and prostate cancer, and that those health benefits are clinically proven. (CCFF ¶¶ 406-13).

c. "Live Long Enough to Watch Your 401(k) Recover" / "Your New Health Care Plan" / "Healthy, ~~Wealthy~~, and Wise" / "The First Bottle You Should Open in 2010" Print Ads (CX0280 / CX0328 / CX0331 / CX0337)

415. POM continued to disseminate POMx print advertisements from 2009 into 2010. For example, four print advertisements headlined "**LIVE LONG ENOUGH TO WATCH YOUR 401(K) RECOVER,**" **"YOUR NEW HEALTH CARE PLAN. (NO TOWN HALL MEETING REQUIRED.),**" "**HEALTHY. ~~WEALTHY.~~ AND WISE (2 OUT OF 3 IN THIS ECONOMY AIN'T BAD.)**," and "**THE FIRST BOTTLE YOU SHOULD OPEN IN 2010**" all contained slightly different subheadlines, but the images and body copy were very similar or identical. (CX0280; CX0328; CX0331; CX0337). These advertisements stated:

> Emerging science suggests that antioxidants are critically important to maintaining good health because they protect you from free radicals, which can damage your body. Taking one P♥Mx pill a day will help protect you from free radicals and keep you at your healthy best.
>
> ***
>
> P♥Mx – an ultra-potent antioxidant extract made from the same pomegranates as P♥M Wonderful 100% Pomegranate Juice – is the most potent natural antioxidant supplement available. Each 1000 mg P♥Mx pill has the antioxidant power of a full glass of P♥M Wonderful 100% Pomegranate Juice.
>
> ***

> P♥Mx is made from the only pomegranates backed by $25 million in medical research at the world's leading universities. Not only has this research documented the unique and superior antioxidant power of pomegranates, it has revealed promising results for prostate and cardiovascular health.
>
> ***
>
> Our P♥Mx pills are made from the same pomegranates we use to make our P♥M Wonderful 100% Pomegranate Juice, on which each of the following medical studies was conducted.
>
> An initial UCLA study on our juice found hopeful results for prostate health, reporting "statistically significant prolongation of PSA doubling times," according to Dr. Allen *[sic]* J. Pantuck in *Clinical Cancer Research*, '06.
>
> Two additional preliminary studies on our juice showed promising results for heart health. "Stress-induced ischemia (restricted blood flow to the heart) decreased in the pomegranate group," Dr. Dean Ornish reported in the *American Journal of Cardiology*, '05.
>
> "Pomegranate juice consumption resulted in significant reduction in IMT (thickness of arterial plaque) by up to 30% after one year," said Dr. Michael Aviram, *Clinical Nutrition*, '04.

The advertisements contained the same images as in other POMx print ads, including the graphic equating one POMx Pill to an eight-ounce bottle of POM Juice and the POMx Pill bottle next to a pomegranate fruit. They additionally contain an image showing a pill capsule with pomegranate fruits inside. (CX0280 (disseminated at least 70 times in various publications from March to November 2009); CX0328 (*Washington Post*, November 2009); CX0331 (disseminated at least 99 times in various publications from September to October 2009); CX0337 (*New York Times*, January 2010)).

416. The "Live Long Enough to Watch Your 401(k) Recover" advertisement stated that POMx was "backed by $25 million in medical research at the world's leading universities," while the other three advertisements stated POMx was backed by $32 million. (*Compare* CX0280 *with* CX0328, CX0331, CX0337).

417. As with the POMx advertisements referenced in CCFF ¶¶ 407-09, POM used the terms "heart health" and "prostate health," which Dr. Butters testified meant a condition free of disease. (CCFF ¶ 413).

418. The advertisements (CX0280; CX0328; CX0331; CX0337) convey the net impression that taking one POMx Pill daily treats, prevents, or reduces the risk of cardiovascular disease and prostate cancer, and that those health benefits are clinically proven. Because the advertisements specifically note that the studies were done on POM Juice, and that one POMx Pill is equivalent to eight ounces of POM Juice, they also convey the net impression that drinking eight ounces of POM Juice daily treats, prevents, or reduces the risk of cardiovascular disease and prostate cancer, and that those health benefits are clinically proven. (CCFF ¶¶ 415-17).

d. "Take Out a Life Insurance Supplement" / "24 Scientific Studies" Print Ads (CX0342 / CX0348 / CX0350 / CX0353)

419. POMx disseminated print advertisements headlined, "**TAKE OUT A LIFE INSURANCE SUPPLEMENT**" and "**24 SCIENTIFIC STUDIES NOW IN ONE EASY-TO-SWALLOW PILL**," which included similar images and text as the advertisements described in CCFF ¶ 415. However, the body copy in these advertisements referred only to the Pantuck and Ornish studies, and omitted the Aviram study:

> An initial UCLA study on POM Wonderful 100% Pomegranate Juice found hopeful results for prostate health, reporting "statistically significant prolongation of PSA doubling times," according to Dr. Allen [*sic*] J. Pantuck in *Clinical Cancer Research*, 2006. Additional preliminary study on our juice showed promising results for heart health. "Stress-induced ischemia (restricted blood flow to the heart) decreased in the pomegranate group," Dr. Dean Ornish reported in the *American Journal of Cardiology*, 2005.

(CX0342_0001 (disseminated at least three times in various publications in February and March 2010); CX0348_0001 (*Men's Health* magazine and *Popular Science* magazine, April 2010)). POM disseminated additional, very similar advertisements, but which cited $34 million in research, instead of $32 million. (CX0350_0001 (*Time* magazine, April 2010]); CX0353_0001 (disseminated at least six times in various media including the *New York Times* and *Men's Health* magazine in June and September 2010)).

420. POM admits that it had continued to run advertisements promoting the 30% reduction in arterial plaque purportedly shown by the Aviram CIMT/BP Study (2004) (*see, e.g.*, CCFF ¶¶ 410, 415), even after it was aware, as early as 2006, of the inconsistent results of the Davidson CIMT Study (2009) that showed, at most, a 5% decrease in arterial plaque in some patients measured at an interim point in the study. (Tupper, Tr. 965-966.)

421. The Davidson CIMT Study (2009), with its negative results, was finally published in late 2009, and only in mid to late 2010 did POM's advertisements finally omit reference to the results of the Aviram CIMT/BP Study (2004), as in the advertisement cited above. (CCFF ¶ 419).

422. Dr. Butters testified that a viewer of the "24 Scientific Studies" advertisement would find it reasonable to believe that the headline is accurate and that there must be 24 scientific studies on POMx. (Butters, Tr. 2940).

423. Mrs. Resnick testified that she would have seen the POMx advertisement in CX0348 and that she would have approved specific elements of the advertisement, including the headline "24 Scientific Studies Now in One Easy-to-Swallow Pill," the image of the pill equaling eight ounces of POM Juice, and the image of the pomegranates pouring out of the pill. (L. Resnick, Tr. 249-51).

424. These advertisements (CX0342, CX0348, CX0350, and CX0353), by using terms such as "life insurance," citing specific studies, and referencing support by a significant dollar amount of medical research conducted, convey the net impression that taking one POMx Pill daily treats, prevents, or reduces the risk of cardiovascular disease and prostate cancer, and that those health benefits are clinically proven. Because the advertisements specifically note that the studies were done on the POM Juice, and that one POMx Pill is equivalent to eight ounces of POM Juice, they also convey the net impression that drinking 8 ounces of POM Juice daily treats, prevents, or reduces the risk of cardiovascular disease and prostate cancer, and that those health benefits are clinically proven. (CCFF ¶¶ 419, 422).

e. "The Only Antioxidant Supplement Rated X" Print Ads (CX0351 / CX0355)

425. POM disseminated POMx print advertisements headlined, "**THE ONLY ANTIOXIDANT SUPPLEMENT RATED X**," in male-oriented magazines such as *Advocate* and *Playboy*. The advertisements used subheadlines presumably intended to appeal to male readers, such as "Always use protection," "P♥Mx. Super-potent. Like you." "$32 million in research. We're not just playing doctor." and "Is that P♥Mx in your pocket?" However, the body copy was substantially similar to prior POMx print advertisements, with the addition of several claims that POM Juice and therefore, POMx, improves erectile function:

> POMx is made from the only pomegranates backed by $32 million in medical research at the world's leading universities. Not only has this research documented the unique and superior antioxidant power of pomegranates, it has revealed promising results for erectile, prostate and cardiovascular health.
>
> ***
>
> Our P♥Mx pills are made from the same pomegranates we use to make our P♥M Wonderful 100% Pomegranate Juice, on which each of the following medical studies was conducted.
>
> In a preliminary study on erectile function, men who consumed POM Juice reported a 50% greater likelihood of improved erections as compared to placebo. "As a powerful antioxidant, enhancing the actions of nitric oxide in vascular endothelial cells, POM has potential in the management of ED. . . further studies are warranted." *International Journal of Impotence Research*, '07.
>
> An initial UCLA study on our juice found hopeful results for prostate health, reporting "statistically significant prolongation of PSA doubling times," *Clinical Cancer Research*, '06.
>
> A preliminary study on our juice showed promising results for heart health. "Stress-induced ischemia (restricted blood flow to the heart) decreased in the pomegranate group," *American Journal of Cardiology*, '05.

(CX0351_0001 (*Advocate* magazine, June 2010); CX0355_0001 (*Playboy* magazine, July 2010)). The *Playboy* advertisement cited a figure of $34 million in medical research. (CX0355).

426. Respondents' expert, Dr. Butters, testified that speakers of American English would interpret the phrase "erectile function" to relate to the ability of men to achieve and maintain erections and that erectile function and the absence of erectile dysfunction are closely related. (Butters, Tr. 2851).

427. Dr. Butters also stated in his report and testified at trial that this advertisement conveys that preliminary initial studies suggest that pomegranate extract, a strong source of antioxidants, could help alleviate erectile dysfunction. (Butters, Tr. 2943).

428. Mrs. Resnick admits she approved the headline for the POMx print advertisement headlined "The only antioxidant supplement rated X" that appeared in *Playboy* magazine. (L. Resnick, Tr. 266).

429. The advertisements (CX0351 and CX0355) convey the net impression that taking one POMx Pill daily treats, prevents, or reduces the risk of cardiovascular disease, prostate cancer, and erectile dysfunction, and that those health benefits are clinically proven. Because the advertisements specifically note that the studies were done on the juice, and that one pill is equivalent to eight ounces of POM Juice, they also convey the net impression that drinking eight ounces of POM Juice daily treats, prevents, or reduces the risk of cardiovascular disease, prostate cancer, and erectile dysfunction, and that those health benefits are clinically proven. (CCFF ¶¶ 425-27).

f. POMx "Antioxidant Superpill" Package Insert (CX1426_00038 [Compl. Ex. I])

430. A package insert for POMx, disseminated in June 2007, displayed the image of a POMx Pill bottle over the bold headline, "**Antioxidant Superpill**." It went on to state, "P♥Mx is a highly concentrated, incredibly powerful blend of all-natural polyphenol antioxidants made from the very same pomegranates in POM Wonderful 100% Pomegranate Juice." It also used the tag line, "The Power of P♥M. Now in one little pill." and included an image of an eight ounce POM Juice bottle with an equals sign next to a POMx Pill. (CX1426_00039 [Compl. Ex. I, p. 2]).

431. The package insert quoted Dr. Aviram as saying, "POM Wonderful Pomegranate Juice has been proven to promote cardiovascular health, and we believe that POMx may have the same health benefits." (CX1426_00042 [Compl. Ex. I, p. 5]). Next to an illustration of a heart was the following text:

> In two groundbreaking preliminary studies, patients who drank POM Wonderful 100% Pomegranate Juice experienced impressive cardiovascular results. A pilot study at the Rambam Medical Center in Israel included 19 patients with atherosclerosis (clogged arteries). After a year, arterial plaque decreased 30% for those patients who consumed 8 oz of POM Wonderful 100% Pomegranate Juice daily.
>
> [footnote omitted]

> An additional study at the University of California, San Francisco included 45 patients with impaired blood flow to the heart. Patients who consumed 8 oz of POM Wonderful 100% Pomegranate Juice daily for three months experienced a 17% improvement in blood flow. Initial studies on POMx share similar promise for heart health, and our research continues.
>
> (CX1426_00042 [Compl. Ex. I, p. 5]).

432. The same 2007 package insert for POMx made claims about prostate cancer, including:

> **Prostate health.**
>
> Prostate cancer is the most commonly diagnosed cancer among men in the United States and the second-leading cause of cancer death in men after lung cancer. [footnote omitted]
>
> **Time pill.**
>
> Stable levels of prostate-specific antigens (or PSA levels) are critical for men with prostate cancer. Patients with quick PSA doubling times are more likely to die from their cancer. [footnote omitted] According to a UCLA study of 46 men age 65 to 70 with advanced prostate cancer, drinking an 8oz glass of POM Wonderful 100% Pomegranate Juice every day slowed their PSA doubling time by nearly 350%. [footnote omitted]
>
> 83% of those who participated in the study showed a significant decrease in their cancer regrowth rate. [footnote omitted]

(CX1426_00041 [Compl. Ex. I, p. 4]).

433. Mrs. Resnick testified that she was very involved in developing the POMx brochure when it was first produced, and that the information under "Prostate Health" on fourth page of the package insert was in fact discussing prostate cancer. (L. Resnick, Tr. 246; CX1426_00041 [Compl. Ex. I, p. 4]).

434. The net impression from the POMx package insert, including the detailed description of several studies, is that eight ounces of POM Juice or one POMx Pill taken daily, prevents, treats, or reduces the risk of heart disease, including by decreasing arterial

plaque, or improving blood flow to the heart; that eight ounces of POM Juice or 1 POMx Pill taken daily prevents, treats, or reduces the risk of prostate cancer, including by prolonging PSA doubling time; and that these benefits for heart disease and prostate cancer are clinically proven. (*See* CCFF ¶¶ 430-32).

g. POMx Heart and Prostate Newsletters (CX1426_00046 [Compl. Ex. M] / CX1426_00049 [Compl. Ex. N])

435. A POMx newsletter dated "Summer '07" and labeled "Volume 1, Issue 1: FOR YOUR HEART," claimed "NEW RESEARCH OFFERS FURTHER PROOF OF THE HEART-HEALTHY BENEFITS OF POM WONDERFUL JUICE." (CX1426_0004-48 [Compl. Ex. M, pp. 1-3]).

436. The newsletter begins with the bolded heading "**What's New in the Lab by Dr. Mark Dreher**" followed by a photograph of Dr. Dreher next to his title:

> Mark Dreher, PhD
> Chief Science Officer
> POMWonderful, LLC

The newsletter opens with, "Hi, I'm Dr. Mark Dreher, Chief Science Officer at POM, and your guide to continuing new research on the benefits of POMx and POM Wonderful pomegranates as they relate to your health." (CX1426_00046-47 [Compl. Ex. M, pp. 1-2]).

437. The heart benefits were described as:

> **30% DECREASE IN ARTERIAL PLAQUE**
> After one year of a pilot study conducted at the Technion Institute in Israel involving 19 patients with atherosclerosis (clogged arteries), those patients who consumed 8 oz of POM Wonderful 100% Pomegranate Juice daily saw a 30% decrease in arterial plaque.
>
> **17% IMPROVED BLOOD FLOW**
> A recent study at the University of California, San Francisco (UCSF) included 45 patients with impaired blood flow to the heart. Patients who consumed 8 oz of POM Wonderful 100% Pomegranate Juice daily for three months experienced 17%

improved blood flow. Those who drank a placebo experienced an 18% decline.

PROMOTES HEALTHY BLOOD VESSELS

An in vitro study at the University of California, Los Angeles (UCLA) showed that pomegranate juice uniquely possesses enough antioxidant activity to protect nitric oxide (an important biochemical that helps maintain healthy blood vessels for proper blood flow) against oxidative destruction thereby enhancing its biological activity. In other words, pomegranate juice by protecting nitric oxide promotes healthy blood flow.

(CX1426_00048 [Compl. Ex. M, p. 3]).

438. A text box within the newsletter equated the effects of POM Juice and POMx, stating, "In his 2006 POMx study, Dr. Michael Aviram, one of the world's pre-eminent cardiovascular researchers from the Technion Institute in Israel, remarked that '*POMx is as potent an antioxidant as pomegranate juice and just like pomegranate juice, POMx may promote cardiovascular health*.'" (CX1426_00048 [Compl. Ex. M, p. 3])).

439. Another newsletter dated "Fall '07" and labeled "Volume 1, Issue 2: PROSTATE HEALTH," also begins with the bolded heading "**What's New in the Lab by Dr. Mark Dreher**" followed by an photograph of Dr. Dreher next to his title:

Mark Dreher, PhD
Chief Science Officer
POMWonderful, LLC

In this newsletter, Dr. Dreher is quoted as saying, "Research studies like the ones discussed in this newsletter and conducted by UCLA "my alma mater" serve to validate the many reasons I am proud to be affiliated with POM Wonderful and POMx." (CX1426_00050 [Compl. Ex. N, p. 2]).

440. This newsletter stated:

Prostate Cancer Affects 1 Out of Every 6 Men

Prostate cancer is the second leading cause of cancer related death in men in the United States according to the National Cancer

Institute. Prostate cancer incidence rates rose dramatically in the late 1980's with improved detection and diagnosis through widespread use of prostate-specific antigen (PSA) testing.

***

What's New in the Lab by Dr. Mark Dreher

***

POM Wonderful 100% Pomegranate Juice and POMx are backed by a $25 million dollar investment in world-class scientific research. This includes ten clinical studies published in top peer-reviewed medical journals that document the pomegranate's antioxidant health benefits such as heart and prostate health.

***

In fact, studies funded by POM represent the vast majority of human medical research ever conducted on pomegranates.

***

NEW POMEGRANATE RESEARCH OFFERS HOPE TO PROSTATE CANCER PATIENTS

A preliminary UCLA medical study involving POM Wonderful 100% Pomegranate Juice revealed promising news. 46 men who had been treated for prostate cancer with surgery or radiation were given 8oz *[sic]* of POM Wonderful 100% Pomegranate Juice to drink daily.

A majority of the patients experienced a significantly extended PSA doubling time. Doubling time is an indicator of prostate cancer progression – extended doubling time may indicate slower disease progression.

Before the study, the mean doubling time was 15 months. After drinking 8oz *[sic]* of pomegranate juice daily for two years, the mean PSA doubling time increased to 54 months. Testing on

> patient blood serum showed a 12% decrease in cancer cell proliferation and a 17% increase in cancer cell death (apoptosis).
>
> In another study, in vitro laboratory testing at UCLA showed that POMx significantly decreased human prostate cancer cell growth and increased cancer cell death.

(CX1426_00050-51 [Compl. Ex. N, p. 2-3]).

441. The net impression from the heart newsletter, including the detailed description of several studies, is that eight ounces of POM Juice or one POMx Pill taken daily, prevents, treats, or reduces the risk of heart disease, including by decreasing arterial plaque, or improving blood flow to the heart, and that these benefits are clinically proven. (*See* CCFF ¶¶ 435-38). The net impression from the prostate newsletter is that eight ounces of POM Juice or one POMx Pill taken daily prevents, treats, or reduces the risk of prostate cancer, including by prolonging PSA doubling time; and that these benefits are clinically proven. (*See* CCFF ¶¶ 439-40).

E. Health Claims in Internet Advertising

442. POM's websites include pomwonderful.com, pomegranatetruth.com, and pompills.com. (JX0003 ¶ B.11; Rushton, Tr. 1354-55; Leow, Tr. 433).

1. Pomwonderful.com Made Establishment Claims Regarding Heart Disease, Prostate Cancer, and Erectile Dysfunction

443. In April 2009, the pomwonderful.com homepage featured a large comic book-themed animation depicting the POM Juice bottle announcing, "**Risk your health in this economy!?! NEVER!**" and the copy "**The Antioxidant Superpower. Learn about POM's promising health benefits**." (CX0473 (Compl. Ex. E-2 at 00:04)). The homepage also featured a similarly styled animation, with the POM Juice bottle warning, "**HURRY! Prostates everywhere are in danger!**" in the first frame and then in the second, "**I'm off to save PROSTATES!**" (CX0473 (Compl. Ex. E-4 at 00:05)). A prominent hyperlink led to the "Health Benefits" section of the website. (CX0473 (Compl. Ex. E-2 at 00:15)).

444. The first page of the "**Health Benefits**" section of pomwonderful.com displayed a large graphic depicting the POM Juice bottle hanging upside down on a pole, with the juice running through a tube at the bottom of the bottle, in the manner of a hospital intravenous

line. The introductory text stated, "POM Wonderful 100% Pomegranate Juice is the only pomegranate juice backed by $25 million in medical research. Actually, we are the only pomegranate juice backed by any medical research at all." It also urged the viewer to "keep in mind that all of the research has been done on POM Wonderful 100% Pomegranate Juice" and stressed that "[n]o other pomegranate juice can claim these distinctions, and no other brand has been clinically tested." (CX0473 (Compl. Ex. E-2 at 00:17)).

445. To illustrate these statements, the first page of "Health Benefits" also presented "medical results on POM Wonderful 100% Pomegranate Juice" under the bolded headings, "**Cardiovascular**," "**Prostate Health**," "**Erectile Function**," and "**Antioxidant Superpower**." (CX0473 (Compl. Ex. E-2 at 00:17-00:24)).

446. The "**Prostate Health**" section presented a "medical result" from the Pantuck Phase II Prostate Cancer Study (2006):

> A preliminary UCLA medical study, published by The American Association for Cancer Research, found hopeful results for prostate health. The study followed 46 men previously treated for prostate cancer either with surgery or radiation. After drinking 8 oz POM Wonderful 100% Pomegranate Juice daily for two years, these men experienced significantly slower PSA doubling times – from 15 months at the beginning of the study to 54 months at the end. PSA is a biomarker for prostate cancer, and slower PSA doubling time may indicate slower disease progression.

(CX0473 (Compl. Ex. E-2 at 00:24)).

447. The "**Erectile Function**" section presented a "medical result" from the Forest Erectile Dysfunction Study (2007):

> A pilot study released in the International Journal of Impotence Research in 2007 examined 61 male subjects with mild to moderate erectile dysfunction. Compared to participants taking a placebo, **those men drinking 8oz. of POM Wonderful 100% Pomegranate Juice daily for four weeks were 50% more likely to experience improved erections**.

(CX0473 (Compl. Ex. E-2 at 00:24)).

448. The "**Antioxidant Superpower**" section "medical results" were that "[n]umerous independent laboratory tests have shown that POM Wonderful 100% Pomegranate Juice has superior antioxidant content, ounce-for-ounce, compared to other juices and beverages . . . ." (CX0473 (Compl. Ex. E-2 at 00:24)).

449. The "**Cardiovascular**" section presented "medical results" from the Ornish MP Study (2005) and the Aviram CIMT/BP Study (2004):

> ♥ A 2005 study published in the American Journal of Cardiology showed improved blood flow to the heart in patients drinking 8oz. daily of POM Wonderful 100% Pomegranate Juice for 3 months. Researchers studied a total of 45 patients with coronary heart disease who had reduced blood flow to the heart. Patients drinking POM Wonderful 100% Pomegranate Juice experienced a 17% improvement in blood flow, compared to a 18% worsening in patients drinking a placebo . . . Read more
>
> ♥ One pilot study on 19 patients with atherosclerosis (clogged arteries) at the Technion Institute in Israel demonstrated a reduction in arterial plaque growth. After one year, arterial plaque decreased 30% for those patients who consumed 8oz of POM Wonderful 100% Pomegranate Juice daily, compared to a 9% worsening for patients who drank a placebo . . . Read more.

(CX0473 (Compl. Ex. E-2 at 00:24)).

450. The "Read more" link after the discussion of the Ornish MP Study (2005) directed the consumer to a page titled "**Heart Health – Emerging Science**." Despite an initial reference to "heart health," the introductory text immediately shifted the discussion to "heart disease," specifically:

> What does the current research say about heart health? Let's start with some facts – heart disease is one of the leading killers in America for women as well as men. Atherosclerosis, or too much plaque in the arteries, is a leading factor in heart attacks.
>
> Where does this plaque come from? The problem starts in your arteries. Emerging science suggests that free radicals may be the culprits that can oxidize LDL . . . "bad" cholesterol . . . turning it into the plaque that clogs up arteries. Initial Laboratory research suggests that antioxidants may help minimize the oxidation of

LDL cholesterol.

(CX0473 (Compl. Ex. E-2 at 00:30) (underlined hyperlinks in original) (footnote links omitted)).

451. This description of heart disease was followed by links to information on the Ornish MP Study (2005), the Aviram CIMT/BP Study (2004), and the Aviram ACE/BP Study (2001). (CX0473 (Compl. Ex. E-2 at 00:30)).

452. The link to the first study, the Ornish MP Study (2005), took the consumer to the published study results. (CX0473 (Compl. Ex. E-2 at 00:45)).

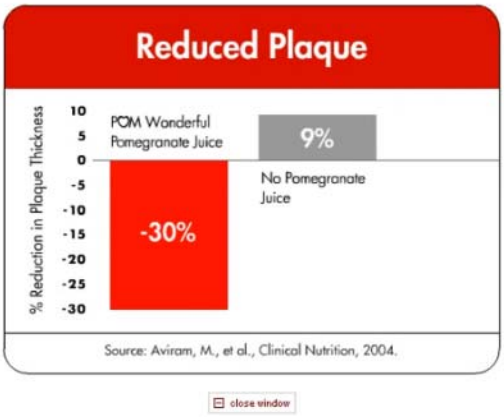
453. The link to the second study, the Aviram CIMT/BP Study (2004), took the consumer to a page with text and graphs. (CX0473 (Compl. Ex. E-2 at 01:00)). At the top of this page was a quote attributed to Dr. Aviram that "[t]he present study clearly demonstrates for the first time that pomegranate juice consumption by patients with carotid artery stenosis possesses anti-atherosclerotic properties." (CX0473 (Compl. Ex. E-2 at 01:00)). Study results were presented as follows:

> This randomized controlled pilot study of 19 patients (ages 65-75) is the first to show that pomegranate juice may reduce the amount of plaque in the arteries of patients with heavy plaque buildup (severe carotid artery stenosis) as well as substantially benefiting several important blood parameters. Ten patients consumed 8 oz. a day of POM Wonderful pomegranate juice for 1 year. Nine patients who did not consume pomegranate juice served as controls. The intima-media thickness (IMT) of the carotid artery wall was measured and blood samples were taken at the beginning of the study and at 3, 6, 9 and 12 months. After 1 year, those patients who did not consume pomegranate juice showed a 9% increase in IMT, while those consuming juice showed a decrease in IMT of up to 30%. Furthermore, for those drinking pomegranate juice, systolic (but not diastolic) blood pressure was reduced by 21%, total antioxidant status of the blood increased by 130%, LDL oxidation decreased by 90%, antibodies to oxidized LDL decreased by 19% and serum paraoxonase 1 (PON1) increased by 83%. Major blood biochemical markers were not affected, including levels of LDL and HDL cholesterol. Benefits were maintained in five patients who continued drinking pomegranate juice for 2 additional years, with further

improvements in serum lipid peroxidation.

(CX0473 (Compl. Ex. E-2 at 01:00)).

454. To emphasize the Aviram CIMT/BP Study (2004) results, a large bar graph titled **"Reduced Plaque"** appeared below the study summary. The "Reduced Plaque" bar graph measured the "% Reduction in Plaque Thickness," with a bar in red highlighting "-30%" for POM Wonderful Pomegranate Juice and a bar in gray showing "9%" for "No Pomegranate Juice." (CX0473 (Comp. Ex. E-2 at 01:00)). When "view full-size" was clicked, a larger version of the chart appeared. The red and gray bars were animated, strikingly depicting the "decrease in IMT of up to 30%" reported in the summary paragraph, with the red bar for POM Juice moving downward, and the gray bar for "No Pomegranate Juice" moving upward. (CX0473 (Complaint Ex. E-2 at 01:06)).



455. The link to the third study, the Aviram ACE/BP Study (2001), also took the consumer to another page with text and graphs. (CX0473 (Complaint Ex. E-2 at 01:25)). At the top of this page appeared a quote attributed to Dr. Aviram that:

> the significant inhibitory effect of pomegranate juice on serum ACE activity and the minor attenuation in blood pressure . . . in addition to its potent inhibitory effect on lipid peroxidation, suggests that pomegranate juice consumption may offer wide protection against cardiovascular diseases.

(CX0473 (Compl. Ex. E-2 at 01:25)). Study results were presented as follows:

> This pilot study demonstrates that pomegranate juice lowers blood pressure in patients with hypertension. Ten patients, ranging in age from 62 to 77, with an average blood pressure of over 155±7/83±7 drank 8 oz. (1.5 mmol total polyphenols equivalent) of POM Wonderful pomegranate juice each day for 2 weeks. This resulted in a 5% decrease in systolic blood pressure. ACE (angiotensin converting enzyme), which helps lower blood pressure, prevent heart disease and reduce the risk of stroke, was also decreased by 36%. Patients were already on ACE inhibitors or calcium channel blockers.

(CX0473 (Compl. Ex. E-2 at 01:25)).

456. To emphasize the Aviram ACE/BP Study (2001) results, a large bar graph titled "**Decreased ACE Activity**" appeared below the study summary. The graph measured "Average Serum ACE Activity," with a shorter red bar for average ACE activity after two weeks of POM Juice consumption (8oz./day) displayed next to a taller gray bar representing average ACE activity before POM Juice consumption. (CX0473 (Compl. Ex. E-2 at 01:25)). When "view full-size" was clicked, a larger version of the chart appeared, in which the bars were animated to depict the reported reduction in ACE activity after two weeks of POM Juice consumption. (CX0473 (Compl. Ex. E-2 at 01:28)).

457. The "Health Benefits" section pomwonderful.com also featured pages on "**Antioxidants**," "**Cancer**," "**Aging**," and "**Glossary**." (CX0473 (Compl. Ex. E-2 at 01:44)).

458. The "**Antioxidants**" page, depicting the POM Juice bottle with a superhero's cape, described the role of antioxidant-rich POM Juice in combating disease-causing free radicals: "Emerging science suggests that unstable little molecules called free radicals may be linked to disease. . . . Antioxidants like those found in POM Wonderful Pomegranate Juice fight hard to help prevent free radicals from doing their damage." (CX0473 (Compl. Ex. E-2 at 02:49) (underlined hyperlinks in original)).

459. The "**Antioxidants**" page also linked to "**The Importance of Antioxidants**" page, which elaborated on the mechanism of action involving free radicals, disease, and the "Antioxidant Superpower" POM Juice's ability to neutralize free radicals:

> Emerging science suggests that antioxidants are scavengers that can neutralize free radicals, which may help to prevent the cell and tissue damage that may be linked to disease. . . . Emerging science further suggests that when we eat fruits and vegetables, they may help protect us just as they help protect plants. With incredibly high levels of naturally occurring polyphenol antioxidants, POM Wonderful Pomegranate Juice is truly the Antioxidant Superpower™.

(CX0473 (Compl. Ex. E-2 at 03:10) (underlined hyperlinks in original)).

460. The "**Cancer**" page stated: "Emerging science has shown that diets rich in fruits and vegetables that contain antioxidants, along with regular exercise, might slow or help prevent the development of cancer. Two great sources of antioxidants are POM Wonderful Pomegranate Juice and POM Tea." The page featured a link to the Pantuck Phase II Prostate Cancer Study (2006). (CX0473 (Compl. Ex. E-2 at 03:45)).

461. The "**POM Glossary**" page defined terms used throughout pomwonderful.com, such as "ACE," "Atherosclerosis," "Free Radicals," and "Plaque." (CX0473 (Compl. Ex. E-2 at 04:15-07:08)).

462. The "POM Glossary" definitions advertised the benefits of POM Juice. For example, the definition of "ACE" (*i.e.*, angiotensin-converting enzyme) included the statement, "[r]esearch shows POM Wonderful reduced ACE by 36% in ten elderly patients with high blood pressure after drinking an 8 oz. glass a day for only 2 weeks and also lowered their systolic blood pressure by 5%." (CX0473 (Compl. Ex. E-2 at 04:15)).

463. The "POM Glossary" definition of "Atherosclerosis" concluded with "Naturally, the less plaque, the better. And that's where POM Wonderful comes in. A pilot study of 19 elderly patients with atherosclerosis showed that an 8 oz. glass a day can reduce plaque build-up in the arteries by up to 30%." (CX0473 (Compl. Ex. E-2 at 5:04)).

464. Similarly, the "POM Glossary" definition of "Plaque" stated: "What we're talking about is a common cause for heart attack and stroke. Naturally, the less plaque, the better. And that's where POM Wonderful comes in. A pilot study of 19 elderly patients with atherosclerosis showed that an 8 oz. glass a day can reduce plaque build-up in the arteries by up to 30%." (CX0473 (Compl. Ex. E-2 at 06:36) (hyperlink omitted)).

465. At the bottom of the "POM Glossary" page was a link button labeled "**Healthcare Professionals**," and the medical caduceus symbol. (CX0473 (Compl. Ex. E-2 at 07:03)). This "Healthcare Professionals" link button appeared at the bottom of nearly all of the pages in the "Health Benefits" section of pomwonderful.com. (*See*, *e.g.*, CX0473 (Compl. Ex. E-2 at 00:23, 00:44, 01:25, 02:45, 07:18)).

466. The main page of the **"Healthcare Professionals"** section depicted the POM Juice bottle wearing a stethoscope. (CX0473 (Compl. Ex. E-2 at 07:22)). The POM logo at the top of the page also contained the silhouette of the caduceus symbol within the red heart-shaped "O" in "POM." Other related pages in this section depicted POM Juice being poured into a teaspoon with the headline "**Powerful Antioxidant Prescription**." (CX0473 (Compl. Ex. E-2 at 07:28)).

467. Another "Healthcare Professionals" page titled "Getting Your Patients Started," displayed the POM Juice bottle on a medicine cabinet shelf, and referenced "[y]ears of research" and ongoing clinical studies "based on consumption of 8 oz. of 100% POM Wonderful Pomegranate Juice daily." (CX0473 (Compl. Ex. E-2 at 07:40)). The page also displayed the following warnings for "Special Patient Populations":

- According to the American Dietetic Association, 3.5 oz of POM Wonderful 100% Pomegranate Juice equals one fruit serving for diabetics.
- Because the juice contains high levels of potassium, patients who must avoid potassium should not drink pomegranate juice.

(CX0473 (Compl. Ex. E-2 at 08:02)).

468. Pomwonderful.com also included a page titled, "**The Science of POM Wonderful**." (CX0473 (Compl. Ex. E-2 at 08:58)). The page depicted the POM bottle alongside a microscope with the text,

> A number of top scientists in their fields, including a Nobel Laureate, are researching areas covering antioxidant activity, cardiovascular disease, circulation, cancer and others. To date, multiple pilot, peer-reviewed studies have been completed and published, while a number of others are still in progress.

(CX0473 (Compl. Ex. E-2 at 08:58) (underlined hyperlink in original)).

The "peer-reviewed studies" link took the consumer to another page titled, "**Real Studies. Real Results**," which summarized and provided explanatory text and graphs on

the Aviram CIMT/BP Study (2004) and the Aviram ACE/BP Study (2001). (CX0473 (Compl. Ex. E-2 at 09:01); *see* CCFF ¶¶ 435-456)).

469. "The Science of POM Wonderful" page also listed studies in bibliography format under the headings, "Cardiovascular Studies," "Cancer Studies," "Erectile Function," "Antioxidant Composition Studies," "Diabetes Studies," and "Bioavailability Studies." The study listings included links to the study papers. (CX0473 (Compl. Ex. E-2 at 10:15-12:09)).

470. In addition, pomwonderful.com has featured a gallery of previous and current advertisements that have appeared in other media. (Rushton, Tr. 1364). The "**POM Ads**" section of pomwonderful.com contained a selection of video ads, including one that opened with the image of three adults wearing white lab coats, seated at a table. In the video, the scientist seated in the center holds a pomegranate as a voice-over narrates,

> *Pomegranate contains powerful antioxidants needed to prevent cancer and diseases.*
>
> As the scientist seated on the left struggles to open the pomegranate, the scientist seated on the far right places a straw into a bottle of POM Juice and effortlessly drinks. The voiceover adds,
>
> *POM Juice makes it a little easier.*

(CX0473 (Compl. Ex. E-3 at 00:20)).

471. The pomwonderful.com website, through textual references, graphs, and medical imagery, touts POM Juice's "health benefits," "real studies [and] real results," and POM's research on heart disease, prostate cancer, erectile dysfunction, and other health conditions. . The pomwonderful.com website conveys the net impression that drinking eight ounces of POM Juice daily treats, prevents, or reduces the risk of heart disease, prostate cancer, and erectile dysfunction, and that these health benefits are clinically proven. *(See* CCFF ¶¶ 443-470).

2. The "Community" Version of Pomwonderful.com Made Establishment Claims Regarding Heart Disease, Prostate Cancer, and Erectile Dysfunction

472. The pomwonderful.com site was frequently updated and reworked to satisfy Mrs. Resnick. (Rushton, Tr. 1372; *see also* CCFF ¶ 242 (regarding the launch of the "Community" version of pomwonderful.com)).

473. On the October 2009 homepage of pomwonderful.com, the rotating frames displayed the text:

> **Backed by Science.**
>
> POM Wonderful products are backed
> by $32 million in medical research.
>
> **READ OUR PUBLISHED STUDIES ►**

(CX0473 (Oct. 2009, pomwonderful.com at 00:23)).

The "$32 million" in medical research statistic was also noted in other parts of the website, including under "**Our Health Story**," in the "**Health**" section, and on the "**Our Company**" and "**POM Truth**" pages in the "**About**" section. (CX0473 (Oct. 2009, pomwonderful.com at 01:00, 05:17, 05:50, 06:30); *see also* CX0473 (Jan. 2010, pomwonderful.com at 01:38, 01:47, 1:58)).

474. In December 2009, one of the rotating frames on the pomwonderful.com homepage displayed the headline "Let's Talk about Prostate Cancer with David Heber, MD. Center for Human Nutrition, UCLA. What is the relationship between nutrition and cancer? See what the doctor says ►" (CX0473 (Dec. 2009, pomwonderful.com at 00:15)).

475. The "See what the doctor says" link took the consumer to a page in the "Community" section of pomwonderful.com titled "The relationship between cancer and nutrition," where the video, "Let's Talk about Prostate Cancer with David Heber, MD," could be viewed. The introductory text on this page noted that "David Heber, MD is the Director of the Center for Human Nutrition at UCLA. You can find POM Wonderful studies by Dr. Heber in the POM Health section of our site." (CX0473 (Dec. 2009, pomwonderful.com at 00:15-07:15) (hyperlinks omitted)).

476. In the "Let's Talk about Prostate Cancer" video, Dr. Heber answered questions about prostate cancer, including:

> THE QUESTION
> Is there anything new you're working on now that is particularly exciting?
>
> [DR. HEBER:] We're working a lot on pomegranate juice and pomegranate extracts right now . . . . We've found that the pomegranate inhibits inflammation in the prostate gland, that it also inhibits prostate cancer growth in animals, both in early prostate cancer and advanced prostate cancer. And in humans, we were able to reduce the rate of rise of PSA in men with prostate cancer. There are some large trials now confirming that early trial, which hopefully will be completed within the next year. So I think that's a very interesting area. . . .

(CX0473 (Oct. 2009, pomwonderful.com at 05:53-07:15)).

477. In October 2009, pomwonderful.com's "**Health**" section included pages titled "**POM Health**," "**Research Study Synopses**," "**Glossary**," "**Healthcare Professionals**," and "**Expert Articles**." (CX0473 (Oct. 2009, pomwonderful.com at 00:50)).

478. The "**Health**" section included a page on "**Other Protective Effects**," stating, "[i]n addition to being the superior free radical scavenger, POM Wonderful's unique antioxidants have been shown to have other protective effects against oxidative stress." (CX0473 (Oct. 2009, pomwonderful.com at 01:50)). Under the bold heading "**Inhibition of LDL Oxidation**," the page stated:

> Pomegranate juice has a superior ability to prevent LDL cholesterol from being oxidized by free radicals. Emerging science suggests that LDL oxidation may be a precursor to atherosclerosis or arterial plaque.
>
> This point was further emphasized with a graph showing POM Juice beating other antioxidant containing beverages in "Inhibition of LDL Oxidation" and a citation to a paper by N. Seeram, et al., on *Comparison of Antioxidant Potency of Commonly Consumed Polyphenol-Rich Beverages in the United States*.

(CX0473 (Oct. 2009, pomwonderful.com at 01:55) (underlined hyperlinks in original)).

479. The "**Other Protective Effects**" page also featured a section on "**Protecting Nitric Oxide**." The section cited a 2006 published study by Louis J. Ignarro, identified as the "recipient of the Nobel Prize in Medicine," that "documented that pomegranate juice is uniquely potent in inhibiting the destruction of nitric oxide." The discussion concluded with "POM Wonderful 100% Pomegranate Juice was shown [in Dr. Ignarro's study] to be over one hundred times more potent than blueberry juice, concord grape juice and red wine." (CX0473 (Oct. 2009, pomwonderful.com at 01:56)).

480. The "**Health**" section page on "**Other Resources**," cited a 2009 article by Dr. Heber titled, "Oxidant Stress and Antioxidants." Next to a photo of Dr. Heber was a short biography and a description of Dr. Heber's "primary areas of research," including "the role of nutrition, phytochemicals, and botanical dietary supplements in the prevention and treatment of common forms of cancer and cardiovascular disease." (CX0473 (Oct. 2009, pomwonderful.com at 02:20)).

481. The "**Health**" section also included a page of "**Research Study Synopses**." The introductory text explained that the published studies were on POM Juice and POMx. (CX0473 (Oct. 2009, pomwonderful.com at 02:43)). The study synopses, which also contained links to the full study texts, were grouped under categories such as "**Cardiovascular,**" with subgroups "Atherosclerosis" and "Blood Flow/Pressure"; "**Prostate Cancer**"; "**Diabetes – Type II**"; and "**Erectile Function.**" (CX0473 (Oct. 2009, pomwonderful.com at 02:45-02:52)). These synopses appeared on a page titled "**Featured Scientific Studies**" in December 2009 and January 2010. (CX0473 (Jan. 2010, pomwonderful.com at 00:21-00:50); CX0473 (Dec. 2009, pomwonderful.com at 07:40)).

482. In October 2009, the "**Atherosclerosis**" subsection cited the Davidson CIMT Study (2009) as "a randomized, placebo-controlled, double-blind clinical trial follow[ing] 289 subjects at moderate risk for coronary heart disease. These subjects consumed 8 ounces per day of either [POM Juice] or a placebo beverage." (CX0473 (Oct. 2009, pomwonderful.com at 02:45)).

483. Although the description of the Davidson CIMT Study (2009) conceded that "[a]fter 18 months, there was no reduction in the progression of intima-media thickness of the carotid artery (CIMT) in the POM group as a whole," the paragraph continued with the caveat, "[h]owever, further analysis revealed that the rate of CIMT progression slowed in

nearly one third of POM patients, those with elevated cardiovascular disease risk factors." (CX0473 (Dec. 2009, pomwonderful.com at 07:40-07:44)).

484. Further defusing the finding of no reduction at 18 months, the paragraph went on to describe the positive results of the Aviram studies, reporting, for example, a 30% reduction in intima-media thickness of the carotid artery and a 20% decrease in the amount of LDL cholesterol oxidation. Although there were links to "read the study," the paragraph did not disclose that these positive results came from studies published in 2001 and 2004 with less than 30 people total, well before the 289-person study. (CX0473 (Oct. 2009, pomwonderful.com at 02:45); CX0473 (Dec. 2009, pomwonderful.com at 07:40-07:44); *see also* CX0542; CX0611).

485. The "**Prostate Cancer,**" subsection, in addition to describing the Pantuck Phase II Prostate Cancer Study (2006), noted "[a] longer term (6-year) continued evaluation of active sub-group patients showed a further increase in PSA doubling time to 88 months [from 54]." (CX0473 (Jan. 2010, pomwonderful.com at 00:38)). This information is not part of a published study. (PX0061; CX0815; CX0955).

486. In December 2009 and January 2010, pomwonderful.com featured blog posts by "Pom Experts" like Dr. Aviram. (CX0473 (Dec. 2009, pomwonderful.com at 08:06); CX0473 (Jan. 2010, pomwonderful.com at 00:54-01:01)).

487. In his blog post on "The Unique Antioxidants of Pomegranates," Dr. Aviram stated:

> [P]omegranates are superior to other antioxidants in protecting LDL ("the bad cholesterol") from oxidation (Aviram, Am Clin Nutr, 2000), and as a result, it inhibits atherosclerosis development, even in humans (Aviram, Clin Nutr, 2004), as well as its consequent cardiovascular events better than any other nutritional antioxidant. . . .
>
> Furthermore, pomegranate antioxidants are unique in their ability to increase the activity of the HDL ("the good cholesterol") . . . which breaks down harmful oxidized lipids in the atherosclerotic plaque.
>
> Finally, the unique antioxidants in pomegranates beneficially affect
> two additional important atherosclerotic processes by decreasing

blood pressure (Aviram, At *[sic]* Atherosclerosis, 2001).

(CX0473 (Oct. 2009, pomwonderful.com at 07:00-07:25)).

488. In the "**Community**" section of pomwonderful.com from December 2009, a page titled "**POM's Health Benefits: Fact or Fiction**" quoted Respondent Tupper as stating:

> "Based on the research that's been published on POM Juice, it's clear that Mother Nature gave this unique fruit some very special properties. As our scientists like to say, POM Juice is truly 'health in a bottle.' When you look at the medical research that has been conducted on POM and compare it to research that's been done on other foods and beverages, what's been done on POM is way, way more extensive. It's almost more akin to research being done on pharmaceutical drugs."

(CX0336_0001)

489. The same "**POM's Health Benefits: Fact or Fiction**" page quoted Dr. Gillespie, identified as "Vice President of Clinical Development," as stating, "[s]ome of our research areas are beginning to accumulate quite impressive clinical data. For example, I think the human evidence in prostate health is one of the strongest areas, and we continue to fund more research here. Also, there could be some additional research done in cardiovascular health and erectile function, as well as several other areas." (CX0336_0001).

490. In the "**Community**" section of pomwonderful.com from December 2009, a page titled "**POM: Sweet – And Safe for Diabetics**" quoted Mr. Tupper as stating,

> There have actually been several studies published about diabetic patients who consume 8 ounces of POM juice every day over an extended period. Over the course of the studies, various parameters of diabetics, blood sugar as well as other important blood markers did not worsen.
>
> On the flipside, the patients' state of oxidative stress, which is a measurement of how much free radical pressure exists in your body, actually decreased. Diabetes is a very complicated disease, with many potential side effects. Diabetics are at risk for heart disease, kidney disease and other complications, many of which

> are fundamentally a result of oxidative stress. Since diabetics often experience higher levels of oxidative stress, the uniquely strong natural antioxidants that make POM so healthy are particularly beneficial.

(CX0336_0003 (hyperlinks omitted)). *But see* CCFF ¶ 467 (POM included warning to healthcare professionals elsewhere on its website that according to the American Dietetic Association, only 3.5 oz of POM Juice equals one fruit serving for diabetics).

491. In the "**Community**" section of pomwonderful.com from December 2009, a page titled "**What Exactly Are Antioxidants Anyway?**" quoted Mr. Tupper as stating,

> It's fine to say a product works as an antioxidant in a test tube, but that's just scratching the surface. What you really have to do is make sure that your product – and the antioxidants – end up being absorbed by your body, get transported through your blood stream, and make it to your vital organs, because that's really where the benefit occurs. Which is why we go beyond the test tube and do all this clinical research. <u>It isn't until you see an effect in humans with measurements that are medically meaningful that you know you've got something going on.</u>

(CX0336_0010 (emphasis added)).

492. The "**POM Community**" section of pomwonderful.com in December 2009 included consumer testimonials. (CX0336_0011-19). One message from a consumer stated, "I have been drinking POM for about a month, daily . . . I can tell you that I feel much better!! My cholesterol and Blood pressure are slightly lower . . . I do not know if these things are related but I Swear by POM! I call it 'Pomegranate Power!!'" (CX0336_0015).

493. Also in the "**POM Community**" section, another consumer stated, "I'm writing to tell you what POMwonderful *[sic]* has done for my mother suffering from a severe heart infection," continuing, "[w]e have stocked up on the juice and she swears that the pomegranate juice helped keep her immunity up through her vulnerable time and is also what has kept [the] infection from getting worse due to keeping her heart functions strong and the bloo[d] flowing more efficiently." (CX0336_0017).

494. The October 2009, December 2009, and January 2010 versions of pomwonderful.com,

through textual references, graphs, medical imagery, consumer testimonials, and "expert articles," tout POM Juice's "health benefits," "medical results," and POM's research on heart disease, prostate cancer, and erectile dysfunction, and other health conditions. Pomwonderful.com conveys the net impression that drinking eight ounces of POM Juice daily treats, prevents, or reduces the risk of heart disease, prostate cancer, and erectile dysfunction, and that these health benefits are clinically proven. (*See* CCFF ¶¶ 473-493).

495. More recently, pomwonderful.com has made marketing claims for POM's sports recovery drink that were similar in tone to the challenged claims in this case. For example, the website's description of the drink included statements like, "How did POM perform in published clinical research?"; "**Speeds muscle recovery** – POM reduced post-exercise strength loss by more than 30% compared to a placebo."; "**Reduces muscle soreness**" – POM reduced post-exercise soreness by 28% compared to a placebo." The page also displayed under the heading "Super effective," a graph illustrating "Faster Strength Recovery," comparing the drink to the placebo. Explanatory bullet points accompanying the graph state: "Preliminary clinical studies have shown promising post-exercise benefits, including faster strength recovery and reduced pain following weight lifting" and "Results based on daily 2oz dosage." (CX0473 (May 2010, pomwonderful.com at 00:40-01:38)).

3. Pomegranatetruth.com Made Establishment Claims Regarding Heart Disease, Prostate Cancer, and Erectile Dysfunction

496. The pomegranatetruth.com homepage was titled "**The truth about our pomegranates**" and stated at the center of the page in a bold subheading, "**Backed by science.** Directly following this heading, flanked by a large image of the medical caduceus symbol, was the explanatory text:

> POM is the only pomegranate juice backed by $25 million in medical research. To date, numerous published clinical studies have documented the benefits of drinking pomegranate juice, benefits that include improved heart and prostate health and better erectile function. **All of these studies featured patients who drank POM Wonderful 100% Pomegranate Juice, not any other brands.** Read more.

(CX0473 (Compl. Ex. E-1 at 00:10)).

497. The "Read more" link directed the consumer to a page titled, in large, bold, red letters,

"**Backed by Science**." (CX0473 (Compl. Ex. E-1 at 01:15)). The "**Backed by Science**" page reiterated that "POM is the only pomegranate juice backed by $25 million in medical research," continuing, "Actually, we are the only pomegranate juice backed by any medical research at all." Reinforcing the scientific theme was a large image of the POM Juice bottle depicted with projecting arms of a molecular model chemistry set. (CX0473 (Compl. Ex. E-1 at 01:15)).

498. After urging the consumer to "keep in mind that all of the research has been done on POM Wonderful 100% Pomegranate Juice" and that "[n]o other pomegranate juice can claim these distinctions, and no other brand has been clinically tested," the "**Backed by Science**" page states, "So what are the medical results on POM Wonderful 100% Pomegranate Juice?" (CX0473 (Compl. Ex. E-1 at 01:17); *see also* CX0473 (Compl. Ex. E-1 at 03:58) (stating on the "Wonderfully superior" page of pomegranatetruth.com that "POM is the only pomegranate juice made exclusively from the Wonderful variety, which is the only variety featured in all of the promising medical research you have heard about," and "[p]atients drinking POM Wonderful 100% Pomegranate Juice in clinical trials have experienced promising results in hearth health, prostate health, and erectile function.")).

499. Selected "medical results" from the Ornish MP Study (2005), the Pantuck Phase II Prostate Cancer Study (2006), and the Forest Erectile Dysfunction Study (2007) were presented under the bold subheadings "**Heart Health**," "**Prostate Health**," "**Erectile Dysfunction**," respectively. (CX0473 (Compl. Ex. E-1 at 01:25)). The study descriptions were substantially similar to those on the pomwonderful.com website. (*See* CCFF ¶¶ 445-447, 449).

500. The pomegrantetruth.com website, through textual references and medical imagery, touts POM Juice's "health benefits," "medical results," and POM's research on heart disease, prostate cancer, and erectile dysfunction, and other health conditions. The pomegrantetruth.com website conveys the net impression that drinking eight ounces of POM Juice daily treats, prevents, or reduces the risk of heart disease, prostate cancer, and erectile dysfunction, and that these health benefits are clinically proven. (*See* CCFF ¶¶ 496-499).

4. Pompills.com Made Establishment Claims Regarding Heart Disease, Prostate Cancer, and Erectile Dysfunction

501. The pompills.com website was an e-commerce site and had everything from learning about the product to ordering the product. (CX1347 (Glovsky, Dep. at 134)).

502. The pompills.com homepage displayed the large, bold heading "**Antioxidant Superpill**," accompanied by the image of a bottle of POMx Pills. The equivalence of POMx Pills to POM Juice was immediately communicated in the subheading "**The Power of POM. Now in a single pill**," and by the image in the center of the homepage of a bottle of POMx Pills connected by an equals sign to an eight-ounce bottle of POM Juice. The caption under this image stated, "[a]ll the antioxidant power of an 8oz. glass of POM Wonderful 100% Pomegranate Juice in the convenience of a calorie-free capsule." A red button to "**BUY NOW**" appeared prominently below this description. (CX0473 (Compl. Ex. E-8 at 00:10)).

503. In April 2009, the menu bar at the top of the pompills.com homepage included links to "**Health Benefits**," "**Potency**," "**POMx Pills**," "**POMx Liquid**," and "**Buy Now**." (CX0473 (Compl. Ex. E-8 at 00:10)). In January 2010, "**Health Benefits**," was replaced with "**Medical Research**" on the menu bar. (CX0473 (Compl. Ex. E-9 at 00:04)).

504. The "**POMx Pills**" page displayed the headline "**Take it daily. Feel it forever.**" The message that POMx Pills are equivalent to POM Juice was conveyed in the subheadings, "**One POMx Pill = the antioxidant power of an 8oz glass of POM Wonderful 100% Pomegranate Juice**," and "**POM in a Pill**"; in the text "All of the antioxidant power of POM Wonderful 100% Pomegranate Juice is now available in a supplement. So you can still get your daily antioxidants from an 8oz. glass of juice, or now the convenience of a calorie-free pill"; and in a caption to a diagram of a POMx Pill reading "fact 2. The antioxidant power of an 8oz. glass of juice, in a calorie-free pill." (CX0473 (Compl. Ex.

E-8 at 00:15-00:25)).

505. The "**POMx Pills**" page also displayed a red "**BUY NOW**" button. (CX0473 (Compl. Ex. E-8 at 00:15-00:25)).

506. The toll-free number for placing orders, 1-888-POM-PILL, appeared at the bottom of nearly all pages on the pompills.com website. (CX0473 (Compl. Ex. E-8 at 04:23)).

507. The "**POMx Pills**" page stated, "Research has shown that the naturally occurring polyphenol antioxidants in pomegranates have extraordinary health benefits." Continuing down the page, other bold subheadings touted POMx Pills as "**The Most Concentrated Source of Pomegranate Antioxidants Available**" and "**Ultra Potent**." (CX0473 (Compl. Ex. E-8 at 00:25)).

508. Under the subheading "**Science, Not Fiction**," the "**POMx Pills**" page stated:

- Made from the only pomegranates backed by $25 million in medical research and the POM Wonderful brand
- Clinically tested
- Proven to be easily absorbed
- Guards your body against free radicals
- Promotes prostate and heart health

(CX0473 (Compl. Ex. E-8 at 00:35)).

509. The "**POMx Liquid**" page featured the headline "**Not for the Faint of Heart**." Directly below this headline, a subheading stated, "**POMx Liquid: The most concentrated source of pomegranate antioxidants available**," elaborating, "[t]ake your antioxidants into your own hands. The Antioxidant Superpower is now available in a single teaspoon. POMx Liquid is a highly concentrated, incredibly powerful blend of all-natural polyphenol antioxidants made from the very same pomegranates in POM Wonderful 100% Pomegranate Juice." (CX0473 (Compl. Ex. E-8 at 01:00)).

510. The "**POMx Liquid**" page also depicted the POMx Liquid bottle and teaspoon with the caption, "One teaspoon = the antioxidant power of 8oz. of POM Wonderful 100% Pomegranate Juice" and a link to "BUY NOW." (CX0473 (Compl. Ex. E-8 at 01:00)).

511. The "**POMx Liquid**" page contained substantially similar language touting the research behind the product as the POMx Pills page. (*Compare* CX0473 (Compl. Ex. E-8 at 00:35) *with* (CX0473 (Compl. Ex. E-8 at 01:15)).

512. The "**Health Benefits**" section of pompills.com featured links to web pages titled "Research," "Antioxidant Benefits," "Heart Health," and "Prostate Health." (CX0473 (Compl. Ex. E-8 at 01:38)).

513. A list of study citations followed this introduction under the headings "**Cardiovascular Studies**," "**Cancer Studies**," "**Chemical Composition Studies**," "**Diabetes Studies**," and "**Bioavailability Studies**." (CX0473 (Compl. Ex. E-8 at 01:43-04:23)).

514. The "**Cardiovascular Studies**" listed on the "**Research**" page included those with titles like, "Pomegranate juice improves myocardial perfusion in coronary heart patients," "Pomegranate juice pilot research suggest anti-atherosclerosis benefits," and "Pomegranate juice helps promote normal systolic blood pressure." (CX0473 (Compl. Ex. E-8 at 01:41)). These titles were POM's paraphrases of the studies' actual titles. (CX0473 (Compl. Ex. E-8 at 01:43-02:31)). For example, the study POM listed as "Pomegranate juice improves myocardial perfusion in coronary heart patients," was published with the title "Effects of Pomegranate Juice Consumption on Myocardial Perfusion in Patients with Coronary Heart Disease." (CX0473 (Compl. Ex. E-8 at 02:05-02:10)).

515. The "**Cancer Studies**" listed on the "**Research**" page included those with titles like, "Pomegranate juice delays PSA doubling time in humans," "Pomegranate polyphenols have anti-inflammatory effects on colon cancer cells," and "Pomegranate juice shows superior anti-cancer bioactivity when compared to its purified compounds." (CX0473 (Compl. Ex. E-8 at 02:56)). These titles were POM's paraphrases of the studies' actual titles. (CX0473 (Compl. Ex. E-8 at 02:34-03:10)). For example, the study POM listed as "Pomegranate juice delays PSA doubling time in humans," was published with the title "Phase II Study of Pomegranate Juice for Men with Rising Prostate-Specific Antigen Following Surgery or Radiation for Prostate Cancer." (CX0473 (Compl. Ex. E-8 at 02:34-02:45)).

516. The "**Diabetes Studies**" listed on the "**Research**" page included those with titles like, "Pomegranate juice has antioxidant benefits for people with type 2 diabetes," and "Pomegranate juice stimulates unique antioxidant function relevant to diabetes." (CX0473 (Compl. Ex. E-8 at 02:56)).

517. Another page, titled "**Why take an antioxidant supplement?**" described free radicals as "unstable molecules [that] aggressively destroy healthy cells in our bodies and may be linked to everything from the wrinkles we get as we age to more serious health threats like cancer and heart disease. In fact, scientists have already linked free radicals to as many as 60 different types of diseases." (CX0473 (Compl. Ex. E-8 at 04:37)). Farther down the page, under the red, bold subheading "POMx: The Antioxidant Superpill," was the text:

> It's enough to make other antioxidants feel inferior: in the fight against free radicals, POMx is the Antioxidant Superpill. POMx fights free radicals with more concentrated pomegranate antioxidants than any other 100% pomegranate supplement. . . . POMx is made from the only pomegranates with $25 million in medical research behind them, and backed by the POM Wonderful brand. A single capsule or teaspoon of POMx gives you all the antioxidant power of an 8oz. glass of POM Wonderful 100% Pomegranate Juice – the very same juice that in a preliminary UCLA medical study showed hopeful results for men with prostate cancer.

(CX0473 (Compl. Ex. E-8 at 04:50)).

518. A section on "**Heart Health**" stated:

> We have researched the effects of pomegranate juice on cardiovascular health for almost 10 years, and findings suggest that pomegranate juice may help counteract factors leading to arterial plaque build-up, as well as inhibit a number of factors associated with heart disease. Initial pre-clinical tests have shown that POMx has equivalent cardiovascular benefits to POM Wonderful Juice, and additional studies are now going on. Learn more.

The "Learn more" link took the consumer to a page titled "**The Heart of The Matter**."

(CX0473 (Compl. Ex. E-8 at 05:05) (underlined hyperlink in original)).

519. "**The Heart of The Matter**" page displayed a large image of the medical caduceus symbol. Directly under this image was a link to "Order POM Pills Now!" Next to the medical caduceus symbol was the subheading in red, "Amaze your cardiologist. Take

POMx." The explanatory text under "Amaze your cardiologist" stated:

> POMx is made from the only pomegranates supported by $25 million of initial scientific research from leading universities . . . . The very same pomegranates in POM Wonderful 100% Pomegranate Juice that showed encouraging results in initial cardiovascular health studies.
>
> Let's start with some facts: atherosclerosis (or too much plaque in the arteries) is a leading cause of heart disease. Emerging science suggests that free radicals may be the culprits that can oxidize LDL
> (also known as "bad" cholesterol) – turning it into plaque that clogs up arteries. And science also tells us that pomegranate antioxidants neutralize free radicals.

(CX0473 (Compl. Ex. E-8 at 05:09)).

520. "**The Heart of the Matter**" page also presented summaries of the Aviram CIMT/BP Study (2004) and the Ornish MP Study (2005) that were substantially similar to those on pomwonderful.com. (CX0473 (Compl. Ex. E-8 at 05:10); *see also* CCFF ¶ 449 (summaries of the Aviram and Ornish studies)).

521. The "**Prostate Health**" section of the "**Health Benefits**" page stated "A preliminary UCLA medical study on POM Wonderful 100% Pomegranate Juice showed hopeful results for men with prostate cancer who drank an 8oz. glass of pomegranate juice daily. And every POMx capsule provides the antioxidant power of an 8oz. glass of POM Wonderful 100% Pomegranate Juice. Learn more." (CX0473 (Compl. Ex. E-8 at 05:50)). The "Learn more" link took the consumer to a page titled "**Pomegranates and Prostate Health**." (CX0473 (Compl. Ex. E-8 at 05:55) (underlined hyperlink in original)).

522. Like "**The Heart of the Matter**" page, the "**Pomegranates and Prostate Health**" page also prominently displayed the medical caduceus symbol. Directly under the caduceus symbol was a quote from the July 4, 2006 issue of *The New York Times* that "Findings from a small study suggest that pomegranate juice may one day prove an effective weapon against prostate cancer." (CX0473 (Compl. Ex. E-8 at 05:55)).

523. On the "**Pomegranates and Prostate Health**" page the explanatory text under the

subheading "**Prostate Health**" focused on prostate cancer:

> Prostate cancer is the most commonly diagnosed cancer among men in the United States, and the second leading cause of cancer death in men, after lung cancer. However, emerging science suggests that diet, lifestyle and dietary supplements may improve prostate health.

(CX0473 (Compl. Ex. E-8 at 05:55)).

524. Following this statement about prostate cancer, the "**Pomegranates and Prostate Health**" page referenced the Pantuck Phase II Prostate Cancer Study (2006), interpreting the reported result as indicating a "350% increase" in PSA doubling time:

> Men who had been treated surgically or with radiation for prostate cancer were given 8oz. of POM Wonderful 100% Pomegranate Juice. A majority of the 46 men participating in the study experienced a significantly extended PSA doubling time. . . . Before the study of pomegranate juice, the average PSA doubling time for the participants was 15 months. After drinking 8oz. of juice daily, the average PSA doubling time increased to 54 months. That's a 350% increase.

(CX0473 (Compl. Ex. E-8 at 05:55)).

The page also explained that "PSA (prostate-specific antigen) is a marker that is thought to be associated with the progression of prostate cancer; a slower PSA doubling time may reflect slower progression of the disease." Placing the mouse over the hyperlinked word "doubling time" produced a pop-up text box that reiterated, "The amount of time it takes for the prostate-specific antigen[s] (also called PSA levels) to double in men with prostate cancer may reflect the progression of the disease. A longer doubling time may indicate a slower growing cancer." (CX0473 (Compl. Ex. E-8 at 05:55-05:59) (underlined hyperlink in original)).

525. Consistent with the statement on the "**Health Benefits**" page that "every POMx capsule provides the antioxidant power of an 8oz. glass of POM Wonderful 100% Pomegranate Juice," (*see* CCFF ¶ 524) the "**Pomegranates and Prostate Health**" page quoted Dr. Heber, identified as "Director of UCLA's Center for Human Nutrition," as stating:

> ***The most abundant and most active ingredients in Pomegranate***

Juice are also found in POMx. Basic studies in our laboratory so far indicate that POMx and Pomegranate Juice have the same effect on prostate health.

(CX0473 (Compl. Ex. E-8 at 05:59)).

526. The pompills.com website also featured an "**FAQs**" page. (CX0473 (Compl. Ex. E-8 at 07:51)). The first set of FAQs, under the subheading "**Pomegranates and Health**," included questions like, "**Heart Disease: How does drinking pomegranate juice help the fight against cardiovascular disease?**"; "**Prostate Cancer: There has been promising news on the benefits of pomegranate juice in the fight against prostate cancer. Is this really true?**"; and "**Erectile Dysfunction: Can pomegranate juice benefit men with erectile dysfunction?**" (CX0473 (Compl. Ex. E-8 at 07:51)).

527. The response to the FAQ "**Heart Disease: How does drinking pomegranate juice help the fight against cardiovascular disease?**" discussed "Improved Cardiac Blood Flow" and "Decrease in Arterial Plaque," again summarizing the results from the Ornish MP Study (2005) and the Aviram CIMT/BP Study (2004). (CX0473 (Compl. Ex. E-8 at 09:05)).

528. The response to the FAQ "**Heart Disease: How does drinking pomegranate juice help the fight against cardiovascular disease?**" also stated that "Initial pre-clinical tests have shown that POMx has equivalent cardiovascular benefits as POM Wonderful 100% Pomegranate Juice, and human studies are now ongoing" and quoted Dr. Aviram, identified as "one of the world's preeminent cardiovascular researchers," as commenting, "*The results of our pre-clinical studies showed that POMx is as potent an antioxidant as pomegranate juice, and just like pomegranate juice may promote cardiovascular health*." (CX0473 (Compl. Ex. E-8 at 09:05); *but see* CCFF ¶ 395).

529. The response to the FAQ "**Prostate Cancer:** There has been promising news on the benefits of pomegranate juice in the fight against prostate cancer. Is this really true?" once again summarized the Pantuck Phase II Prostate Cancer Study (2006). (CX0473 (Compl. Ex. E-8 at 09:05)). The answer went on to state that "[a] new study is underway to more fully investigate the potential of POMx to extend PSA doubling time" and quoted Dr. Heber, identified as "Director of UCLA's Center for Human Nutrition," as commenting, "*The most abundant and most active ingredients in pomegranate juice are also found in POMx. Basic studies in our laboratory so far indicate that POMx and pomegranate juice may have the same effects*." (CX0473 (Compl. Ex. E-8 at 09:05)).

530. The response to the FAQ "**Erectile Dysfunction: Can pomegranate juice benefit men with erectile dysfunction?**" cited the Forest Erectile Dysfunction Study (2007), stating: "Initial results linking POM Wonderful 100% Pomegranate Juice and erectile performance are promising. In a soon-to-be-published clinical study on men with erectile dysfunction, the group who consumed 8oz. of POM Juice daily experienced better erectile performance than the group who drank a placebo." (CX0473 (Compl. Ex. E-8 at 9:05)).

531. The response to the FAQ "**Why are pomegranates and pomegranate juice so healthy?**" assured consumers that "Today, modern science confirms that the pomegranate is truly a medical marvel." (CX0473 (Compl. Ex. E-8 at 8:45) (emphasis added)).

532. Other FAQs repeatedly stressed the "extraordinary health benefits" of POMx and its polyphenol antioxidants. For example, in response to the FAQ, "**How long does it take for my system to get benefits of POMx?**" the response stated, "[b]ecause the polyphenol antioxidants in POMx are absorbed rapidly by the body, they can begin their healthy disease-fighting effects almost immediately. However, studies on POM Juice consumption have shown that it can take 1 to 2 years to see benefits." (CX0473 (Compl. Ex. E-8 at 10:34-10:53)).

533. The response to the FAQ "**Dosage: How much POMx should I take?**," stated "Whether you choose pills or liquid, it is important to remember that to reap POMx's full health benefits, you must take it every day." (CX0473 (Compl. Ex. E-8 at 11:03)).

534. In January 2010, under the subheading "**Science Not Fiction**, the "**POMx Pills**" and "**POMx Liquid**" touted that the amount of money POM purportedly spent on medical research was $32 million." (CX0473 (Compl. Ex. E-9 at 00:16, 00:30)). This $32-million figure also appeared throughout the rest of pompills.com, including in the "**Medical Research**" section, the "**Research**," "**Antioxidant Benefits**," and "**Heart Health**" pages, and the "**About Us**" section of the website. (*See, e.g.,* CX0473 (Compl. Ex. E-9 at 00:36, 00:55, 01:01, 01:22, 02:12)).

535. The pompills.com website, through textual references, graphs, and medical imagery, touts the "medical benefits" of POMx Pills and POMx Liquid, and POM's research on heart disease, prostate cancer, and erectile dysfunction, and other health conditions. The pompills.com website conveys the net impression that taking one POMx Pill or one teaspoon of POMx Liquid, daily, treats, prevents, or reduces the risk of heart disease,

prostate cancer, and erectile dysfunction, and that these health benefits are clinically proven. In addition, in representing that one POMx Pill or one teaspoon of POMx Liquid is equivalent to eight ounces of POM Juice, the pompills.com website also conveys the net impression that drinking eight ounces of POM Juice, daily, treats, prevents, or reduces the risk of heart disease, prostate cancer, and erectile dysfunction. (*See* CCFF ¶¶ 501-534).

5. Banner Ads Made Efficacy Claims Regarding Heart Disease and Prostate Cancer

a. "Heart Therapy" Banner Ad (CX0463)

536. In December 2008, POM disseminated an animated banner ad with the headline "Heart Therapy" depicting a bottle of POM Juice reclining on a couch, as in a therapist's office. The heart in the "POM" logo was animated to expand and contract, like a beating heart. The animation also included the sound effect of a beating heart. Under the image was the copy, "Backed by $25 million in medical research," with a link "Learn more" that directed the consumer to the pomwonderful.com website. (CX0463).

537. In an internal document on "POM On-line Banner ads," from October 2008, copy points for a "Heart Therapy," banner ad included: "POM Wonderful 100% Pomegranate Juice is backed by $25 million in medical research with promising results for cardiovascular health," "Only our pomegranate juice has real, proven heart health benefits," and "Keep your heart healthy and drink a glass a day." The document also described the "close" of the ad as "Call to action to get consumer to click-through to learn more about POM Juice and heart health: http://www.pomwonderful.com/health_benefits." (CX0246_0002).

538. The "Heart Therapy" banner ad, with the imagery and audio of the beating heart, "Heart Therapy" headline, and reference to "$25 million in medical research," conveys the net impression that POM Juice prevents or reduces the risk of heart disease. This net impression is even stronger if a consumer, as directed by the ad, were to click through to the pomwonderful.com website section on "Health Benefits." (*See* CCFF ¶¶ 536-37).

b. "I'm Off to Save Prostates" Banner Ad (CX0466)

539. In February 2009, POM disseminated an animated banner ad with the headline "HURRY! Prostates everywhere are in danger!" showing the POM Juice bottle flying like a super hero, then landing and announcing "I'm off to save PROSTATES!" The banner also displayed the copy "The Antioxidant Superpower," and a link to "Learn

more." (CX0466).

540. This banner ad, with its animated copy of "HURRY! Prostates everywhere are in danger!" and "I'm off to save PROSTATES!" conveys the net impression that POM Juice prevents or reduces the risk of prostate cancer. This net impression is amplified if a consumer, as directed by the ad, were to click through to the pomwonderful.com website. (*See* CCFF ¶ 539).

F. Health Claims in Public Relations Communications

1. POM's Press Releases Made Establishment Claims Regarding Heart Disease, Prostate Cancer, and Erectile Dysfunction

a. January 2003 Press Release (CX0013_0002-05)

541. POM issued a press release in January 2003 titled "Consumer Demand for POM Wonderful's Refrigerated All-Natural Pomegranate Juice Grows as the Health Benefits of Pomegranate Juice Become Recognized" with the subtitle "Scientific support indicates that drinking pomegranate juice provides the body with an active source of antioxidants and shows promise against cardiovascular disease." (CX0013_0002).

542. The press release touted that "the antioxidant activity of POM Wonderful pomegranate juice exceeds that of other popular beverages known for their antioxidant properties" and "antioxidants may be useful in counteracting premature aging, Alzheimer's, and cancer." (CX0013_0002).

543. Noting that "cardiovascular diseases rank as America's No. 1 killer," the press release stated that "[m]edical research shows that daily consumption of just 1.5 mmol of polyphenols from pomegranate juice (the equivalent of an 8 fl oz serving of P♥M Wonderful pomegranate juice) confers heart health benefits by lessening factors that contribute to atherosclerosis (plaque in the arteries)." (CX0013_0002).

544. The press release presented, among other research, the results of the Aviram ACE/BP Study (2001), a "human study show[ing] that consuming pomegranate juice reduce[d] . . . ACE." Explaining that "[i]nhibition of ACE lessens the progression of atherosclerosis," the press release stated that "[p]omegranate juice inhibited ACE by 36% after two weeks of juice consumption." (CX0013_0003).

545. The press release neither disclosed that Respondents sponsored the Aviram ACE/BP Study (2001) nor Respondents' relationship with Dr. Aviram. (CX0013).

546. The press release included a link to the pomwonderful.com website. (CX0013_0004).

547. Ms. Posell noted that this 2003 press release was timed "to coincide and support [POM's] marketing efforts in Southern California" and that "[i]t communicates two critical consumer messages – that pomegranate juice contains more antioxidants than other beverages that are typically considered to be high in antioxidants and – that drinking pomegranate juice daily confers heart health benefits by lessening factors that contribute to atherosclerosis (plaque in the arteries)." (CX0013_0001).

548. The net impression of this press release is that drinking 8 ounces of POM Juice daily treats, prevents, or reduces the risk of heart disease, including by reducing arterial plaque, and a clinical study proves this effect. (CCFF ¶¶ 541-47).

b. September 2005 Press Release (CX0044)

549. POM issued a press release in September 2005 titled "Pomegranate Juice May Affect the Progression of Coronary Heart Disease," which highlighted the results of the Ornish MP Study (2005). The release further stated, "Men and women with coronary heart disease who drink one glass of pomegranate juice daily may improve blood flow to their heart, according to a new study." (CX0044_0001).

550. The press release presented the Ornish MP Study (2005) as "the first randomized, double-blind, placebo-controlled trial showing that pomegranate juice may affect the progression of coronary heart disease, which is the #1 cause of death in the U.S. and in most of the world" and that "results . . . [would] be published in . . . the American Journal of Cardiology, one of the leading peer-reviewed cardiology journals." (CX0044_0001).

551. The press release reported the results of the Ornish MP Study (2005) as a statistically-significant improvement of approximately 17% in the pomegranate juice group and a worsening of approximately 18% in the comparison group, the equivalent of a 35% "relative between-group difference." (CX0044_0001).

552. Dr. Ornish, identified as senior author of the study, founder of the Preventive Medicine Research Institute, and clinical professor of medicine at UCSF, is quoted as stating,

"pomegranate juice may have important clinical benefits in those with coronary heart disease" and that "[a]lso, it may help to prevent it." (CX0044_0002).

553. The press release stated that "[p]omegranate juice from POM Wonderful was used in this study." (CX0044_0002). It also provided a link to the pomwonderful.com website. (CX0044_0002).

554. The press release did not disclose that POM had funded the Ornish MP Study (2005), and Ms. Posell noted in an email concerning this release that "we never cite the source of funding nor do we link the Resnicks to POM in press releases." (CX0044_0001). Ms. Posell also stated that she did not know "why [POM] would have issued [the press release] at all if [it] hadn't stated that the researchers used POM Wonderful pomegranate juice. This would not have been in POMs best interests." (CX0044_0001).

555. The net impression of this press release is that drinking 8 ounces of POM Juice daily treats, prevents, or reduces the risk of heart disease, including by improving blood flow to the heart, and clinical studies, research, or trials prove these effects. (CCFF ¶¶ 549-54).

c. July 2006 Press Release (CX0065)

556. A press release POM issued in July 2006, titled "POMx, a Highly Concentrated Form of Healthy Pomegranate Antioxidants, Becomes Available to Consumers for the First Time," discussed research published by the American Association for Cancer Research "indicat[ing] that a daily pomegranate regimen has a positive effect for men with prostate cancer" and that

> [s]pecifically, drinking 8 ounces of P♥M Wonderful pomegranate juice daily prolonged post-prostate surgery PSA doubling time from 15 to 54 months (*Clinical Cancer Research, July 1, 2006*). PSA is a protein marker for prostate cancer and the faster PSA levels increase in the blood of men after treatment, the greater their potential for dying of prostate cancer.

(CX0065_0002).

557. The press release also quoted Dr. Heber, identified as "Professor of Medicine and Director, UCLA Center for Human Nutrition," as stating, "[b]asic studies indicate that the effects of POMx and POM Wonderful pomegranate juice on prostate cancer are the

same. The most abundant and most active ingredients in pomegranate juice are also found in POMx." (CX0065_0002).

558. Ms. Glovsky testified that Dr. Heber "ha[d] been around the supplement market for a long time," and that "sometimes you'll have a product and you want to use a physician, a professor's name, that . . . helps give it credibility." (CX1347 (Glovsky, Dep. at 93)).

559. In an email pertaining to this press release, Ms. Posell wrote, "[t]his press release supports our overall strategy to explain the power of the Wonderful variety of pomegranate and to announce that we have developed POMx which is a new and healthy alternative to [POM Juice]. We need news, and this press release has it!! I use the prostate cancer study to substantiate our statements about POMx." (CX0062_0001).

560. Referring to a 2006 study on POMx, the press release also quoted Dr. Aviram as stating, "[t]he results showed that P♥Mx is as potent an antioxidant as pomegranate juice and just like pomegranate juice may protect against cardiovascular as well as other diseases." (CX0065_0001). The press release did not disclose that this 2006 study was on mice. (CX0062; CX0787_0002).

561. Ms. Glovsky testified that she believed the July 2006 press release was "premature" because no POMx product was available for purchase yet. (CX1347 (Glovsky, Dep. at 91)).

562. The net impression of this press release is that drinking 8 ounces of POM Juice or taking one POMx Pill daily, treats prostate cancer by prolonging PSADT, and prevents or reduces the risk of heart disease, and clinical studies, research, or trials prove this effect. (CCFF ¶¶ 556-60).

d. June 2007 Press Release (CX0128)

563. POM issued a press release in June 2007 titled "POM Wonderful 100% Pomegranate Juice May Improve Mild to Moderate Cases of Erectile Dysfunction, Study Finds." (CX0128_0002). Presenting the Forest Erectile Dysfunction Study (2007), the press release stated, "[r]esearch shows 8 ounces a day of POM Wonderful 100% Pomegranate Juice may help the management of erectile dysfunction" and "[a]ccording to a pilot study released in the *International Journal of Impotence Research* (http://www.nature.com/ijir), POM Wonderful 100% Pomegranate Juice was found to have beneficial effects on erectile dysfunction (ED), a disorder that affects 1 in 10 men

worldwide and 10 to 30 million men in the United States alone." (CX0128_0002).

564. The press release did not disclose that one of the study measures cited, the GAQ, was not validated to measure erectile dysfunction. (CX0128_0003).

565. The press release quoted study co-author Dr. Harin Padma-Nathan, identified as Clinical Professor of Urology at the Keck School of Medicine, University of Southern California," as stating, "[t]hese findings are very encouraging as they suggest there is a non-invasive, non-drug way to potentially alleviate [ED] . . . . Drinking pomegranate juice daily could be an important addition to the diet in the management of this condition." (CX0128_0003-04).

566. The press release included links to the pomwonderful.com and pompills.com websites. (CX0128_0004).

567. The net impression of this press release is that drinking 8 ounces of POM Juice daily treats erectile dysfunction, and clinical studies, research, or trials prove this effect. (CCFF ¶¶ 563-65).

2. In Media Appearances, Respondents Made Efficacy and Establishment Claims Regarding Heart Disease, Prostate Cancer, and Erectile Dysfunction

568. In her book *Rubies in the Orchard*, Mrs. Resnick wrote:

> In addition to being featured on all the great cooking shows, we have become a staple on the morning news, with pomegranate recipes and decorating tips, but above all with medical breakthroughs from POM Wonderful. You can't beat that kind of exposure for brand building, with credible, third-party endorsements – no matter how much money you spend.

(CX0001_0026).

569. She also wrote that she had become acquainted with television host Martha Stewart and would send Ms. Stewart a case of pomegranates each year at the beginning of the harvest. Later, Ms. Stewart did a twelve-page spread on pomegranates in her magazine, *Martha Stewart Living*, and featured Mrs. Resnick on her television show touring the

pomegranate orchards. (CX0001_0025; L. Resnick, Tr. 136-37).

a. November 2008 *The Martha Stewart Show* Interview with Lynda Resnick (CX0473 (Compl. Ex. E-6))

570. In a television appearance on NBC's *The Martha Stewart Show* in November 2008, Lynda Resnick stated:

> **MRS. RESNICK**: . . . But, the Wonderfuls are the [pomegranates] ones that we grow because they're the sweetest and they have the health benefits.
>
> * * *
>
> **MRS. STEWART**: But, the medical benefits even outweigh the mythical benefits?
> **MRS. RESNICK**: Oh, they do, they do. I mean, it is the magic elixir of our age and of all ages, and we know that it helps circulation, it helps Alzheimer's, it helps all sorts of things in the body--
> **MRS. STEWART**: Antioxidants.
> **MRS. RESNICK**: Antioxidants. Polyphenol antioxidants off the chart.
> **MRS. STEWART**: Right.
> **MRS. RESNICK**: And if you know a man that you care about or you are a man, make him drink eight ounces of pomegranate juice a day because what it does for prostate cancer is amazing.

(CX0473 (Compl. Ex. E-6)).

571. The net impression of Mrs. Resnick's statements, including her response to Ms. Stewart's question about the "medical benefits" of POM, is that drinking 8 ounces of POM Juice a day treats, prevents, or reduces the risk of prostate cancer. (*See* CCFF ¶ 570).

b. June 2008 *Fox Business* Interview with Matthew Tupper (CX0473 (Compl. Ex. E-7))

572. In a television interview on *Fox Business* in June 2008, Mr. Tupper stated:

> **MR. TUPPER**: With pomegranate, the dose that's been shown to be effective is eight ounces a day . . . pomegranate is the one fruit that's actually been tested in human beings by dozens of researchers across the globe. There's actually been a study published recently on prostate cancer. Men suffering from advanced stages of prostate cancer drinking eight ounces a day saw the progression of the prostate cancer actually slow dramatically. In addition, there have been a number of studies published on cardiovascular disease in which sick patients again consuming eight ounces of pomegranate juice every day saw dramatic improvements in things like atherosclerosis, which is plaque in the arteries, the amount of blood flow delivered to the heart.
>
> * * *
>
> **MR. SULLIVAN**: There's a lot of different pomegranate things. How many more products can you put out there, and how much of it is just hooey, . . . you know, pomegranate pills, et cetera?
>
> **MR. TUPPER**: *** The products that we put into the market, though, all stem from the fundamental science of the pomegranate, and everything that we put into the market, whether it's juice, whether it's tea, whether it's the supplements that we sell, are all backed by an enormous investment in science. We've actually funded more than $25 million of scientific research worldwide since we started the business. And, therefore, every product that we sell is backed by that science. Every product that we sell contains those unique antioxidants. We don't do things for scents and flavors. We do them for the health benefits and for the science.

(CX0473 (Compl. Ex. E-7)).

573. The net impression of Mr. Tupper's statements, including his references to published studies on prostate cancer and cardiovascular disease, his statement that "the dose [of pomegranate] that's been shown to be effective is eight ounces a day," and his statement that "everything that we put into the market … [is] backed by an enormous investment in science" is that drinking 8 ounces of POM Juice a day (1) treats heart disease including by decreasing arterial plaque and improving blood flow to the heart and (2) treats prostate cancer, and that these health benefits are clinically proven. (CCFF ¶¶ 572).

c. February 2009 *Early Show* Interview with Lynda Resnick (CX0472)

574. In a February 2009 interview on CBS's *Early Show* on the topic "Making it Happen: Turning Ideas into Ca$h," Mrs. Resnick described how POM started marketing POM Juice:

> [E]veryone knew in mythology that the pomegranate was the secret of everlasting life. And we decided to see if that was true, and we started doing scientific, peer-reviewed research. And we found out that, indeed, the pomegranate has all these health-giving properties. There isn't a man in America that shouldn't drink 8oz. a day [of pomegranate juice] because it keeps you from getting prostate cancer or from your PSA from rising. It's really an amazing, amazing thing. And good for circulation, too.

(CX0472 at 01:40-2:07). She also stated:

> . . . [POM] is the antioxidant superpower. And once we realized the health-giving benefits, that was our marketing direction. And, people didn't know what a pomegranate was, but once they found out, they sure wanted it.

(CX0472 at 02:36)

575. Mrs. Resnick's statements expressly convey the net impression that drinking 8 ounces of pomegranate juice a day treats, prevents, or reduces the risk of prostate cancer, and clinical studies, research, or trials prove these effects. (CCFF ¶ 574).

d. March 2009 *Newsweek.com* Interview with Lynda Resnick (CX1426_00032-35)

576. In a March 20, 2009 interview with *Newsweek.com*, posted on the pomwonderful.com "Blog" page, Mrs. Resnick stated:

> [Interviewer:] Should I take vitamins?
>
> [Lynda Resnick:] I don't know your family history. How's your father?

> [Interviewer:] He's in good health. Had a bout of prostate cancer, but that's—
>
> [Lynda Resnick:] You have to be on pomegranate juice. You have a 50 percent chance of getting it. Listen to me. It is the one thing that will keep your PSA normal. You have to drink pomegranate juice. There is nothing else we know of that will keep your PSA in check. Ask any urologist—your father should be on it. Your father should be on it. I'm sorry to do this to you, but I have to tell you. We just did a study at UCLA, on 43 men … It arrested their PSA. How old are you, 28?
>
> [Interviewer:] Twenty-six.
>
> [Lynda Resnick:] Get a base line now. [*Pause, wink*] It's also 40 percent as effective as Viagra. Not that you need it. But—couldn't hoit [sic]!

(CX1426_00032-35).

577. The net impression of Mrs. Resnick's statements recommending that a healthy, but at-risk person has to be on pomegranate juice, and referring to a study at UCLA, is that drinking POM Juice prevents or reduces the risk of prostate cancer, and that this effect is clinically proven. By comparing POM to Viagra, with a specific percentage measure of effectiveness, her statements also convey the net impression that drinking POM Juice treats, prevents, or reduces the risk of erectile dysfunction, and that this effect is clinically proven. (CCFF ¶ 576).

578. Respondents admitted in their Answer that *The Martha Stewart Show* interview with Mrs. Resnick, the *Fox Business* interview with Mr. Tupper, and the *Newsweek.com* interview with Mrs. Resnick (Complaint Exhibits E-6, E-7, and F (CX0473)) were "advertisements and promotional materials" that they disseminated or caused to be disseminated. (Answer ¶¶ 9-10).

G. Further Evidence of Challenged Claims

1. The Bovitz Survey

579. In March 2009, at the request of Mrs. Resnick, POM asked the Bovitz Research Group ("Bovitz") to design a consumer survey to evaluate the effectiveness of the then-running

"Super Hero" advertising campaign compared to POM's earlier "Dressed Bottle" campaign. (CX0286_0001; CX1378 (Kuyoomjian, OS Dep. at 191-92); CX1357 (Kuyoomjian, Dep. at 236-38); CX1370 (Perdigao, Welch Dep. at 95-96)).

580. Mrs. Resnick was involved in the design and approval of the questionnaire for this campaign research. (CX1378 (Kuyoomjian, OS Dep. at 200-01); CX1359 (L. Resnick, Dep. at 75-78, 234-36)).

581. The Bovitz Survey used a forced exposure methodology (*i.e.,* showing the advertisement for which you want to ascertain the consumer takeaway to the survey respondents) which is the proper method for advertising communication surveys. (CX0369_0004-07; PX0356 (Reibstein, Dep. at 174-75); Mazis, Tr. 2693-95).

582. The Bovitz Survey participants were individuals who "engage in health conscious lifestyle[s] and/or hold attitudes toward improving their overall health" (PX0295a15-0005) and were the appropriate universe for the survey given that such individuals were the target audience for POM Juice advertising. (Stewart, Tr. 3207; Mazis, Tr. 2693-95; CX0286_0002-03).

583. Bovitz conducted the survey by using five "Dressed Bottle" billboards and five "Super Hero" billboards to draw conclusions from survey respondents about ad meaning for both campaigns. (PX0295a15-0004-06, 0010-11).

584. A test of the communications of headlines and images in the context of a billboard ad sheds light on what the same headlines and images would convey in lengthier print ads. (Stewart, Tr. 3205-06, 3221).

585. Four of the billboards tested by Bovitz included headlines and imagery featured in challenged ads. (*Compare* PX0295a15-0010-11 *with* CX0109_0001 and CX0463 ("Heart therapy."), CX0103_0001 ("Decompress."), CX0036_0001 and CX0188_0001 ("Cheat death."), CX0274_0001 and CX0466 ("I'm off to save PROSTATES!")). The headline of one test billboard included a reference to "$25 million in medical research," which was similar to references used in numerous challenged ads. (*See* PX0295a15-0010; *see*, *e.g.*, CX0274_0001).

586. Respondents were shown one of six test ads chosen from the ten campaign ads being tested and asked one open-ended question, "Other than trying to get you to buy the

product, what do you think is the main idea" that the ad "is trying to get across to you?" (CX0369_0004-07; Stewart, Tr. 3207, 3213).

587. Such a question is reliable and it is appropriate to draw conclusions about advertising communication from open-ended questions without the use of any controls. (Stewart, Tr. 3213, 42).

588. The main ideas for each of three relevant ads surveyed were as follows:

- Fourteen percent of the general target audience and seventeen percent of POM Juice users in the Bovitz Survey, when shown an advertisement picturing a POM Juice bottle inside a blood pressure cuff, with the headline "Decompress" and a sub-headline "POM Wonderful Pomegranate Juice. The Antioxidant Superpower," said the ad's main idea was "helps/lowers blood pressure." (PX0295a15-0011, 0018, 0046; Stewart, Tr. 3213-14). This significant consumer takeaway as surveyed is consistent with findings that the imagery and language of the challenged "Decompress" print advertisement (CX0103_0001; CCFF ¶ 357) created a net impression to consumers that POM Juice treats, prevents, or reduces the risk of heart disease, including by reducing blood pressure. (*See* CCFF ¶¶ 361, 540; *see also* Stewart, Tr. 3221).

- Forty-three percent of the general target audience and forty-eight percent of POM Juice users in the Bovitz Survey, when shown an advertisement picturing a POM Juice bottle saying, "I'm off to save PROSTATES!" and a sub-headline "The Antioxidant Superpower," said the ad's main idea was "good for prostates." (PX0295a15-0010, 17, 45). This significant consumer takeaway as surveyed is consistent with a finding that the challenged "I'm off to save PROSTATES!" print ad (CX0274_0001; CCFF ¶ 372) and banner ad (CX0466; CCFF ¶ 534) communicated a message that drinking POM Juice treats, prevents, or reduces the risk of prostate cancer. (*See* CCFF ¶ 376).

- Twenty-two percent of the general target audience and thirty-one percent of POM Juice users in the Bovitz Survey – who were shown an advertisement picturing a POM Juice bottle saying, "HOLY HEALTH! $25 million in medical research" and a sub-headline "The Antioxidant Superpower" – said the ad's main idea was "$25 million spent on research/research based." (PX0295a15-0010, 0017, 0045). This significant consumer takeaway as surveyed is consistent with findings that a number of the challenged ads communicated that the claimed benefits were research-based. (*See, e.g.*, CCFF ¶¶ 372-88, 398-429).

589. Bovitz Survey respondents were also exposed to all five tested ads from the "Super Hero" campaign or all five tested ads from the "Dressed Bottle" campaign and asked an open-ended question, "Based on the ads you just saw, what are the specific benefits, if any, of drinking POM Wonderful?" (CX0369_0008-09; Stewart, Tr. 3214-16). This open-ended question was not leading. (Stewart, Tr. 3216).

590. Of the survey respondents exposed to the five "Dressed Bottle" ads, which included the images and headlines of the challenged "Decompress" print ad and the challenged "Heart Therapy" print and banner ads, 38% of the general target audience said that a benefit of drinking POM Juice was "good for your heart" and 21% said a benefit was "helps/lowers blood pressure." (PX0295a15-0011, 0020; Stewart, Tr. 3216-17). There were similar results among POM users. (PX0295a15-0048; Stewart, Tr. 3217).

591. The Bovitz Survey's open-ended communication of "good for your heart" and "helps/lowers blood pressure" from the images and headlines of the "Dressed Bottle" campaign is consistent with findings that the challenged "Heart Therapy" print ad (CX0109_0001; CCFF ¶ 363) and banner ad (CX0463; CCFF ¶ 536) communicated a message that POM Juice prevents or reduces the risk of heart disease (s*ee* CCFF ¶ 367, 538) and a finding that the "Decompress" print ad (CX0103_0001; CCFF ¶ 357) communicated a message that POM Juice treats, prevents, or reduces the risk of heart disease, including by reducing blood pressure (s*ee* CCFF ¶ 361).

592. Bovitz Survey respondents who were exposed to the five "Super Hero" ads, which included an ad picturing a POM Juice bottle saying, "HOLY HEALTH! $25 million in medical research," were asked a close-ended question, "Based on the ads you just saw, which of the following do you think are true about POM Wonderful?" Respondents were provided a multiple-choice list and told to select as many or as few that applied. (PX0295a15-0033).

593. In response to this closed-ended question, 63% of the general target audience and 78% of POM Juice users said based on the ads, POM Juice had "proven health benefits." (PX0295a15-0033-34).

594. Because this was a closed-ended question, there is the possibility of yea-saying, *i.e.,* .the tendency to give a yes or more socially desirable response in an effort to be agreeable. (*See* Stewart, Tr. 3218-19). To analyze the responses conservatively, one of the other

attributes can be used as a control. (Stewart, Tr. 3219). Here, following that approach, if one were to use the response option "Will help you live longer" as a control attribute, as none of the five "Super Hero" billboards explicitly addressed longevity (although they might have implied it), and deducted the responses for that attribute, 43% of the general target audience (*i.e.*, 63% minus 20%) and 46% of POM Juice users (*i.e.*, 78% minus 32%) thought that POM Juice had "proven health benefits." (PX0295a15-0010, 0033-34).

595. The Bovitz Survey's closed-ended communication of "proven health benefits" from the images and headlines of the "Super Hero" campaign is consistent with findings that many of the challenged advertisements communicated establishment claims. (*See, e.g.*, CCFF ¶¶ 372-88, 398-429).

596. Respondents used the Bovitz Survey to make decisions regarding their advertising campaigns. Lynda Resnick used the Bovitz Survey to determine that POM would continue using the then-running "Super Hero" advertising campaign. (CX0313_0002; CX1378 (Kuyoomjian, OS Dep. at 205); CX1357 (Kuyoomjian, Dep. at 252), CX1359 (L. Resnick, Dep. at 236). The conclusions drawn from the Bovitz Survey applied across all media formats and were not limited to a narrow analysis of campaign billboards. As Mrs. Resnick wrote in her book, *Rubies in the Orchard*,

> A concise, potent message travels well. You can publish it in a magazine and mount it on a billboard. You can put it on a Web site or embroider it on a baseball cap. The shorter the message, the more easily it adapts to different circumstances – and the more readily it travels between different media.

(CX0001_0020).

2. Butters and Stewart

597. Respondents called Dr. Ronald Butters as a linguistics expert to testify about the meanings of the challenged advertisements. (Butters, Tr. 2816-17). The Court recognized Dr. Butters as an expert in linguistics, including the meaning of language and symbols and the context in which they appear, but Dr. Butters admitted that he is not a marketing expert and does not have any expertise in advertising consumer products or in consumer buying behavior. (Butters, Tr. 2816, 2954-55). Dr. Butters also acknowledged that he had never previously testified as an expert in a case which involved alleged deceptive advertising. (Butters, Tr. 2956).

598. Complaint Counsel called Dr. David W. Stewart as a rebuttal witness to respond to Dr. Butters. The Court recognized Dr. Stewart as an expert in advertising, marketing, consumer behavior, and survey methodology. (Stewart, Tr. 3168).

599. Dr. Stewart is a full Professor of Marketing in the A. Gary Anderson Graduate School of Management, University of California at Riverside, where he served as Dean of the business school for four years. (PX295a01-0002, 0041; Stewart, Tr. 3161; CX1295 (Stewart, Report at 0002)). During his long and distinguished academic career, Dr. Stewart has taught a variety of graduate and undergraduate level courses related to advertising, consumer behavior, marketing research, and marketing strategy. (PX295a01-0050-51; Stewart, Tr. 3160-61; CX1295 (Stewart, Report at 0003-04)).

600. Dr. Stewart has authored or co-authored eight books on advertising related issues and has written over 125 articles which have been accepted in peer reviewed academic journals. (Stewart, Tr. 3162-63; PX295a01-0002, 0005, 0008-17; CX1295 (Stewart, Report at 0002)). Dr. Stewart has served as the editor, associate editor, or member of the editorial board of numerous academic journals. (PX295a01-0043-47; CX1295 (Stewart, Report at 0002); Stewart, Tr. 3161). Dr. Stewart has served as the President of the Academic Council of the American Marketing Association and chairman of the Section on Statistics in Marketing of the American Statistical Association. (Stewart, Tr. 3161-62; PX295a01-0002, 43). He is a past president of the Society of Consumer Psychology of the American Psychological Association. (Stewart, Tr. 3162; PX295a01-0002, 0045; CX1295 (Stewart, Report at 0003)).

601. According to Dr. Stewart, Dr. Butters's analysis of Respondents' advertising communication ignores an enormous body of theory and empirical research related to how consumers use information, process advertising messages, and make decisions in the market place. (CX1295 (Stewart, Report at 0006); Stewart, Tr. 3170-71).

602. For example, Dr. Butters analyzed the challenged ads from the perspective of the ordinary adult user of the English language in America. (Butters, Tr. 2831, 2833-34). Dr. Butter's total population framework ignores POM's practice of specifically targeting consumers who are very concerned about or already have health problems. (CX1295 (Stewart, Report at 0012-13); Stewart, Tr. 3182-84, 3186-87). Such consumers are likely to be both more attentive to health claims and more likely to draw specific inferences about the benefits of POM's products than the general universe of American speakers of English. (CX1295 (Stewart, Report at 0013); Stewart, Tr. 3187-88).

603. In his report and during his testimony, Dr. Butters asserted that the effect of humor in advertising for the POM Products is to reduce or block the communication of any serious health claims. (PX0158 (Butters, Report at 0004); PX0350 (Butters, Dep. at 62); Butters, Tr. 2864).

604. Dr. Butter's assertion is contrary to research on the use of humor in advertising. (CX1295 (Stewart, Report at 0008-09); Stewart, Tr. 3200-01). There is no evidence in the marketing literature that consumers would be skeptical of claims that employ humor and the literature suggests that appropriately used humor disarms consumers, reduces counter arguing, and increases persuasion. (CX1295 (Stewart, Report at 0009); Stewart, Tr. 3200-01). This is consistent with the testimony of Lynda Resnick who said, "if you make someone laugh . . . you've broken through . . . their guard goes down a little and they listen to you." (CX1359_0242-44).

605. During redirect at trial, Dr. Butters changed his testimony and acknowledged that the humor in POM ads does not block the serious statements that are made in the body copy of the ads or in footnotes. (Butters, Tr. 2958).

606. During redirect, Dr. Butters still asserted that POM's exaggerated and humorous headlines and images will not be seen as making claims. (Butters, Tr. 2958).

607. The Bovitz Study, which tested POM's humorous headlines and images by themselves, contradicts Dr. Butters, showing significant communication of specific health benefits claims, including that POM Juice is good for prostates, good for your heart, and helps/lowers blood pressure. (Stewart, Tr. 3202, 3204-06, 3213-14, 3216-17, 3218-20; CCFF ¶¶ 588, 590).

608. Dr. Stewart testified that although some humorous headlines like "Amaze your cardiologist" and "Floss your arteries" might not to be taken literally, they [can] still communicate serious health messages, such as that POM Juice offers significant cardiovascular health benefits and such headlines contribute to the overall net impressions from the advertisements. (Stewart, Tr. 3202, 3204-06, 3230-31, 3240).

609. Contrary to a net impression analysis, Dr. Butters parsed the text of the challenged ads in analyzing individual elements or words. (Stewart, Tr. 3173; CX1295 (Stewart, Report at 0006)).

610. Dr. Butters asserted that POM's ads were sufficiently qualified by words such as "can," "may," "pilot" and "preliminary." (Butters, Tr. 2822-23, 2912-14, 2925; PX0158 (Butters, Report at 0023, 0043)). Dr. Butters, however, was not aware of any academic literature to support his position. (*See* Butters, Tr. 2915-16, 2921; PX0350 (Butters, Dep. at 93, 97)).

611. Asked whether reasonable consumers take the claim "can reduce" to mean "reduces," as alleged in the Complaint, Dr. Butters stated that there is no clear yes or no answer because of the intrinsic ambiguity of the word "reduces." (PX0350 (Butters, Dep. at 92-93)). Moreover, Dr. Butters admitted that there is no academic literature to support a conclusion that reasonable consumers will not take a claim like "can reduce" to mean "reduces." (PX0350 (Butters, Dep. at 93)).

612. Dr. Stewart testified that the members of the audience for a POM ad are processing the totality of the ad, not nuances of individual words. (Stewart, Tr. 3172-74). Dr. Stewart asserted that the academic literature offers empirical evidence that the presence of qualifiers actually increases the credibility of claims. (Stewart, Tr. 3189-90; CX1295 (Stewart, Report at 0016-17); PX0295a07)).

613. Even a linguistics textbook frequently used by Dr. Butters for his introduction to linguistics course asserted, in a section titled "Language in Advertising," that the use of qualifiers, such as those noted by Dr. Butters, "encourage the audience of the advertisements to infer that a stronger claim is intended than the one that is actually entailed." (Butters, Tr. 2916-19).

614. Dr. Stewart believed that the typical consumer would likely have little understanding of what "initial" or "pilot" means. (Stewart, Tr. 3191).

615. Furthermore, such terms as "initial" or "pilot" are often used in POM advertising in connection with mentions of a well-respected medical school (UCLA), "leading universities," reference to professional journals in which support of the claims is found, reference to a Nobel laureate, and reference to the sum of money spent on research that is represented as supporting the advertising claims (*e.g.*, $25 million), all of which have the effect of establishing the credibility of claims for the POM Products. (CX1295 (Stewart, Report at 0017)). Dr. Butters conceded that if a "pilot" study is described in an ad as having been published in a medical journal, it could affect how the consumer views it in the context. (Butters, Tr. 2925).

3. POM's Communications with Consumers and POM's Views on Consumer Takeaway

616. POM was aware from communications with consumers that people with heart disease or who were at risk for heart disease were drinking POM Juice for the purpose of treating, preventing, or reducing their risk of heart disease, arterial plaque, or high blood pressure, and that consumers believed that POM products could treat, prevent, or reduce the risk of heart disease, arterial plaque, or high blood pressure. The consumer comments included:

- "My dad has heart problems and I'd like to have him on a regimen of drinking POM juice daily[.]" (CX0485_0083);
- "I've started pomegranate juice to help with a small blockage in my heart." (CX0485_0649);
- "I need to buy your 48 ounce 100% pom juice to lower my blood pressure. A study in Israel revealed that 75 to 85 year old patients who drank 8 ounces of the juice for one year, reduced arterial plaque by thirty percent. Needless to say, I want to reduce my plaque and lower my blood pressure also. . . . I need to start drinking this right away." (CX0485_0510-11);
- "I want to continue using your product, please let me know because I do not mind paying for the juices you make, because they are nutritious, and I need them because of my health problems with my blood pressure." (CX0485_1088-89);
- "If people's arterial plaque was decreased by 30% in one year, does that mean that after about 3 years and 4 months it would be all gone and your arteries would be clean as a whistle? . . . I am concerned about heart health because I am almost 59 and had a heart attack a year ago." (CX0485_2296); and
- "Caller said that he has been consuming the juice daily for three years, and he has not seen a reduction in his blood pressure. He believes that the studies shown on the website are inaccurate and false." (CX0485_1390).

617. POM also was aware from numerous communications with consumers that men with prostate cancer, or who were at risk for prostate cancer, were drinking POM Juice or taking POMx for the purpose of treating, preventing, or reducing their risk of prostate cancer, and that consumers believed that POM products could treat, prevent, or reduce the risk of prostate cancer. The consumer comments included:

- "I have read the UCLA study and have been unsuccessful in finding Pomegranate

Juice. I have found a mixture but not 100% Pomegranate Juice. This is important to me since I have 2nd recurrence [sic] of prostate cancer." (CX0485_0155);

- "My problem is that I have prostate cancer and have been a cancer survivor for 10 years...It has recently flared-up [sic] I contacted UCLA about your sponsored study and was told that I didn't qualify....But I could 'go it alone' with the regimine [sic], and drink 8 oz of your product per day. 'Desperite [sic] situations need desperite [sic] actions.'" (CX0485_0165);

- "I'm doing a single subject, controlled study of the juice's efficacy in controlling the growth of my existing prostate cancer." (CX0485_0192);

- "I suffer from prostate cancer and presently drink a third of a bottle of Pomwonderful [sic] per day in the hope that this will reduce the rate of increase in my psa. It is too early to assss [*sic*] the results but in the meantime a routine blood check by my GP who is monitoring my high blood pressure has disclosed an increase in my potassium level and this will require medication. I understand that pomegranate is a source of potassium and I wonder if you are able to tell me if your product contains a sufficiently high element to cause the problem. Unless it is significant, I do not intend stopping drinking Pomwonderful [sic] in view of the important potential benefit to me [sic] cancer but will appreciate your advices." [sic] (CX0485_0193);

- "I have been drinking POM 100% Pomegranate juice for about 8 months for prostate cancer prevention." (CX0485_0384);

- "I'm an 89 year old man with prostate cancer. I've been treated with radiation but I have an aggressive cancer (Gleason 9) and my PSA is rising. I've just started using the POM wonderful 100% pomegranate juice. . . . In checking your web site I saw that it is available in pill form. Has then [sic] been proven as effective as the liquid form in treating prostate cancer?" (CX0485_1049-50);

- "I just purchased a re-occuring monthly supply of Pom Pills. My brother recently was diagnosed with advanced prostate cancer at 48 years old, which puts me (44) in a high risk category." (CX0485_1339-40).

618. Mr. Resnick testified that if consumers are interpreting from Respondents' "Decompress" ad that POM Juice lowers blood pressure, "[i]t's not my problem . . . it's their problem." (CX1376 (S. Resnick, OS Dep. at 309-10)).

619. Similarly, Mr. Resnick testified that if POM's "ads communicate to consumers that POM

can prevent or delay the onset of prostate cancer," he is very comfortable with that claim. (CX1376 (S. Resnick, OS Dep. at 156)).

620. POM itself boasted that its marketing efforts have caused consumers to associate pomegranate juice with certain nutritional and health benefits: "Due to POM's marketing efforts and funding of research, and substantial research not funded by POM, many consumers now associate pomegranate juice with certain nutritional and health benefits." (CX1404_0037; *see also* CX1395_0004 ("A key element of POM Wonderful's marketing campaign has been its concentration on the health benefits associated with pomegranates and pomegranate juice, and its emphasis on the high level of antioxidants contained in POM Wonderful brand juice.")).

621. Respondents paid close attention to the net impression of competitors' product claims that they believed to be misleading to the "average consumer." (*See, e.g.*, CX1364 (Tupper, TCCC Dep. at 141-43, 149-50, 155-58) (repeatedly referring to the "average consumer")).

622. For example, Mr. Tupper testified that "any reasonable consumer" in a grocery aisle would be drawn to the large font words ("[p]omegranate is in big font") and visual images ("pictures of . . . two big red pieces of fruit against this blobby green backdrop") and conclude from the label that the competitor's juice is healthy pomegranate juice. (CX1369 (Tupper, Welch Dep. at 178-79, 181); *see also* CX1364 (Tupper, TCCC Dep. at 148) ("You see pomegranate blueberry and your eyes is then drawn at the picture of pomegranate and blueberries. That is what your brain processes. As I'm sure you can see, in addition to those big things, a bunch of small stuff that I believe most consumers, if not all consumers, are going to gloss over and ever pay attention to it.")).

623. Mr. Tupper also acknowledges that a statement "may be factually true on the surface" and yet misleading because "it lends a level of credibility as to the healthfulness of the product" that may not be backed up. (CX1364 (Tupper, TCCC Dep. at 142)).

624. Likewise, Mr. Tupper recognizes that "many consumers may not read" or take the time to process information presented in small font on a label. (CX1364 (Tupper, TCCC Dep. at 125-26, 150, 164, 167-68) (noting that information about the competitor's juice blend is "small font, buried at the bottom, the label has a lot of information to process, and as I said before I think what the consumer is going to process is Minute Maid, help nourish your brain, pictures of the pomegranates and the blueberries and the name pomegranate-blueberry")).

VI. RESPONDENTS' CLAIMS ARE MATERIAL

A. Respondents' Challenged Claims Are Presumptively Material

625. The challenged ads present the POM Products as treating, preventing, and/or reducing the risk of heart disease, prostate cancer, and/or erectile dysfunction and therefore make significant health claims. (*See supra* Sections V.D – V.F).

626. Health benefits are the central characteristic and purpose of using POMx and are a central characteristic of POM Juice as it was advertised. (*See supra* CCFF ¶¶ 153-57, Sections V.C – V.F).

627. Challenged claims were often made expressly or so strongly implied as to be virtually express. (*See supra* Sections V.D – V.F).

628. Respondents intended to make the challenged claims. (*See, e.g.,* CCFF ¶¶ 281-318, 334, 337-38, 350, 354, 359-60, 369, 373-74).

B. Respondents Admit the Health Benefits of the POM Products Are Important to Consumers' Purchase Decisions

629. Respondents' marketing strategy for the POM Products was premised on convincing consumers that the claimed health benefits are the reason to buy their expensive products. In March 2004, Mr. Regal, POM's then Vice-President of Marketing, sent an email to Mr. Tupper summarizing consumer research as showing "People are interested in . . . [h]ealth benefits – this is why they put up with the price." (CX0283_0002).

630. Respondents' marketing presented statistics on the prevalence of heart disease, prostate cancer, and erectile dysfunction as a reason for consumers to be concerned, and presented POM Juice or POMx products as the solution to treat, prevent, or reduce the risk of these diseases or medical conditions. For example,

- "Remember: heart disease is America's number one killer. For women as well as men. . . . To keep your heart healthy: exercise regularly. Eat a healthy diet. And drink 8 ounces of POM Wonderful Pomegranate Juice." (CX0029_0002);
- "[A]t least 58.8 million Americans suffer from some form of heart disease. . . . To date, our scientists have found that pomegranate juice may help counteract factors leading to arterial plaque build up, as well as inhibit a number of factors associated with heart

disease." (CX1426_00047-48).

- "Prostate Cancer Affects 1 Out of Every 6 Men[.] Prostate cancer is the second leading cause of cancer related death in men in the United States. . . . New pomegranate research offers hope to prostate cancer patients." (CX1426_00050-51); and
- "POM Wonderful 100% Pomegranate Juice was found to have beneficial effects on erectile dysfunction (ED), a disorder that affects 1 in 10 men worldwide and 10 to 30 million men in the United States alone." (CX0128_0002).

631. POM believes that the millions of dollars it has spent promoting pomegranate juice for health in fact created the market for the juice. (CCFF ¶ 176).

632. Mr. Resnick acknowledged that the kinds of health benefits that POM's scientific research revealed are the primary reason people buy pomegranate juice. (CX1372 (S. Resnick, Trop Dep. at 31)). Stewart Resnick also stated that consumers buy pomegranate juice "because they believe and in fact it does postpone the onset of prostate cancer, which postpones the onset of death." (CX1376 (S. Resnick, OS Dep. at 217)).

633. Similarly, Mrs. Resnick stated that she knew "that 72 percent of the people who buy pomegranate juice buy it for health reasons." (CX1362 (L. Resnick, TCCC Dep. at 97)).

634. According to Lynda Resnick, POM was being purchased more by "people that have heart disease or prostate cancer in their family, or have a fear of having it themselves." (CX1368 (L. Resnick, Welch Dep. at 66-67)).

635. According to a September 2006 press article, Ms. Posell, POM's then vice president of corporate communications, said every time a new study was released touting a health benefit of pomegranate juice, there was a spike in sales, and she gave the example of a then-recent prostate cancer study. (CX0433_0004).

636. Respondents conducted a test of two POMx Pill ads and found that the one with medical copy discussing the specifics of heart and prostate cancer studies generated more orders than one with less medical copy. (CX0264_0001-02; CX0266_0002; Tupper, Tr. 1009-10).

637. Mr. Perdigao, the head of Fire Station, noted in an email that the "consumer benefit" of proposed advertisements that did not reference prostate or heart health was less compelling than POM had hoped. (CX0320_0002; L. Resnick, Tr. 90; *see also* Perdigao, Tr. 670-73). He testified that in attempting to develop a television marketing campaign

without reference to heart, cardiovascular, or prostate health, POM and its advertising agency found that the consumer benefit was not as compelling because the claims were more vague. (Perdigao, Tr. 670-73).

638. Even Respondents' marketing expert, Dr. David Reibstein conceded that it was likely that consumers in POM's target audience who were concerned about heart disease would find a claim that drinking a bottle of POM Juice a day prevents or treats heart disease to be important, that those concerned about prostate cancer would find a prostate cancer prevention or treatment claim important, and that those concerned about erectile dysfunction would find an erectile dysfunction prevention or treatment claim important. (PX0356 (Reibstein, Dep. at 117-19)).

C. Respondents' Own Consumer Research Demonstrates the Importance of Specific Health Benefits to Consumers' Purchase and Use of POM Products

639. In the ordinary course of business, Respondents conducted consumer research to understand the motivations behind the purchase and use of pomegranate juice by consumers. (*See*, *e.g.*, CX0370; CX0292).

640. In June 2009, OTX, a consumer research firm, conducted an Attitudes and Usage consumer survey ("A&U study") on POM's behalf. (CX0370_0002, 0004). The A&U study's sample of 218 then-current POM Juice drinkers was a sufficient and fairly normal sample size. (Mazis, Tr. 2689-90). The POM Juice drinkers were asked, "Which of the following reasons are why you personally drink pomegranate juice?" (CX0370_0011; PX0227-0006; Reibstein, Tr. 2557; Mazis, Tr. 2681; CX1297 (Mazis, Report at 0012)). They were presented with a list of five reasons and given the opportunity to give another reason not on the list. (CX0370_0011; PX0227-0006; Mazis, Tr. 2681-82).

641. Eighty-five percent (85%) of then-current POM Juice drinkers chose "healthy/good for my health," which the given reason more often than "I like the taste," "It's a new/interesting food trend," "It's all natural," and "I like pomegranates." (CX0370_0011; Mazis, Tr. 2683; CX1297 (Mazis, Report at 0012)).

642. Those POM Juice drinkers who cited "health" as a reason for using pomegranate juice were asked a follow-up question, "Which specific health reasons below describe why you personally drink pomegranate juice?" and were presented with a list of nine or ten reasons, depending on whether they were male or female. (CX0370_0012; PX0227-0006; Reibstein, Tr. 2558-59; Mazis, Tr. 2682-83).

643. These survey respondents cited "contains naturally occurring antioxidants" (91%), "helps promote heart health" (57%), and "helps protect against prostate cancer" (47%) (males only) as the top three reasons why they drank pomegranate juice. (CX0370_0012; Mazis, Tr. 2683-84; CX1297 (Mazis, Report at 0012-13); *see also* Reibstein, Tr. 2559-60).

644. POM's Senior Vice-President of Marketing testified that she was not surprised by OTX survey results that 47 percent of male POM users buy POM Juice because it helps protect against prostate cancer. (CX1357 (Kuyoomjian, Dep. at 259-60)).

645. According to Dr. Mazis, because "helps promote heart health" and "helps protect against prostate cancer" are second and third ranked, after "contains naturally occurring antioxidants," they are important health benefits motivating drinkers of POM Juice. (Mazis, Tr. 2686; *see also* CX1297 (Mazis, Report at 0013)).

646. The A&U study shows that consumers would find claims that drinking POM Juice treats, prevents or reduces the risk of heart disease or prostate cancer to be important to their purchase or use decisions. (Mazis, Tr. 2688-89; CX1297 (Mazis, Report at 0013)).

647. Respondents' marketing expert, Dr. Reibstein, acknowledged that he would not completely disregard the responses to "helps protect against prostate cancer" as a reason that consumers consume POM Juice. (PX0356 (Reibstein, Dep. at 158).

648. The 2009 A&U results are consistent with an August 2007 Zoomerang online study commissioned by Respondents. (*See* CX0292_0025; CX0136_0001). Among 287 heavy pomegranate juice drinkers in the Zoomerang study, the leading reason for purchase was long-term health (74%), which was ahead of taste (67%). (CX0292_0026).

649. Asked to rank six health benefits of drinking pomegranate juice in order of importance to them personally, heavy pomegranate juice drinkers in the Zoomerang study ranked cardiovascular health as the most important benefit, "followed by [anti]aging & prostate" health. (CX0136_0006; CX453_0004).

650. Among a larger sample population, which included drinkers of other juices, over 60% of Zoomerang study participants ranked cardiovascular health as the first or second most important benefit, 40% of males ranked prostate health as the first or second most important benefits, and approximately 18% of males did so for erectile dysfunction.

(CX0136_0002, 07-08; CX453_0004).

D. Respondents' Litigation Survey Does Not Measure the Materiality of Respondents' Claimed Health Benefits

651. To attempt to rebut the presumption of materiality of the claims for POM Juice, Respondents presented a purchase motivation study designed by Dr. David Reibstein, a marketing professor at The Wharton School, University of Pennsylvania. (Reibstein, Tr. 2481, 2487, 2525-26). The Court recognized Dr. Reibstein as an expert in marketing and marketing research. (Reibstein, Tr. 2486).

652. At the time he designed his study, Dr. Reibstein was neither familiar with the FTC's Deception Policy Statement nor was he familiar with the concept of materiality in an FTC case. (PX0356 (Reibstein, Dep. at 13, 41-42)).

653. Complaint Counsel called Dr. Michael Mazis as an expert rebuttal witness to address Dr. Reibstein's testimony, and the Court recognized Dr. Mazis as an expert in marketing and marketing research. (CX1297 (Mazis, Report at 0002, 004-05); Mazis, Tr. 2659). Dr. Mazis is a Professor Emeritus of Marketing at the Kogod School of Business, American University. (PX0296a01-0001; Mazis Tr. 2653). He was a Professor of Marketing at American University from 1981 to 2008, serving ten years as chair of the Department of Marketing. (PX0296a01-0001; Mazis, Tr. 2653). Dr. Mazis is a former director of the Association for Consumer Research. (PX0296a01-0010). He was Editor of the Journal of Public Policy & Marketing from 1992 to 1995 and Associate Editor of The Journal of Consumer Affairs from 1998 to 2001. (PX0296a01-0002; Mazis, Tr. 2654). Among his duties as an editor and associate editor, Dr. Mazis would review and critique survey research. (Mazis, Tr. 2655-56). Dr. Mazis has conducted hundreds of surveys and research studies, including over one hundred surveys for use in legal proceedings. (Mazis, Tr. 2657).

654. Dr. Reibstein's survey has no relevance to either the materiality of the challenged POMx claims or the purchase motivations of POMx purchasers. (Reibstein, Tr. 2565-66; CX1297 (Mazis, Report at 0004, 07)).

655. Dr. Reibstein's survey was conducted in October 2010. (Reibstein, Tr. 2541). Dr. Reibstein did not expose consumers to the challenged ads. (Reibstein, Tr. 2494). He surveyed individuals who had purchased POM Juice in the prior six months and asked them to state why they purchased, would repurchase, or recommend POM Juice.

(PX0237-0002; PX0223 (Reibstein, Report at 0004-05)). In response to these three open-ended questions, 35.2% of POM Juice purchasers volunteered that they bought or would repurchase POM Juice because it was "healthy" and 46.8% stated that they would recommend it to a friend because it was "healthy." (PX0223 (Reibstein, Report at 0006-08)).

656. Very few respondents, however, volunteered that they purchased POM Juice because it would treat, prevent, or reduce the risk of heart disease, prostate cancer, or erectile dysfunction. (PX0223 (Reibstein, Report at 0010-11, 0020)).

657. Dr. Reibstein's assessment of consumer motivations does not provide a valid measure of the likely importance that the challenged POM Juice claims would have to consumers' purchase or use decisions. (CX1297 (Mazis, Report at 0008-09); Mazis, Tr. 2673).

658. In order to measure whether a particular claim is likely to affect consumers purchase behavior, survey respondents must be exposed to the claim and asked how important they think that claim would be in their potential purchase decision. (Mazis, Tr. 2728; CX1297 (Mazis, Report at 0008-09)). Dr. Reibstein acknowledged that his survey did not explicitly ask respondents to evaluate the importance of any of the challenged claims at issue in this matter in terms of whether those claims were likely to have an effect on their decision to purchase or to use POM Juice. (Reibstein, Tr. 2526-28).

659. Thus, there is a disconnect between what Dr. Reibstein sought to assess, which is why people bought, and materiality, which is how important a particular claim is to a potential purchaser and whether that claim would affect decision-making if the person knew of the claim. (See Mazis, Tr. 2673).

660. The Reibstein survey only asked broad open-ended questions with no probing. (CX1297 (Mazis, Report at 0009-10); Mazis, Tr. 2731). Consumers' beliefs that pomegranate juice is a healthy drink is a major reason they purchase the juice. (Reibstein, Tr. 2553; CX1297 (Mazis, Report at 0009-10)). The Reibstein survey should have explored what Respondents meant by their healthy response and whether there were specific reasons or benefits that underlay "healthy" responses. (Mazis, Tr. 2709).

661. The Reibstein survey failed, however, to follow-up its purchase motivation questions to determine whether some or all of these consumers believed that pomegranate juice is "healthy" because it treats, prevents, or reduces the risk of heart disease, prostate cancer, and/or erectile dysfunction. (CX1297 (Mazis, Report at 0010); *see also* Mazis, Tr. 2705-

06, 2707-08).

E. Respondents' Persistence in Using the Challenged Claims after Receiving Warnings That the Claims Are Deceptive Is Evidence of Materiality

662. In March 2005, the New York Attorney General's office sent POM a letter expressing concerns that POM's advertising was false or misleading. The letter asked for POM's substantiation regarding several claims, including those related to atherosclerosis and reduction of plaque. Moreover, the letter stated that the phrase "Amaze your cardiologist" was "an implication that drinking POM Wonderful Pomegranate juice will provide substantial benefits to a consumer's heart" and similarly, that the phrase "Floss your arteries" was "an implication that drinking POM Wonderful Pomegranate Juice will reduce plaque build-up in a consumer's arteries." (CX1419_0002-0003).

663. Respondents' health claims for POM Juice have been the subject of two decisions by the Council for Better Business Bureaus' National Advertising Division (NAD). In March 2005, the NAD, as part of its regular monitoring program, reviewed the "Amaze your cardiologist" and "Floss your arteries" advertisements, along with the Aviram CIMT/BP Study (2004) cited therein. The NAD concluded that POM's use of the Aviram study in the "Amaze your cardiologist" advertisement did not clearly articulate the preliminary nature of the study or its details; and furthermore, that the "Floss your arteries" advertisement carried the message that healthy people could prevent buildup of arterial plaque with POM Juice. (CX0037_0008-0010).

664. The NAD recommended that the "Amaze your cardiologist" advertisement be modified and that the "Floss your arteries" advertisement be discontinued or modified to avoid misleading consumers. (CX0037_0010-11).

665. Mr. Tupper stated that POM implemented the NAD's 2005 requests and suggestions, although it disagreed with them ("[T]hey had some requests and suggestions for what I think amounted to some minor modifications in phraseology and such, which we respectfully disagreed with, but implemented nonetheless."). (CX1364 (Tupper, TCCC Dep. at 305-06)).

666. POM, however, continued to cite the Aviram CIMT/BP Study (2004), and specifically the 30% plaque reduction finding, in its advertising until at least 2009. (*See, e.g.*, CCFF ¶¶ 406-418, 430-437, 449, 451, 453-454, 520, 527). The NAD later determined that POM failed to discontinue the "prevent arterial plaque build-up" claim that was

challenged in 2005, and had even disseminated new advertising making the same express claim, a fact that "particularly disturbed" the NAD. (CX0055_0044).

667. In April 2006, the NAD reviewed POM's advertising again in response to a challenge from Welch Foods, Inc. (CX0055_0001).

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

669. In this 2006 decision, the NAD rejected many of POM's assertions attempting to minimize its claims, which are similar to the arguments made in this matter. For example, the NAD rejected the notion that POM's advertising claims were puffery, finding that POM made "objectively provable claims requiring substantiation." (CX0055_0047).

670. Moreover, the NAD rejected POM's argument that its advertisements merely stated that POM Juice has high levels of antioxidants and therefore simply claimed that it is beneficial to one's health: "[T]his is a generous reading of the challenged advertisements. . . . [T]hese claims are not as tentative as the advertiser suggests[.] . . .[T]he advertiser most assuredly makes strong unqualified performance claims – claims requiring concomitant supporting evidence." (CX0055_0035-36).

671. The NAD stated that it "had concerns about the sufficiency of [POM's] research to substantiate the claims which promise specific results from use of the advertised product" and recommended that its claims regarding cardiovascular benefits be "substantially modified to clearly disclose the limitations of the scientific findings[.]" (CX0055_0038, 0046).

672. The NAD decision specifically stated that it "harmonize[s] its own efforts with the regulatory framework developed by the FDA and FTC regarding food labeling and advertising." (CX0055_0034).

673. Even after NAD specifically recommended in 2006 that POM "discontinue its claims,

either express or implied, that simply drinking eight ounces of POM Wonderful daily can reduce one's risk of cancer or that, with respect to cancer, consumers can 'Cheat Death' by drinking POM Wonderful," (CX0055_0042), Mr. Tupper has testified that POM continued to run advertisements with that exact headline: "I don't think we were ever making claims that consumers can cheat death. We continue to run the headline, I believe, but I don't think that's what this refers to. . . . We used the headline cheat death, as a headline by itself. I'm not sure how that relates to this [the NAD's] paragraph." (CX1364 (Tupper, TCCC Dep. at 335-36)).

674. Although Mr. Tupper stated that he was aware of NAD's 2006 recommendation to discontinue express claims that drinking POM can prevent arterial plaque build-up, and has testified that POM changed its communication accordingly after the NAD decision came out (CX1364 (Tupper, TCCC Dep. at 336-37), in fact POM continued to cite the Aviram CIMT/BP Study (2004), and specifically the 30% plaque reduction finding, in its advertising until at least 2009. (*See, e.g.,* CCFF ¶¶ 406-418, 430-437, 449, 451, 453-454, 520, 527).

675. In May 2008, POM sought clearance from NBC for a television commercial, which included a line stating that POM Juice contained antioxidants that may promote prostate health. NBC reviewed POM's prostate cancer study, and found that it failed to meet the network's clinical testing guidelines. NBC required human studies for health claims, but the prostate cancer study relied upon by POM was neither randomized nor controlled, and clearly stated the need for further research to prove validity. Therefore, NBC did not consider the prostate health claim to be adequately documented. (CX0193; Tupper, Tr. 1056-59; Perdigao, Tr. 662-63).

676. Although POM did not run this particular television advertisement, it continued to run advertising making claims citing the prostate cancer study after May 2008. (*See, e.g.*, CCFF ¶¶ 377-81, 415, 419, 425, 572).

677. Similarly, in 2008 Comcast objected to a proposed POM television advertisement showing the bottle with noose and the tagline "Cheat Death." Comcast's lawyers wanted to know whether POM had substantiation that drinking POM would extend a person's life. (CX0242).

678. In January 2008, the FTC sent POM a letter alerting the company to its concerns about the advertising claims for POMx. (JX 0001).

679. POM stated to the FTC in April 2008 that POM's scientific findings

The company also stated that it had

(CX0967_0004, 0008, *in camera*) (emphasis added). As set forth in CCFF ¶¶ 879-949, POM was aware of inconsistent study results at the time of its statement to the FTC.

680. Dr. Liker kept in his files a printout (dated September 26, 2005) of an FTC press release, complaint and settlement with Tropicana Products, Inc., in which the FTC had alleged that Tropicana had made unsubstantiated health claims (including cholesterol and blood pressure reduction claims) about its orange juice. (CX0747). Dr. Liker testified that this document was likely sent to him from someone at POM or Roll who wanted him to be aware of it. (CX1350 (Liker, Dep. at 259-60)).

681. In February 2010, the FDA issued a warning letter to POM, finding POM made therapeutic claims on its website about POM Juice and that it was intended for use in the cure, mitigation, treatment, or prevention of diseases such as prostate cancer, erectile dysfunction, and heart disease. The FDA drew the same conclusion about POM's website claims for POMx Pills, including claims about heart disease and prostate cancer. (CX0344_0001-05).

682. Mr. Tupper testified that he considered the FDA's warning letter "very unimportant because my view is that the FDA is totally off base for singling us out. I think it's actually an extreme example of urgent and not at all important in the greater scheme of things." (CX1369 (Tupper, Welch Dep. at 198-99)). He said of FDA, "They're off their rocker." (CX1371 (Tupper, Trop. Dep. at 190)).

683. POM could have sought FDA approval for a qualified health benefit claim for pomegranate juice with a certain level of polyphenols. In 2001, Respondents' then Medical Director acknowledged the importance of conducting research on how the product works for purposes of substantiation "as we go to the FDA or the FTC for claims." (CX0003_001). In a 2003 proposal to POM, a consultant noted that a qualified health claim "allow[s] food and dietary supplement manufacturers to communicate emerging scientific information about the health benefits of their products, as long as it is truthful and not misleading." (CX0017_0002). POM chose not to go through this process because it would have provided no benefit to POM against its competitors.

(Tupper, Tr. 3032-33). Mr. Tupper also expressed concern, in an 2009 internal summary he drafted, that although POM could seek a "reduced risk of prostate cancer" health claim from the FDA, unless POM's cancer data was "outstanding, the resulting claim could be weak, [e.g.], the tomato claim is: '*Preliminary scientific research suggests that eating ½ cup of tomatoes / tomato sauce a week may reduce the risk of prostate cancer. FDA concludes that there is little scientific evidence supporting this claim*.'" (CX1029_0004) (emphasis in original). Similarly, in the 2009 summary, Mr. Tupper noted POM could seek a "reduced risk of heart disease" health claim from the FDA, but indicated it was "[p]robably not worth pursuing" because, among other reasons, "[t]he claim would not be specific to POM, but rather it would be generic to all pomegranate products meeting a minimum level of polyphenol content[.]" (CX1029_0003 (emphasis omitted)).

684. Mr. Tupper testified that POM did not make any specific changes to its marketing in response to receiving the letters from the FTC and the FDA. (Tupper, Tr. 1059-60). Moreover, Mr. Resnick testified at trial that he does not refer to any FDA or FTC standards in considering whether to make a claim. He stated that "Well, I haven't seen any standard that we can adhere to for what we're doing, so I can't say that we're hitting your standard or not. We're hitting my standard, and my standard I think is a very, very critical one. . . . [W]e don't make any claims unless we're very comfortable that we've done adequate work and the results are adequate enough to make those claims." Mr. Resnick further testified that he believes his standard is "an adequate standard . . . [o]r more than adequate." (S. Resnick, Tr. 1655-56).

685. The fact that Respondents persisted in making their unsupported health benefit claims after inquiries and warnings from the New York Attorney General's office, the NAD, NBC, the FDA, and the FTC is evidence that the health benefit claims are material. (CCFF ¶¶ 666, 673-74, 676, 684).

F. POM Assured Researchers and Research Institutions That It Would Not Promote Disease Treatment, Cure, or Prevention Claims, but Did So Anyway

686. On several occasions, the Institutional Review Boards (IRBs) for at least five research institutions have questioned whether POM's prostate cancer studies were intended to support a significant change in advertising in the product, or whether POM intended to market its tested product for the treatment, cure, or prevention of disease, which would require an Investigational New Drug application (IND) on file with the FDA. (JX0003 ¶¶ A.10-11; *see, e.g.*, CX0774_0001 [2005 inquiry from UCLA]; CX0811_0001 [2006 inquiry from MD Anderson]; CX0936_0001-02 [2007 inquiry from Johns Hopkins];

CX0975_0001 [May 2008 inquiry from UCLA]; CX1020_0002 [December 2008 inquiries from University of Miami and University of Indiana]; CX1056_0001 [2009 email from Johns Hopkins]).

687. In the May 2008 correspondence from UCLA, Dr. Pantuck noted that the IRB was concerned about POM's marketing because "the company previously assured the IRB that the studies would not be used as marketing for prostate cancer treatment." He also noted that he had sent POM an example "where it looked like POM was saying PJ [POM Juice] was beneficial for a disease – prostate cancer." (CX0975_0001).

688. In December 2008, the University of Miami IRB obtained guidance from FDA that since the objective of POM's proposed study was to determine the effect of POMx treatment on PSA levels in prostate cancer patients, its use would be considered a drug and would require an IND. Similarly, the University of Indiana IRB stated they needed confirmation of IND exemption from the FDA in order to proceed. These conclusions were relayed to Dr. Liker at POM. (CX1020_0007).

689. To mollify the IRBs, POM typically sent a response (either directly or through the principal investigator) stating that it would not make claims associated with the treatment, cure, or prevention of any disease, and therefore was exempt from IND filing requirements. (*See, e.g.*, CX0762_0002; CX0976_0006; CX0811_0001; CX0939_0001; CX0942_0007; CX1012_0001; Dreher, Tr. 581-82).

690. For example, in May 2008, Dr. Dreher of POM sent a letter to Dr. Pantuck at UCLA stating that POM "strictly adheres to the Food and Drug Administration (FDA) and Federal Trade Commission (FTC) claims guidelines for foods and dietary supplements. . . . As a policy, POM does not make drug related disease claims associated with treatment, cure, prevention or diagnosis. I continually reaffirm this with our Marketing team." (CX0255_0034). Dr. Dreher's May 2008 letter to Dr. Pantuck attached a full copy of the FTC's publication "Dietary Supplements: An Advertising Guide For Industry." (CX0255_0002-33).

691. Rather than heed Dr. Pantuck's concern about POM's misuse of his prostate cancer study in its advertising, POM attempted to placate him with false claims of regulatory compliance. (*See* CCFF ¶ 690). Perhaps the more candid view of POM's attitude about regulatory compliance comes from Mrs. Resnick when she testified that if she heard of Dr. Pantuck's concerns (*see* CCFF ¶ 402), she would have disregarded them as "Dr. Pantuck is not a marketing person." (L. Resnick, Tr. 212).

692. In May 2009, the Vice Dean for Clinical Investigation at Johns Hopkins informed Dr. Carducci, the principal investigator of a POMx prostate cancer study, that because POMx was being used to treat a medical condition (rising PSA), an IND was required. The Dean ordered Dr. Carducci to stop enrolling patients. (CX1056_0001).

693. The FDA rejected POM's standard argument against an IND, informing Dr. Carducci that "even if the company has no plan to make any claim, the objective of the study is to prevent the recurrence of cancer and that is a drug use and a serious clinical claim. Thus an IND is required." Nevertheless, POM continued to take the position that an IND was not required. (CX1066_0001-03).

(CX1349 (Gillespie, Dep. at 50); CX1074_0002, *in camera*).

VII. ANALYSIS OF THE SCIENTIFIC EVIDENCE AS PURPORTED SUBSTANTIATION FOR RESPONDENTS' CLAIMS

A. Testifying Experts

1. Complaint Counsel's Experts

a. Stampfer

694. Dr. Meir J. Stampfer is a Professor of Epidemiology and Nutrition, Harvard School of Public Health; Faculty Member, Division of Biological Sciences, Harvard School of Public Health; Professor of Medicine, Harvard Medical School; and Faculty Member, Dana Farber Harvard Cancer Center. (Stampfer, Tr. 689-91; CX1293 (Stampfer, Report at 0001)). He teaches epidemiology, advanced epidemiology, and preventive medicine. (CX1293 (Stampfer, Report at 0001)). Epidemiology is the study of the determination and distribution of disease in humans. (Stampfer, Tr. 691).

695. Dr. Stampfer has been an investigator in several large studies focused on the relationship between nutrition and cancer and cardiovascular disease ("CVD"), and their precursors. (CX1293 (Stampfer, Report at 0003-04)). These include:

- Nurses' Health Study (started 1976, 121,700 women, cancer prevention, CVD, diabetes, other health issues);
- Nurses' Health Study II (started 1989, 116,800 women, same as above);
- Physicians' Health Study (started 1982, 29,000 men, multivitamin supplements, and aspirin, and beta carotene for prevention of CVD and cancer); and

- Health Professionals Follow-up Study (started 1986, 51,529 men, nutritional factors as related to cancer, including prostate cancer, and heart disease).

(CX1293 (Stampfer, Report at 0003-04); Stampfer, Tr. 692-94)). Additionally, he has participated in research investigating risk factors (including food intake and dietary factors) associated with prostate cancer and conducted randomized clinical trials involving nutrition and health, including dietary interventions to reverse atherosclerosis. (Stampfer, Tr. 698-700).

696. Dr. Stampfer has published more than 850 articles in medical journals, including the *New England Journal of Medicine*, *American Journal of Epidemiology*, *Epidemiology*, and *Journal of American Medical Association*. (CX1293 (Stampfer, Report at 0002)). Over 300 of these articles relate to the relationship between nutrition and the prevention or treatment of CVD or prostate cancer. (Stampfer, Tr. 701; *see also* CX1293 (Stampfer, Report at 0002)).

697. In 2003, the Institute for Scientific Information identified Dr. Stampfer as the most cited researcher in clinical medicine and epidemiology in the world during the past 20 years. (CX1293 (Stampfer, Report at 0002)). In 2005, the Institute for Scientific Information identified him as the most cited researcher in clinical medicine over the previous decade. (CX1293 (Stampfer, Report at 0002)).

698. Dr. Stampfer currently is an editor for leading medical journals, including the Journal of the *American College of Nutrition, American Journal of Epidemiology*, *American Journal of Medicine*, and *Clinical Chemistry*. Dr. Stampfer also had editorial positions on the *American Journal of Clinical Nutrition*, *New England Journal of Medicine*, and *American Journal of Medicine*. (Stampfer, Tr. 701; CX1293 (Stampfer, Report at 0001-02)). In connection with his positions on these journals, he has had the opportunity to evaluate articles involving the design and conduct of clinical trials, and articles relating to the relationship between nutrition and CVD or cancer. Dr. Stampfer is a member of professional organizations relating to epidemiology, cancer, and CVD, including the Society of Epidemiological Research, the American College of Nutrition, the American Heart Association, and the American Association for Cancer Research. (Stampfer, Tr. 701-03). He also has consulted for the government on the U.S. Dietary Guidelines. (Stampfer, Tr. 703).

699. Based on his training, experience, and expertise, the Court recognized Dr. Stampfer as an expert on: 1) epidemiology; 2) nutrition, including its relation to the prevention and treatment of CVD and prostate cancer; and 3) clinical testing related to the prevention of prostate cancer and CVD. (Stampfer, Tr. 704-05 (noting no objection by Respondents to

Dr. Stampfer's qualifications); *see also* CX1293 (Stampfer, Report at 0005)).

700. Dr. Stampfer was asked to determine whether the materials submitted by Respondents were sufficient to support claims that:

- drinking eight ounces of POM Juice, or taking one POMx Pill or one teaspoon of POMx Liquid, daily, treats, prevents, or reduces the risk of heart disease, including by decreasing arterial plaque, lowering blood pressure, and/or improving blood flow to the heart;
- tests prove that drinking eight ounces of POM Juice or taking one POMx Pill or one teaspoon of POMx Liquid, daily, treats, prevents, or reduces the risk of heart disease, including by decreasing arterial plaque, lowering blood pressure, and/or improving blood flow to the heart;
- drinking eight ounces of POM Juice, or taking one POMx Pill or one teaspoon of POMx Liquid, daily, treats, prevents, or reduces the risk of prostate cancer, including by prolonging prostate-specific antigen doubling time ("PSADT"); and
- tests prove that drinking eight ounces of POM Juice, or taking one POMx Pill or one teaspoon of POMx Liquid, daily, treats, prevents, or reduces the risk of prostate cancer, including by prolonging "PSADT."

(CX1293 (Stampfer, Report at 0005-06)).

701. To form his opinions, in addition to drawing upon his own expertise in nutrition and CVD and treatment, Dr. Stampfer reviewed materials submitted by Respondents and affiliated researchers, including published and unpublished study reports, protocols, data and data analyses from Respondents' sponsored research, information about ingredients contained in the POM Products, and deposition transcripts of researchers who conducted studies for Respondents and related deposition exhibits and reports. Dr. Stampfer also reviewed materials he found through his independent literature search. (CX1293 (Stampfer, Report at 0006-07); Stampfer, Tr. 734-36; CX1294).

b. Sacks

702. Dr. Frank M. Sacks is a Professor of Cardiovascular Disease Prevention, Department of Nutrition, Harvard School of Public Health, and Professor of Medicine, Harvard Medical School. (Sacks, Tr. 1411-12; CX1291 (Sacks, Report at 0001)). He has taught pharmacology, epidemiology, and nutrition courses related to human disease, CVD, biochemistry, or preventative medicine. (Sacks, Tr. 1412-13; CX1291 (Sacks, Report at 0002)).

703. Dr. Sacks has researched CVD and coronary heart disease ("CHD") and their risk factors,

including lipid profiles, hypertension, obesity, and diabetes, and the effects of potential risk-modifying diets, foods, food components, and drugs. (CX1291 (Sacks, Report at 0002); Sacks, Tr. 1415-18). He is the principal investigator of several NIH studies focusing on dietary nutrients and weight loss, carbohydrate amount and type affecting risk of CVD and diabetes, and dietary fat and high-density lipoprotein ("HDL") metabolism in humans. (CX1291 (Sacks, Report at 0005-06)).

704. Dr. Sacks has published more than 160 articles in peer-reviewed scientific journals relating to CVD, CHD, and the relationship between nutrition and these diseases. (Sacks, Tr. 1412-13, 1424-25; CX1291 (Sacks, Report at 0002-04)). Dr. Sacks has also written over 60 reviews, reports, editorials, and book chapters, addressing CVD, CHD, and the relationship between nutrition and these diseases or their risk factors. (CX1291 (Sacks, Report at 0004)).

705. Through his professional memberships and activities, Dr. Sacks keeps current on new developments and research in the areas of nutrition, CVD, cholesterol disorders, and hypertension. (Sacks, Tr. 1424). He served as an editor for the *American Journal of Clinical Nutrition*, *Journal of Clinical Lipidology*, a *Nutrition Journal (BioMed Central),* and *The Journal of Lipid Research.* (CX1291 (Sacks, Report at 0006)). In these positions, he reviewed the adequacy of the design, the conduct of clinical research, and the appropriateness and accuracy of the statistical methodology in hundreds of papers submitted for publication. (Sacks, Tr. 1424-25; CX1291 (Sacks, Report at 0006)).

706. Dr. Sacks serves as a chair of the Nutrition Committee of the American Heart Association (AHA), which advises the AHA on matters of science and public policy and devises guidelines and advisory statements to the government, health professionals, and the public on nutrition. (Sacks, Tr. 1426; CX1291 (Sacks, Report at 0006-07)). Dr. Sacks is also a member of the National Cholesterol Education Program of the National Heart, Lung and Blood Institute of NIH, which revises national guidelines on prevention and treatment of CVD. (CX1291 (Sacks, Report at 0007); Sacks, Tr. 1426).

707. Based on his training, experience, and expertise, the Court recognized Dr. Sacks as qualified to provide expert opinions on the areas of nutrition, CVD, CHD, cholesterol disorders, hypertension, and analysis of clinical studies. (Sacks, Tr. 1429-30 (noting no objection by Respondents to Dr. Sack's qualifications); CX1291 (Sacks, Report at 0008)).

708. Dr. Sacks was asked to determine whether the materials he reviewed were sufficient to

support claims that: 1) drinking eight ounces of POM Juice, or taking one POMx Pill, or one teaspoon of POMx Liquid, daily, treats, prevents, or reduces the risk of heart disease, including by decreasing arterial plaque, lowering blood pressure, and/or improving blood flow to the heart; and 2) clinical studies, trials, and/or tests prove that drinking eight ounces of POM Juice, or taking one POMx Pill, or one teaspoon of POMx Liquid, daily, treats, prevents, or reduces the risk of heart disease. (CX1291 (Sacks, Report 0008-09)).

709. To form his opinions, in addition to drawing upon his own expertise in nutrition and CVD treatment, Dr. Sacks reviewed materials submitted by Respondents and affiliated researchers, including published and unpublished study reports, protocols, data, and data analysis from Respondents' sponsored research, information about ingredients contained in the POM Products, and deposition transcripts of researchers who conducted studies for Respondents and related deposition exhibits. Dr. Sacks also reviewed materials he found through an independent literature search. (Sacks, Tr. 1447-49 (identifying materials he reviewed); CX1291 (Sacks, Report at 0008-09); CX1292, Apps. 2, 3, 4).

c. Eastham

710. Dr. James A. Eastham is the Chief of Urology in the Department of Surgery at Memorial Sloan-Kettering Cancer Center in New York. He serves as the Director of Clinical Research, Urology and chairs the protocol review committee for clinical trials in the Department of Surgery. (CX1287 (Eastham, Report at 0001); Eastham, Tr. 1207-08)). He is a board-certified urological surgeon who has treated more than 2,000 patients with prostate cancer, including some who experienced a rise in prostate-specific antigen ("PSA") after receiving initial therapy. (CX1287 (Eastham, Report at 0002); Eastham, Tr. 1206, 1225-28, 1233).

711. Dr. Eastham has extensive experience, including as an investigator, in the design and conduct of clinical trials studying prostate cancer. (Eastham, Tr. 1215-17). As a member of the Data Safety Monitoring Board for the Selenium and Vitamin E Cancer Prevention Trial, he is familiar with the design and performance of the largest prevention trials studying antioxidants and prostate cancer. (CX1287 (Eastham, Report at 0002-03); Eastham, Tr. 1210-11)).

712. Dr. Eastham is a member of professional associations, including the American Urological Association, the Society of Urologic Oncology, and the National Comprehensive Cancer Network ("NCCN") Prostate Cancer Guidelines Committee. He regularly attends and speaks at national and international meetings of professional societies that specialize in urology and prostate cancer. (CX1287 (Eastham, Report at 0003); Eastham, Tr. 1211-

13).

713. Dr. Eastham has peer-reviewed numerous papers involving randomized, double-blinded, controlled human clinical studies ("RCTs") that were submitted to medical journals, such as *Urology*, *Journal of Urology*, and *Journal of Clinical Oncology*. (CX1287 (Eastham, Report at 0003); Eastham, Tr. 1224-25). Dr. Eastham has published over 200 peer-reviewed articles in scientific journals, as well as dozens of book chapters or reviews pertaining to urology and the treatment of prostate cancer. (CX1287 (Eastham, Report at 0003-04); CX1288, Ex. A; Eastham, Tr. 1214-15).

714. Based upon his education, training, and experience, the Court recognized Dr. Eastham as an expert in: 1) urology specializing in prostate cancer, including the prevention and treatment of prostate cancer; and 2) clinical testing related to the prevention and treatment of prostate cancer. (Eastham, Tr. 1234 (noting no objection by Respondents to Dr. Eastham's qualifications); CX1287 (Eastham, Report at 0004)).

715. Dr. Eastham was asked to determine whether the materials he reviewed were sufficient to support claims that: (1) drinking eight ounces of POM Juice, or taking one POMx Pill, or one teaspoon of POMx Liquid, daily treats, prevents, or reduces the risk of prostate cancer, including by prolonging prostate-specific antigen doubling time ("PSADT"); and (2) tests prove that drinking eight ounces of POM Juice, or taking one POMx Pill, or one teaspoon of POMx Liquid, daily, treats, prevents, or reduces the risk of prostate cancer, including by prolonging PSADT. (CX1287 (Eastham, Report at 0004-06)).

716. To form his opinion, in addition to drawing upon his own expertise in the field of urology, specializing in prostate cancer, including the prevention and treatment of prostate cancer, and clinical testing relating to the treatment and prevention of prostate cancer, Dr. Eastham reviewed the materials submitted by Respondents and affiliated researchers, including published and unpublished study reports, protocols, data and data analysis from Respondents' sponsored research, and information about ingredients contained in the POM Products. Dr. Eastham also reviewed materials he found through an independent literature search. (CX1287 (Eastham, Report at 005); Eastham, Tr. 1287-88; CX1288, Ex. B).

d. Melman

717. Dr. Melman is a Professor and Chairman of the Department of Urology at Albert Einstein College of Medicine and Montefiore Medical Center. (Melman, Tr. 1072-73). Dr.

Melman is a board-certified, practicing clinical urologist at Montefiore Medical Center and has treated thousands of patients with erectile dysfunction. (Melman, Tr. 1071-73).

718. Dr. Melman has extensive experience in designing and reviewing protocols for well-designed clinical trials. As an editor of *Sexuality and Disability,* the *Journal of Urology,* and the *International Journal of Impotence Research*, Dr. Melman reviewed hundreds of articles involving erectile dysfunction by evaluating, among other factors, the design, data collection and reporting, and statistical analysis of clinical studies. (Melman, Tr. 1075-77; CX1289 (Melman, Report at 0002)). Furthermore, Dr. Melman was a principal investigator on two National Institutes of Health research grants relating to erectile dysfunction. (Melman, Tr. 1079-80; CX1289 (Melman, Report at 0002-03)).

719. Dr. Melman was chairman of the U.S. Food and Drug Administration's Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee, and was a member of the National Institutes of Health's Urology Special Emphasis Panel. (Melman, Tr. 1077-78; CX1289 (Melman, Report at 0001-02)). Dr. Melman is a member of several professional organizations, including the American Federation for Clinical Research, Society of University Urologists, American Urological Association, American Association of Clinical Urologists, International Society of Urology, and International Academy of Sex Research; and has spoken at national and international meetings of professional societies that specialize in urology and erectile dysfunction. (Melman, Tr. 1077-79; CX1289 (Melman, Report at 0001-02)). Dr. Melman has published more than 200 peer-reviewed articles relating to urology in scientific journals. Many of these published articles relate to erectile dysfunction. (Melman, Tr. 1076-77; CX1289 (Melman, Report at 0002)).

720. Based upon his education, training, and experience, the Court recognized Dr. Melman as an expert in: (1) urology as it relates to the treatment, prevention, and reduction of risk of erectile dysfunction; and (2) clinical testing involving erectile dysfunction. (Melman, Tr. 1080-81 (noting no objection by Respondents to Dr. Melman's qualifications)).

721. Dr. Melman was asked to determine whether the materials he reviewed were sufficient to support claims that: 1) drinking eight ounces of POM Juice, daily, prevents, reduces the risk of, or treats erectile dysfunction; and 2) clinical studies, research, and /or trials prove that drinking eight ounces of POM Juice, daily, prevents, reduces the risk of, or treats erectile dysfunction. (CX1289 (Melman, Report at 0003)).

722. To form his opinions, in addition to relying on his expertise in urology as it relates to the

treatment, prevention, and reduction of risk of erectile dysfunction, and clinical testing involving erectile dysfunction, Dr. Melman reviewed materials submitted by Respondents and affiliated researchers, including included published and unpublished study reports, protocols, and data and data analyses from Respondents' sponsored research. (CX1289 (Melman, Report at 0003); Melman, Tr. 1083). Dr. Melman also reviewed articles he found through his independent research of peer-reviewed journals. (Melman, Tr. 1083; CX1289 (Melman, Report at 0003)).

2. Respondents' Experts

a. Heber

723. Dr. David Heber, a Professor of Medicine and Public Health, directs the University of California Center for Human Nutrition. Since 2001, he has directed the UCLA Risk Factor Obesity Program, which focuses on obesity treatment. He has published over 200 peer-reviewed articles and two books, *What Color Is Your Diet* (2001) and *The L.A. Shape Diet* (2004). His areas of research interest encompass obesity, clinical nutrition, inflammation, phytonutrients, and cancer. (PX0192 (Heber, Report at 0005-06, 0092)).

724. Since approximately 2002, Dr. Heber has worked as Respondents' scientific advisor. (Heber, Tr. 1941, 2013; S. Resnick, Tr. 1637). Dr. Heber testified that he was not paid for his work as an expert in this case. (Heber, Tr. 1942). However, Mr. Resnick and POM's scientific director, Dr. Gillespie, testified that Dr. Heber is on "retainer." (CX1376 (S. Resnick, OS Dep. at 312); CX1349 (Gillespie, Dep. at 268-69)). Rather than compensating Dr. Heber directly, Respondents have paid UCLA for his services. (*See* Heber, Tr. 2016). Respondents provide some of this funding as "gifts." However, to obtain these gifts, Dr. Heber submitted proposed budgets describing his proposed work for the coming year. (Heber, Tr. 2016; CX873_0001-03; CX1006_0001-07; *see* CX897_0001; CX1150_0001). Between 2004 and 2010, Respondents gave UCLA $1.58 million in "gifts" for Dr. Heber's work. (Heber, Tr. 2023-27). Between 2005 and 2010, Respondents also paid UCLA $489,000 in contract awards pursuant to Dr. Heber's work for POM. (Heber, Tr. 2024-25; CX1132_0002-04). Respondents have also paid $670,000 to the University Medical Research Foundation, which Dr. Heber uses to cover shortfalls in the Center for Human Nutrition's operating costs. (Heber, Tr. 2030; CX1027_0001-02). Dr. Heber has named a laboratory at the Center for Human Nutrition after the Resnicks. (S. Resnick, Tr. 1640-41).

725. Dr. Heber has conducted numerous *in vitro* and animal studies on Respondents' pomegranate products, investigated the superiority of Respondents' juices to competitors' products, and researched whether POM Juice or extracts modified various biomarkers in

overweight adults or diabetics. (Heber, Tr. 2015-16; CX0859_0001-03 (overweight adults); CX1109_0002 (diabetes study)). Dr. Heber has also done research for Roll on pistachios and triglycerides, and on Fiji Water and bone health. (Heber, Tr. 2015, 2028-30).

726. Dr. Heber has coordinated POM's research with other scientists, developed manuscripts and abstracts, presented research agendas, and presented at most POM Research Summits. (Heber, Tr. 2019; CX1006; CX1376 (S. Resnick, OS Dep. at 312-13)). He co-edited a book about POM research. (CX1352 (Heber, Dep. at 397)). Dr. Heber also has provided statements for use in POM's marketing materials. (L. Resnick, Tr. 236-37; CX1426_00041; CCFF ¶¶ 475-476, 557). He communicated frequently with Mr. Resnick and Respondents' employees. (Dreher, Tr. 557, 569; Heber, Tr. 2018-19; S. Resnick, Tr. 1638).

727. Dr. Heber also has provided expert testimony for Respondents in four federal court cases, including three where he purportedly appeared "pro bono." PX0192 (Heber, Report at 0007-08; PX0045-0007 (*POM Wonderful LLC v. Tropicana Products, Inc.*); PX0046-0007 (*POM Wonderful LLC v. Welch Foods, Inc.*); PX0047-005 (*POM Wonderful LLC v. Ocean Spray Cranberries, Inc.*); PX0353 (Heber Dep. at 189) (noting that Dr. Heber testified in *POM Wonderful LLC v. Purely Juice*)).

728. Respondents offered Dr. Heber as an expert on the relationship between nutrition and various diseases, including coronary heart disease and prostate cancer, as well as other diseases. (Heber, Tr. 1940-41). Dr. Heber does not hold himself out to be an expert in CVD, is not an expert in CVD treatment, and does not know what kind of evidence experts in the field would require to support a claim that a product could lower blood pressure. (Heber, Tr. 2041; PX0353 (Heber, Dep. at 12, 172); PX0353 (Heber, Dep. at 11-12, 172) (his "expertise would be determined by legal folks")). He admits that he is not an expert in prostate cancer treatment or erectile function treatment. (Heber, Tr. 2034-36, 2038-39; PX0353 (Heber, Dep. at 10-11)).

729. Dr. Heber was asked to comment on Dr. Stampfer's expert report and provide opinions on issues related to pomegranate juice and extract, including: (1) antioxidants found in pomegranates, their potency, and how they act in the body (their mechanisms of action); (2) the health and safety effects; and (3) nutritional research methodology relating to the evaluation of scientific research on health benefits. (PX0192 (Heber, Report at 0004)).

730. Dr. Heber was *not* asked to opine on whether the heart benefit claims challenged in the

complaint were true or substantiated. When asked at his deposition whether competent and reliable scientific evidence supports the conclusion that drinking eight ounces of POM Juice, or taking one POMx Pill, or one teaspoon of POMx Liquid daily, *prevents or reduces the risk of* heart disease including by decreasing arterial plaque, lowering blood pressure, or improving blood flow, Dr. Heber repeatedly stated that "the body of research on pomegranate juice and extract revealing how it acts on the body provides support for *potential* health benefits for heart disease." (PX0353 (Heber, Dep. at 76-79 (emphasis added)); *see also* PX0192 (Heber, Report at 0019) ("the body of research on pomegranate juice and extract provides support for "potential health benefits for heart disease, and prostate cancer")). When asked whether competent and reliable scientific evidence supports the conclusion that drinking POM Juice or taking POMx Pills or Liquid *treats* heart disease including by decreasing arterial plaque, lowering blood pressure, or improving blood flow to the heart, Dr. Heber states that "nutrition is not a treatment for disease. . . since you characterized it with the word 'treatment' I'm not agreeing with your statement." (PX0353 (Heber, Dep. at 81-83)).

731. Similarly, when asked whether clinical studies, research, and/or trials prove that drinking POM Juice, or taking POMx Pills or one teaspoon of POMx Liquid daily, prevents or reduces the risk of heart disease including by decreasing arterial plaque, lowering blood pressure, or increasing blood flow to the heart, Dr. Heber repeated that "my professional opinion is that the body of research including clinical studies on pomegranate juice and extract revealing how they act in the body provides support for *potential* benefits for heart disease" including blood flow. (PX0353 (Heber, Dep. at 87-89) (emphasis added)). Asked whether clinical studies, research, and/or trials prove that POM Juice, POMx Pills, and POMx Liquid *treats* heart disease, including by lowering blood pressure, or improving blood flow to the heart, he repeated that the "body of research . . . provides support for *potential* health benefits for heart disease including blood flow." (PX0353 (Heber, Dep. at 89-90) (emphasis added)).

732. Dr. Heber was not asked to opine on whether the prostate benefit claims challenged in the complaint were true and substantiated. Asked whether competent and reliable scientific evidence supports the conclusion that POM Juice, POMx Pills, or POMx Liquid prevents or reduces the risk of prostate cancer including by prolonging prostate specific antigen doubling time, he stated that "my professional opinion is the body of research on pomegranate juice and extract revealing how they act in the body provides support for *potential* health benefits for prostate cancer including prolongation of PSA doubling time." (PX0353 (Heber Dep. at 84-85)(emphasis added)). Asked whether the challenged prostate *treatment* claims were supported by competent and reliable scientific evidence, he stated that "I would disagree with the term 'treatment' for a nutritional product and say that my professional opinion is that the body of research on pomegranate juice and

extract provides support for *potential* health benefits for prostate cancer." (PX0353 (Heber, Dep. at 85-86)) (emphasis added). When asked whether clinical studies, research, and/or trials prove that POM Juice, POMx Pills, or POM Liquid prevents, reduces the risk of, or treats prostate cancer, including by prolonging PSADT, he stated only that "the body of research . . . provides support for *potential* benefits for prostate cancer including" prolongation of PSADT. (PX0353 (Heber, Dep. at 90-92) (emphasis added)).

b. Ornish

733. Dr. Dean Ornish is the Founder and President of the Preventative Medicine Research Institute ("PMRI") in Sausalito, CA. (PX0025 (Ornish, Report at 0001)).

734. Dr. Ornish's career has focused on testing the theory that comprehensive, intensive lifestyle changes can improve medical risk factors in people with disease, including heart disease. For example, his Lifestyle Intervention Program asked patients to eat a very low-fat, plant based diet, exercise at certain levels, engage in stress management, and attend group support sessions. (Ornish, Tr. 2466). He believes that a comprehensive lifestyle program can treat CVD. (Ornish, Tr. 2467). Dr. Ornish is the author of six books, including *Dr. Dean Ornish's Program for Reversing Heart Disease*; *Eat More, Weigh Less*; and *The Spectrum*. (PX0025 (Ornish, Report at 0003-04)).

735. Dr. Ornish conducted two pomegranate juice studies, sponsored by Respondents; one was published, and one was not. (*See* CCFF ¶¶ 822, 824-74). Other than these two pomegranate juice studies for Respondents, Dr. Ornish has never studied whether a single food product is beneficial in maintaining cardiovascular health or for any other endpoint. (Ornish, Tr. 2464). Nor does his curriculum vitae identify any studies conducted by him to determine whether an individual drug intervention provides cardiovascular or other benefits. (*See* PX0025 (Ornish, Report at 0053-56)). Prior to the time that PMRI conducted the two pomegranate juice studies for Respondents, the Resnicks had provided Dr. Ornish with a "generous" grant to study whether comprehensive lifestyle changes could halt progression of early prostate cancer. (CX1339 (Ornish, Dep. at 215)).

736. Respondents offered Dr. Ornish as an expert in "the relationship between the heart and nutrition and in cardiovascular disease and its relationship to nutrition, nutrients, and such things." (Ornish, Tr. 2321-22).

737. Dr. Ornish was not, according to his expert report, asked to opine on whether the heart

benefit prevention, reduction of risk, or treatment claims alleged in the complaint were substantiated, or whether the heart benefit "establishment claims" (that is, the claims that "clinical studies, research, and/or trials prove heart benefits in terms of prevention, reduction of risk, or treatment) were true. (*See* PX0025 (Ornish, Report at 0004-05)). Instead, he was asked to evaluate Dr. Sacks' expert report and provide an opinion on: (1) whether drinking eight ounces of POM Juice, or taking one POMx Pill, or one teaspoon of POMx Liquid "*may be beneficial* in maintaining cardiovascular health and lessening the risk of CVD;" and (2) whether "basic science, clinical studies, research, and/or trials show that the consumption of POM Juice, POMx Pill, or POMx Liquid *may be beneficial* in maintaining cardiovascular health and lessening the risk of CVD." (PX0025 (Ornish, Report at 0004-05); PX0355 (Ornish, Dep. at 20) (emphasis added)).

738. At trial, Dr. Ornish testified only with regard to the two studies that he had conducted, and opined that they constitute credible and reliable scientific evidence that pomegranate juice lessens the risk of cardiovascular problems by improving blood flow in people who already had heart disease. (Ornish, Tr. 2354). He previously testified, however, that he did not consider his own CIMT study (*see* CCFF ¶ 872) to be a "part of the evidence" relating to whether or not pomegranate juice has beneficial effects on heart disease, and that he did not include those results in reaching his opinions. (PX0355 (Ornish, Dep. at 191-93).

c. deKernion

739. Dr. Jean B. deKernion is the former Chairman of the Department of Urology and Senior Associate Dean for Clinical Operations at the UCLA School of Medicine in Los Angeles, California. (deKernion, Tr. 3039). Dr. deKernion is board certified by the American Board of Surgery and the American Board of Urology and maintains an active urologic oncology practice treating patients for prostate, kidney, and bladder cancer. (deKernion, Tr. 3039-40, 3111-12).

740. Dr. deKernion's major research contributions early in his career were in the field of kidney cancer, focusing on immunomodulation and immunotherapy. (deKernion, Tr. 3111). For the last 30 years, Dr. deKernion has been more of a research administrator and facilitator than a hands-on researcher. (deKernion, Tr. 3110-11).

741. Dr. deKernion has several personal and professional connections to Respondents and the Pantuck Phase II Prostate Cancer Study (2006). (deKernion, Tr. 3112-17). Dr. Pantuck and Dr. Arie Belldegrun conducted the Pantuck Phase II Prostate Cancer Study (2006) and reported to Dr. deKernion, Chairman of the Urology Department at the UCLA

School of Medicine. (deKernion, Tr. 3114). He encouraged Dr. Pantuck and the other investigators to conduct the Pantuck Phase II Prostate Cancer Study (2006) and even sought an exemption from UCLA rules to allow Dr. Pantuck to serve as the primary investigator for the Pantuck Phase II Prostate Cancer Study (2006). (deKernion, Tr. 3113, 3115; CX0570_0001).

742. Dr. deKernion was listed as an investigator on the original protocol for the Pantuck Phase II Prostate Cancer Study (2006) because he helped identify patients under his medical care for the study. (CX0666_0001; deKernion, Tr. 3112-13). Dr. deKernion's department directly benefitted from Respondents' funding of the Pantuck Phase II Prostate Cancer Study (2006). (deKernion, Tr. 3115).

743. Dr. deKernion was a founding member and board member of Agensys until 2007. (PX0351 (deKernion, Dep. at 116-17); deKernion, Tr. 3115). Respondents paid Agensys $1.8 million in 2000 and 2001 for its *in vitro* and animal research on POM Juice. (CX1263_0003). The Pantuck Phase II Prostate Cancer Study (2006) protocol cited the Agensys *in vitro* and animal research on the effect of POM Juice on prostate cancer to support its hypothesis that POM Juice may affect PSA. (CX0666_0008).

744. Dr. deKernion operated on Respondent Stewart Resnick for his prostate cancer. (CX1376 (S. Resnick, Dep. at 152); deKernion, Tr. 3117).

745. Respondents offered Dr. deKernion as an expert to discuss "the experiments, the studies that have been done on the prostate . . . about pomegranate juice and POM products." (deKernion, Tr. 3043-44). Respondents asked Dr. deKernion to rebut the opinions in Dr. Eastham's expert report. (deKernion, Tr. 3108-09).

746. Respondents did not ask Dr. deKernion to determine whether Respondents' evidence, considered as a whole, was sufficient to support the claims that: (1) drinking eight ounces of POM Juice, or taking one POMx Pill, or one teaspoon of POMx Liquid, daily, treats, prevents, or reduces the risk of prostate cancer, including by prolonging PSADT; and (2) clinical studies, research, or trials prove that drinking eight ounces of POM Juice, or taking one POMx Pill, or one teaspoon of POMx Liquid, daily, treats, prevents or reduces the risk of prostate cancer, including by prolonging PSADT. (*See* PX0161 (deKernion, Report at 0003-04); deKernion, Tr. 3061; *see also* PX0351 (deKernion, Dep. at 30) (Respondents did not ask Dr. deKernion to opine on the claims alleged in the Complaint)).

747. To form his opinion, Dr. deKernion reviewed the expert reports of Dr. Eastham and Dr. Miller, the FTC depositions of Dr. Pantuck and Dr. Carducci, protocols for the Pantuck Phase II Prostate Cancer Study (2006), the Carducci Dose Study, and the Pantuck Phase III Study (*see* CCFF ¶ 1026), articles cited in Dr. Eastham's report, scientific articles found by conducting a literature search, and marketing materials. (PX0351 (deKernion, Dep. at 6-8, 27-29); PX0351a4; PX0351a5). Dr. deKernion did not review the Complaint in this matter. (deKernion, Tr. 3109; PX0351 (deKernion, Dep. at 28)).

d. Burnett

748. Dr. Burnett is a Professor of Urology at Johns Hopkins Medical School, Director of the Basic Science Laboratory in Neurourology at the James Buchanan Brady Urological Institute, and Director of the Male Consultation Clinic of the Sexual Medicine Division of Johns Hopkins' Department of Urology. (Burnett, Tr. 2241; PX0149a01-0001). Dr. Burnett has held editor positions on the *Journal of Urology*, *Journal of Sexual Medicine*, *Journal of Andrology*, and *Practical Reviews in Urology*. (Burnett, Tr. 2242). Dr. Burnett has published over 180 peer-reviewed articles and written 40 book chapters. (Burnett, Tr. 2243).

749. Respondents proffered Dr. Burnett as expert in nitric oxide and erectile function. (PX0149 (Burnett, Report at 0004)).

750. Dr. Burnett was asked to provide opinions regarding pomegranate juice, nitric oxide, and erectile health. (PX0149 (Burnett, Report at 0004-0006)). Dr. Burnett offered no opinions on POMx Pills or Liquid. (PX0349 (Burnett, Dep. at 172)).

751. To form his opinion, Dr. Burnett reviewed studies on erectile function and nitric oxide, including POM-sponsored studies such as the Forest Erectile Dysfunction Study (2007) and a few *in vitro* and animal studies. (PX0149 (Burnett, Report at 0004)). Burnett relied upon his "education, experience, and knowledge of developments in the fields of urology and sexual medicine, including the promotion of erectile health and treatment of erectile dysfunction." (PX0149 (Burnett, Report at 0004)).

e. Goldstein

752. Dr. Irwin Goldstein is the Director of Sexual Medicine at Alvarado Hospital and a Clinical Professor of Surgery at University of California at San Diego. (Goldstein, Tr. 2590). Dr. Goldstein was a member of the Nutraceutical Committee for the Sexual Medicine Society of North America. The Nutraceutical Committee included physicians

from various universities. Through this committee, Dr. Goldstein was an author of two articles: *Prevention and Treatment of Erectile Dysfunction Using Lifestyle Changes and Dietary Supplements: What Works and What Is Worthless, Part I* and *Prevention and Treatment of Erectile Dysfunction Using Lifestyle Changes and Dietary Supplements: What Works and What Is Worthless, Part II*, which were published in 2004 in *Urologic Clinics of North America*. (Goldstein, Tr. 2612-15). Dr. Goldstein was also an author of *Erectile Dysfunction*, which was published in *Clinical Evidence* in 2011. (Goldstein, Tr. 2627).

753. Respondents offered Dr. Goldstein as expert in sexual medicine and the impact of pomegranate juice, antioxidants, and nitric oxide on erectile function and dysfunction. (Goldstein, Tr. 2592.)

754. Dr. Goldstein was asked to "determine whether clinicians who regularly treat men with sexual health concerns would conclude that competent and reliable scientific evidence exists to suggest that the consumption of pomegranate juice promotes erectile health." (PX0189 (Goldstein, Report at 0010); *see also* PX0352 (Goldstein, Dep. at 19)). Dr. Goldstein did not evaluate any pomegranate extract product and did not know whether pomegranate pills were safe for human consumption. (PX0352 (Goldstein, Dep. at 169-70, 173)). Dr. Goldstein assumed that any pomegranate extract or pill were equivalent to POM Juice. (PX0352 (Goldstein, Dep. at 169-70, 173)).

755. To form his opinion, Dr. Goldstein reviewed studies on erectile function, nitric oxide, and the Mediterranean diet, including POM-sponsored studies such as the Forest Erectile Dysfunction Study (2007) and several *in vitro* and animal studies. (PX0189 (Goldstein, Report at 0005); PX0352 (Goldstein, Dep. at 125)). Dr. Goldstein relied upon his "education, experience, and knowledge of developments in the fields of urology and sexual medicine, including the promotion of erectile health and treatment of erectile dysfunction." (PX0189 (Goldstein, Report at 0005)).

f. Miller

756. Dr. Denis Miller is a clinical professor at Robert Wood Johnson School of Medicine. (Miller, Tr. 2189).

757. Dr. Miller is an oncologist. He is not a nutritionist or an expert on the role of foods in the prevention and treatment of disease. (Miller, Tr. 2215). Dr. Miller is not an expert in CVD, has never treated patients specifically for CVD, and has never performed a clinical

trial specifically on CVD. (Miller, Tr. 2229). Dr. Miller also is not an expert in erectile dysfunction and has never been involved in clinical trials related to erectile dysfunction. (Miller, Tr. 2230).

758. Dr. Miller states he is an expert in the Food and Drug Administration's ("FDA") post-approval regulatory requirements for drug treatments, and it is part of what qualifies him to offer an opinion on the standard for substantiating claims for POM's products. (Miller, Tr. 2217). However, he is not an expert in the FDA's regulations for dietary supplements, and is not aware of the FDA's regulations governing the standard for making health claims for a food. (Miller, Tr. 2217-18).

759. Respondents proffered Dr. Miller to testify about the applicable standards for substantiating evidence for fruit, fruit juice, and food products in general as opposed to the standard that is applicable for drugs. He was asked to testify about the *standard* only, not about the specific scientific studies on POM or whether Respondents' evidence was sufficient to support POM's claims. (Miller, Tr. 2192).

760. Dr. Miller stated that he was not testifying about the substantiation standard related to foods and CVD, or foods and erectile dysfunction. (Miller, Tr. 2219). Dr. Miller has not published any articles on diet or foods in the prevention or treatment of cancer. (Miller, Tr. 2215). He has not been involved in the design of clinical trials to prevent cancer in healthy people, and has not done any clinical trials for foods. Rather he has only participated in trials involving drugs or biotechnology products. (Miller, Tr. 2218, 2220).

761. Dr. Miller was fired by the FTC due to his simultaneous work on a nonpublic, FTC matter and his work for Respondents. (Miller, Tr. 2224-26).

B. Study Designs for Examining the Relationship between Foods and Nutrients and Disease Outcomes

1. Types of Studies

762. There are four study types for examining the relation between a food or nutrient and a disease outcome: (a) *in vitro* studies; (b) animal studies; (c) human observational studies; and (d) human clinical studies. (CX1293 (Stampfer, Report at 0008)).

a. *In vitro* Studies

763. *In vitro* studies are those where blood elements or cells are removed from the body and tested in a controlled laboratory environment, such as a test tube. (CX1293 (Stampfer, Report at 0008); CX1291 (Sacks, Report at 0015-16); *see* Melman, Tr. 1112)). They are used to identify potential biologic mechanisms and generate hypotheses for studies in humans. (CX1293 (Stampfer, Report at 0008); CX1291 (Sacks, Report at 0015-16)). Human metabolism and disease processes are very complicated and cannot be replicated in a petri dish, and therefore, many *in vitro* studies produce results cannot be replicated in humans. (CX1291 (Sacks, Report at 0015); Sacks, Tr. 1450; *see also* Stampfer, Tr. 725-26 (cannot assume *in vitro* results will be repeated in humans); deKernion, Tr. 3063-64 (even strong *in vitro* evidence does not prove an agent works in humans)).

b. Animal Studies

764. Animal studies are tools for identifying potential treatments, mechanisms, and side effects. (CX1291 (Sacks, Report at 0016)). Animals are not the same as humans, either biologically or psychologically, and therefore, many findings of dietary or drug effects in animals are not confirmed in human testing. (CX1291 (Sacks, Report at 0016); Sacks, Tr. 1451; Melman, Tr. 1112-13; CX1289 (Melman, Report at 0011); *see* PX0355 (Ornish, Dep. at 66) (animal physiology is similar but not identical to humans)). Thus, animal studies alone are not sufficient to show that a tested product will prevent or treat human disease. (Sacks, Tr. 1451-52; Melman, Tr. 1112-13; CX1289 (Melman, Report at 0011); PX0352 (Goldstein, Dep. at 124) ("you have to study humans to make statements about humans"); Goldstein, Tr. at 2644; PX0349 (Burnett, Dep. at 57, 112-13) (stating that he would have concerns with animal studies being the sole basis to establish a product as a treatment for erectile dysfunction)).

c. Human Observational Studies

765. Human observational studies are large human studies that compare intake of various levels of nutrients (for example, low vitamin C versus high vitamin C) with various endpoints, such as disease outcomes, over time. (CX1293 (Stampfer Report at 0008); Stampfer, Tr. 719; *see* Heber, Tr. 2168 (observational studies are population studies that compare intake of different nutrients and endpoints over time)). They can support a conclusion that there is an association between a nutrient and a disease of interest, but generally do not prove causation, due to the potential, even in well-designed studies, for unidentified biases or inadequately controlled confounding factors. (CX1293 (Stampfer, Report at 0008-09); Stampfer, Tr. 720-21; *see* Sacks, Tr. 1418-19 (cannot prove a causal effect between an intervention and reduction of heart disease from observational

research)).

766. In any event, there is no observational study evidence on pomegranates, pomegranate juice, or pomegranate extract. (Heber, Tr. 2168; Stampfer, Tr. 722).

d. Human Clinical Studies

767. Human clinical studies are those in which investigators assign the exposure level to participants -- meaning that the investigators tell the subjects how much of a particular nutrient to consume, in contrast to observational studies, where the investigators study existing exposure levels within a particular population. (CX1293 (Stampfer, Report at 0009)).

768. There is a typical progression in human clinical studies, from exploratory research to RCTs (randomized clinical trials). (PX0025 (Ornish, Report at 0010, 0024) ("Science usually progresses when someone publishes a study of a series of patients with a nonrandomized control group that shows an unprecedented finding which is then replicated by one or more subsequent randomized controlled trials[;]" "[t]here is a logical progression in science which often begins with a pilot study that has no control group")).

769. Some researchers describe the progression of research in terms of "phases," where a: Phase I trial tests a treatments in a small number of patients to find a safe dose (CX1287 (Eastham, Report at 0009); Phase II trial tests the intervention in a larger number of people to identify specific effects (CX1341 (Pantuck, Dep. at 28-29)); Phase III trials test the treatment in a larger number of people, to compare it to "standard treatment;" and Phase IV trial tests a treatment in several hundred to thousands of people to assess long-term safety and effectiveness. (CX1287 (Eastham, Report at 0009); *see also* Burnett, Tr. 2262 (equating RCTs with Phase III trials)).

770. Typically, researchers conduct pilot or exploratory studies to demonstrate the feasibility of larger studies. Such research can reveal potential changes from an intervention, allows the researchers to see if people can tolerate the intervention or if it causes unexpected side effects, and paves the way for more definitive research. (Stampfer, Tr. 747-48; CX1342 (Hill, Dep. at 45-48 (uncontrolled pilot study allows you to determine how to design a good placebo-controlled trial)).

771. Data from RCTs provide the best evidence of a causal relationship between a nutrient and

a disease outcome in humans. (CX1293 (Stampfer, Report at 0009); Stampfer Tr. 716; Goldstein, Tr. 2612-13). A causal link means a cause-and-effect relation, *i.e.*, that the intervention would reliably result in a change and that but for the relationship, the result would not have occurred. (Stampfer, Tr. 716; *see also* RX5007 at 479, 480 (RCTs, if well designed and well executed, provide a high level of certainty that a specific intervention can reliably be counted on to produce a specific effect in a selected population)). For a drug, juice, or lifestyle intervention, when you are trying to determine whether an intervention is *causing* effects, or whether the effects are a coincidence, RCTs are the most rigorous design, because they control for known and unknown sources of bias. (CX1339 (Ornish, Dep. at 19-20)). The elements of RCTs are further discussed below.

2. Randomized Clinical Trials ("RCTs")

772. It is standard practice, in human research, to begin with a *protocol*. (Stampfer, Tr. 760; Sacks, Tr. 1436-37; Heber, Tr. 2044-45 (every study he conducts has a protocol)). A protocol describes the key features of a study, such as objectives, methodology, statistical analysis plan, the definition of the *p* value, and primary outcome variables (endpoints). (Sacks, Tr. 1436-37; Stampfer, Tr. 760; *see* Ornish, Tr. 2367 (agreeing that a researcher should determine in advance how many patients will be needed, what the procedures will be, and what kind of analysis to apply and that "you can't just make it up as you go along")). The purpose of identifying the primary outcomes in advance is to prevent a researcher from using positive results and ignoring negative ones, resulting in bias. (Sacks, Tr. 1475; CX1291 (Sacks, Report at 0021)).

773. A *controlled* study is one that includes a group of patients receiving the purported treatment ("treatment" or "active" group) and a control group ("placebo" or "control" group). (CX1291 (Sacks, Report at 0011)). A control group provides a standard by which results observed in the treatment group can be evaluated. (CX1287 (Eastham, Report at 0013)). A control group allows investigators to distinguish between real effects from the intervention, and other changes, including those due to the mere act of being treated ("placebo effect"), the passage of time, change in seasons, other environmental changes, and equipment changes (such as calibration changes). (CX1291 (Sacks, Report at 0011); Burnett, Tr. 2265; Eastham, Tr. 1268 (a placebo arm balances factors that may influence an endpoint); *see* CX1293 (Stampfer, Report at 0009); Ornish, Tr. 2367 (agreeing that you need to control for the power of belief, because that can affect people's reaction to an intervention)). The control group should be approximately the same size as and meet the same criteria as the treatment group. (Eastham, Tr. 1268-69; CX1287 (Eastham, Report at 0013); CX1291 (Sacks, Report at 0011); Melman, Tr. 1095; CX1289 (Melman, Report at 0009)). It also should receive the same measurements and attention from the researchers as the treatment group. (CX1291 (Sacks, Report at 0011)).

774. *Randomization* means assigning subjects to the active product group or the control group in a random fashion, whether using a computer program, random number table, or coin toss. (Burnett, Tr. 2264-65; CX1291 (Sacks, Report at 0011); CX1339 (Ornish, Dep. at 20); Eastham, Tr. 1266; Melman, Tr. 1096). It is another way to control for bias. (Eastham, Tr. 1266). It increases the likelihood that the treatment and control groups are similar in relevant characteristics, so that any difference in the outcome between the two groups can be attributed to the treatment. (CX1291 (Sacks, Report at 0011-12); CX1293 (Stampfer, Report at 0009); CX1287 (Eastham, Report at 0012-13); CX1339 (Ornish, Dep. at 20) ("By randomizing people, if there were some unknown factor that was biasing your outcomes, it would be likely to be distributed across both groups")). It also prevents the investigator from deciding who gets which treatment, which can introduce bias into the study. (CX1345 (deGroof, Dep. at 62); Melman, Tr. 1096.

775. A *placebo* is an inactive product or treatment given to the control group, in lieu of the intervention being tested. (Stampfer, Tr. 708; Eastham, Tr. 1267-68 (a placebo is a nonactive product); Melman, Tr. 1094-95 (product that does not contain the drug is given to the control group)). For example, in a study of a pill, the placebo would be a pill that looks like the intervention, but does not contain the active ingredient. (Stampfer, Tr. 708). A placebo should be identical, in all ways possible, to the active treatment. (CX1291 (Sacks, Report at 0011); Melman, Tr. 1095). A double blind study, *see* CCFF ¶ 777, blinds participants and investigators as to whether study participants are in the active or placebo group. (CX1293 (Stampfer, Report at 0009); Melman, Tr. 1095-96).

776. It should be noted that, when dealing with diseases for which there is an accepted "standard of care" – that is, a routine medical practice for addressing that disease – and a researcher wants to know whether a new product (or treatment) will produce a *better* result than the standard of care, patients can be given the standard of care product (or treatment), rather than a placebo, to test against the new product or treatment being studied. (Eastham, Tr. 1326, 1350-51).

777. *Blinding* refers to steps taken to ensure that neither the study participants nor the researchers conducting the outcome measurements are aware of whether a patient is in the active group or the control group. (CX1291 (Sacks, Report at 0012); Melman, Tr. 1097). *Double-blinding*, that is, blinding of both the patients and investigators, is optimal to prevent bias arising from actions of the patients or investigators. (CX1293 (Stampfer, Report at 0009); Stampfer Tr. 708-09 (patients aware of group assignment may change their behavior in a way that modifies risk; researchers aware of patient group assignment

may introduce subtle biases in terms of interpreting endpoints); Eastham, Tr. 1267 (patients who learn they are on placebo can try other treatments or otherwise alter behavior in a way that may impact study results; physicians aware of patient group assignment may be influenced in their interpretation of the outcome); Melman, Tr. 1098; CX1287 (Eastham, Report at 0013); *see also* Heber, Tr. 2044 (investigator bias can affect trial results)).

778. Once a randomized controlled trial is completed and all data collected, data for the control and active treatment groups must be compared through use of appropriate *statistical analyses*. (Eastham, Tr. 1272; CX1287 (Eastham, Report at 0014); CX1291 (Sacks, Report at 0012-13)). Only if the results of the treatment group are *statistically significant* from those of the control group at the end of the trial can it be concluded that the tested product is effective. (CX1291 (Sacks, Report at 0012); Burnett, Tr. 2269). This analysis is called a *between-group analysis*. (CX1291 (Sacks, Report at 0012-13)). A *within-group* analysis, where a researcher compares the treatment group participants' "before" data to their "after" data has much less scientific value, because it relies on the assumption that without the intervention there would have been no change in the study participants' condition; this is not a reasonable assumption because "we know that things change over time all the time." (Stampfer, Tr. 714).

779. Evaluating data from a clinical trial for *statistical significance* is the standard practice to demonstrate that a study's hypothesis has been proven. (Burnett, Tr. 2269; CX1287 (Eastham, Report at 0014)). *Statistical significance* is recognized as being attained if the statistical test for probability, referred to as the "*p*" value, is less than or equal to 0.05 ($p \leq 0.05$), which means that there is only a 5 percent or less chance that the difference between the treatment and placebo groups is due to chance. (CX1291 (Sacks, Report at 0012); Eastham, Tr. 1273; Ornish, Tr. 2368 (by convention, most people have arbitrarily accepted the 5 percent cut-off as being statistically significant); Melman, Tr. 1102-03; CX1289 (Melman, Report at 0010)). It means that the results demonstrated would occur no more than 1 time out of 20, and therefore, other causes of the result, such as chance, are less likely as an explanation. (Stampfer, Tr. 710-11).

780. *Endpoints*, *outcomes*, *or variables* are the outcomes being measured in a study. (CX1287 (Eastham, Report at 0009); Eastham, Tr. 1273)).

781. *Validated* endpoints or surrogate markers are those outcomes that, while not direct endpoints, have been shown to be so closely linked to a direct endpoint that a change in the surrogate marker is confidently predictive of a change in the disease. (*See* CX1291 (Sacks, Report at 0013); *see* CX1287 (Eastham, Report at 0010) ("changes in a surrogate

are expected to reflect changes in a clinically meaningful endpoint")). *Validated* measures or assessment tools are those that have been established as reliable through rigorous assessments involving a large number of individuals. (Burnett Tr. 2266-67; Melman, Tr. 1100).

782. *Clinical significance* means that the treatment makes a real difference in a patient's life. (Melman, Tr. 1103; Eastham, Tr. 1274). A result may be statistically significant, but not clinically significant. (Melman, Tr. 1104; Eastham, Tr. 1274).

783. *Replication* ensures that the results obtained in one study are not due to chance. (Sacks, Tr. 1446; CX1291 (Sacks, Report at 0014-15)). Even with the safeguards contained in an RCT, the results contained in any one study may be due to chance or may not be generalizable due to uniqueness of the study sample. Most scientists believe that at least two well-designed RCTs, conducted by independent researchers, and each showing strong results, are needed to constitute reliable evidence that an intervention causes a result. (Sacks, Tr. 1446; CX1291 (Sacks, Report at 0014-15); Melman, Tr. 1092-93; Burnett, Tr. 2264 (experts would require two to three randomized, controlled human trials to reach a conclusion)).

C. Analysis of Respondents' Research Related to Heart Disease

1. Background Information

784. To substantiate a claim that a food or a diet supplement can *treat* heart disease, one needs appropriately analyzed data from well-designed, well-conducted RCTs showing significant changes in valid surrogate markers of cardiovascular health. The study subjects must have established CVD or CHD. (CX1291 (Sacks, Report at 0010_11)). The same evidence is needed to show that such benefits are scientifically proven. *Prevention and risk reduction* claims also require well-conducted RCTs measuring valid surrogate markers, but the study subjects may be persons with *or* without CVD or CHD. (CX1291 (Sacks, Report at 0010-11)). There must be a sufficient number and diversity of subjects tested to conclude that the measured effect can be generalized to a larger population. The study also must be of sufficient duration to show that the effect will last. (CX1291 (Sacks, Report at 0014)).

785. Direct endpoints of heart disease are heart attack, unstable angina, or the need for coronary artery bypass or angioplasty. (CX1291 (Sacks, Report at 0013)). FDA recognizes blood pressure and LDL cholesterol as validated surrogate markers. Most

(but not all) experts also recognize C-reactive protein, HDL cholesterol, and triglycerides as valid surrogate markers. (Sacks, Tr. 1441; CX1291 (Sacks, Report at 0013)).

786. In addition, measures of carotid intima media thickness ("CIMT"), *i.e.,* the combination of the vessel muscle and atherosclerosis (arterial plaque), are usually relevant to cardiovascular health. (Sacks Tr. 1442; CX1291 (Sacks, Report at 0013-14)). However, such measures alone are not conclusive evidence that an intervention treats existing heart disease. (Sacks, Tr. at 1441-44; CX1291 (Sacks, Report at 0014); *see also* Stampfer, Tr. 745). A recent article in a leading cardiology journal analyzed CIMT in relation to cardiovascular events. It found that among a meta-analysis of 41 randomized trials, "there was no significant relationship between IMT regression and CHD . . . events . . . CBV [cerebrovascular] events. . . and for all-cause death." As a result, there is broad consensus that at least two types of imaging studies must be obtained to make inferences on benefit to cardiovascular disease. (CX1291 (Sacks, Report at 0014)).

787. Respondents' interrogatory responses did not identify the specific studies that they relied on in support of the challenged heart benefit claims. (CX1381_0014 (POM states in its Supplemental Response to First Set of Interrogatories that it relied on the "body of scientific knowledge")). Nonetheless, Respondents' internal documents, and their heart experts, focused primarily on nine human studies – two by Dr. Aviram, two by Dr. Ornish, two by Dr. Davidson, and two conducted on overweight individuals and one on diabetic patients – that looked at heart-related endpoints. (*See* CX1029_0003 (POM Medical Research Portfolio identifying human heart studies by Aviram, Ornish, Davidson, and biomarker studies by Drs. Heber and Hill); PX0192 (Heber, Report at 000038, 0052-54, discussing Aviram, Ornish, Davidson, and "biomarker" studies; and at 0038, discussing Rock diabetes study); PX0025 (Ornish, Report at 0009-25) (discussing Aviram, Ornish, Davidson, and Denver and San Diego overweight studies)). Additionally, at trial Dr. Heber testified as to the negative results of two studies that he and Dr. Hill conducted on diabetics. (*See* CCFF ¶¶ 946-49). As further discussed below, these studies do not substantiate Respondents' heart benefit efficacy claims, or their heart benefit establishment claims.

2. Heart Disease Studies

a. Aviram Studies

788. Dr. Aviram is a professor and head of the Lipid Research Laboratory, Technion Faculty of Medicine, Rappaport Institute for Research in the Medical Sciences and Rambam Medical Center, in Haifa, Israel. (CX1116_0001).

789. Dr. Aviram has a Ph.D. in biochemistry. (CX1116_0001). He is not a medical doctor. (CX1116_0001; CX1363 (S. Resnick, TCCC Dep. at 64)).

790. Dr. Aviram has worked with Respondents since 1998. (CX1358 (Aviram, Dep. at 4)). Respondents have paid Dr. Aviram approximately $4 million dollars for his retainer, research, and consulting fees. (CX1276_0003-04; S. Resnick, Tr. 1641-42; *see also* CX1380_0005 (Response to Request for Admission No. 42); CX1358 (Aviram, Dep. at 66-72) (testifying he was paid between $350,000 to $500,000 per year for his research, including a retainer for his services); CX1353 (Tupper, Dep. at 268) (stating he expected Dr. Aviram to join a meeting with the FTC for free in consideration of payment for his services); CX1349 (Gillespie, Dep. at 265-67) (agreeing that Aviram would be paid a $150,000 retainer and an additional $150,000 for research)). POM would also pay Dr. Aviram for any "a-la-carte analytical projects." (CX1349 (Gillespie, Dep. at 266-67).

791. Dr. Aviram also served as an expert endorser for Respondents, providing POM with quotes for marketing and advertising materials for the POM Products. For example, on June 30, 2006, Dr. Aviram provided POM with a quote that "[POMx] is a better protector against cardiovascular and other disease, than pomegranate juice." (CX0813_0001). On January 22, 2007, Dr. Dreher asked Dr. Aviram to provide a statement to "support our structure-function claim that POMx promotes cardiovascular health" for POM's files. (CX0865; CX1358 (Aviram, Dep. at 50-51)). In response, Dr. Aviram provided a statement describing his studies on pomegranates and stating "in my opinion it is justified to claim that POMx . . . indeed promotes cardiovascular health." (CX0865_003; CX1358 (Aviram, Dep. at 50-51)).

792. Despite giving these statements to POM to be used in publicity, at his deposition in March 2011, Dr. Aviram admitted that "[v]ery little was done with POMx" and that he could not confidently say POMx would work the same as POM Juice before testing it. (CX1358 (Aviram, Dep. at 48)). Indeed, in May 2009, Dr. Aviram stated that "I feel that it is important to learn more about the relationships between POM ([Juice], and the Pill, which, unlike PJ, we know very little on it from mechanistical point of view) . . . ." (CX1060_0001; CX1358 (Aviram, Dep. at 48)).

793. Dr. Aviram conducts primarily mechanistic studies (*in vitro* and animal studies) and pilot human studies (studies on a small number of patients). (CX1363 (S. Resnick, TCCC Dep. at 69) ("[H]e does a lot of the research in the mechanistic, of how it works and why it works and the cellular levels . . . different measures of all things around cholesterol and heart issues"); CX1358 (Aviram, Dep. at 17); *see also* CX1029_0002 (POM Medical Research Portfolio describing Aviram's heart disease research as "mechanistic.")). As

Dr. Aviram explained in his deposition, "I always do my human studies on a small number of patients because that's my profession. I'm a biochemist, a basic scientist. I'm interested in mechanism of action, and I want to show that this mechanism of action has relevance to the disease itself, to the cardiovascular disease, to the atherosclerosis process." (CX1358 (Aviram, Dep. at 17)).

794. Among other things, Respondents commissioned Dr. Aviram to conduct two small human studies to explore mechanisms involving patients with heart disease and their reaction to pomegranate juice: (1) Aviram M. and Dornfeld L., *Pomegranate juice consumption inhibits serum angiotensin converting enzyme activity and reduces systolic blood pressure*, 158 Atherosclerosis 195 (2001) ("**Aviram ACE/BP Study (2001)**") (CX0542; *see* JX0003 ¶ B.15); and (2) Aviram M, *et al.*, *Pomegranate juice consumption for 3 years by patients with carotid artery stenosis reduces common carotid intima-media thickness, blood pressure and LDL oxidatio*n, 23 Clin. Nutr. 423 (2004) ("**Aviram CIMT/BP Study (2004)**") (CX0611; *see* JX0003 ¶ B.15).

795. Dr. Aviram's human studies were small exploratory pilot studies that were unblinded and not placebo-controlled. (CX1358 (Aviram, Dep. at 12-13, 28); *see also* PX0353 (Heber, Dep. at 173) (agreeing that Dr. Aviram's studies were unblinded and uncontrolled)). The purpose of these human studies was to confirm his mechanistic and animal studies. (CX1358 (Aviram, Dep. at 28)).

(1) Aviram ACE/BP Study (2001)

(a) About the Study

796. In the Aviram ACE/BP Study (2001), ten elderly patients with high blood pressure drank 50 ml of pomegranate concentrate daily, for two weeks. (CX0542_002; CX1358 (Aviram, Dep. at 21) (Respondent POM provided the concentrate)). In addition to being unblinded (CCFF ¶ 795), the study had no control group; instead, each patient's "before" measures were compared to his or her "after" measures. (CX1358 (Aviram, Dep. at 22-24); CX0025_0012 (describing study design as "uncontrolled"); CX1339 (Ornish, Dep. at 66) (agreeing sample size was small and study was controlled)).

797. This study measured angiotensin-converting enzyme ("ACE") activity and blood pressure. (CX0542_0001). ACE is an enzyme that alters the function of angiotensin,

which relates to blood pressure for each patient. (Stampfer, Tr. 742). POM's own website explained, "ACE inhibitors make blood vessels relax, helping lower blood pressure and allowing more oxygen-rich blood to reach the heart." (CX0473 (Compl. Ex. E-2 at 04:15)).

798. According to the published article, seven of the ten patients experienced a statistically-significant 36% reduction in serum ACE activity from their baseline measure. (CX0542_0001). The article does not reveal what happened to the ACE levels of the other three patients or analyze the overall results in all ten patients. (CX1291 (Sacks, Report at 0016-17); CX0542_0002-03; *see also* Stampfer, Tr. 741-42; CX1293 (Stampfer, Report at 0017-18)). Dr. Aviram testified that there was "no effect" from pomegranate juice on the other three patients' ACE levels. (CX1358 (Aviram, Dep. at 23)).

799. The article reports that all ten patients experienced a statistically significant 5% reduction in systolic blood pressure from their baseline blood pressure measure. (CX0542_0002-03; CX1291 (Sacks, Report at 0016-17)).

800. The article concludes that, "pomegranate juice consumption can offer a wide protection against cardiovascular disease." (CX0542_0003). Dr. Aviram stated that this was his "thinking" and "opinion." (CX1358 (Aviram, Dep. at 26)).

801. The co-author of this study was Leslie Dornfeld, POM's former medical director and personal family doctor of the Resnicks, which was not disclosed in the study. (CX0542_0001; CCFF ¶ 158; CX1375 (L. Resnick, TCCC Dep. at 32)).

(b) Expert Analysis

802. Drs. Sacks and Stampfer opined that: (1) the sample size of ten patients is too small to provide reliable evidence that the observed effects would be generally applicable to a larger population (CX1291 (Sacks, Report at 0017); Stampfer, Tr. 748); (2) the two-week period of the study was too short to provide reliable evidence that the reported improvement in ACE activity and blood pressure would be enduring. (CX1291 (Sacks, Report at 0017); *see also* Stampfer, Tr. 748); and (3) ACE (one of the study endpoints) is not a recognized surrogate marker of cardiovascular disease. (CX1291 (Sacks, Report at 0017)).

803. Although blood pressure reduction is a validated surrogate for heart disease, this study

does not provide competent and reliable evidence to support a heart benefit claim, because it was not a blinded, placebo-controlled study. (Sacks, Tr. at 1453; CX1291 (Sacks, Report at 0017); Stampfer, Tr. 748, 771; CX1293 (Stampfer, Report at 0019)). Given the lack of a control group, it is not possible to conclude what caused the reported improvements in the subjects' blood pressure levels. (CX1291 (Sacks, Report at 0017); Sacks, Tr. at 1452-54; *see also* Stampfer, Tr. 748, 771). Without a control group, this study was simply an observational study on patients given pomegranate juice concentrate. (CX1291 (Sacks, Report at 0017)).

804. Respondents' expert Dr. Ornish agreed with Drs. Sacks and Stampfer that "this study was limited in scope." (PX0025 (Ornish, Report at 0009); *see also* Heber, Tr. 2094-95 (describing study as "exploratory")).

(2) Aviram CIMT/BP Study (2004)

(a) About the Study

805. In the Aviram CIMT/BP Study (2004), a group of ten patients with severe carotid artery stenosis consumed 50 ml of concentrated pomegranate juice daily for one year and five of them continued for up to three years. (CX611_0001-02). Dr. Aviram described the study population as "people who [were] very sick." (CX1358 (Aviram, Dep. at 28); JX0003 ¶¶ A.3-4).

806. A second group of nine patients who did not consume pomegranate juice acted as a "control." (CX0611_0002). The article sometimes described the two groups as "randomized" and at other times as "matched." (CX0611_0002, 0004). Dr. Aviram testified that he decided who should go into the control group, by trying to "match" control group participants to active group participants based on characteristics such as age, gender, and medical drug use. (CX1358 (Aviram, Dep. at 29)).

807. Although the study report sometimes used the term "placebo" to refer to this control group, no actual placebo was used in this study. (CX0611_0002, 06; CX1358 (Aviram, Dep. at 28)). Dr. Ornish and Mr. Resnick acknowledged this study was not placebo-controlled. (PX0355 (Ornish, Dep. at 106); CX1339 (Ornish, Dep. at 66); CX1360 (S. Resnick, Dep. at 201) (indicating he did not believe this study was placebo-controlled); *see also* CX1350 (Liker, Dep. at 89) (control group did not drink a placebo)). The study also was unblinded. (CX1358 (Aviram, Dep. at 31)).

808. The patients in the two groups received dissimilar treatment. Patients in the first group

(pomegranate juice group), had "blood analyses and echo Doppler of the carotid arteries performed at the beginning of the study and 3, 6, 9, 12, 22, 28 and 36 months after PJ consumption." For the second "control" group, "echo Doppler of the carotid arteries was only performed at the beginning of the study and after 1 year." (CX0611_0002; CX1358 (Aviram, Dep. at 29-30)).

809. The article reports that in the group of patients that consumed pomegranate juice, mean CIMT was reduced by 35% at 12 months in comparison to their baseline values. (CX0611_0004). It should be noted that the abstract stated instead that "PJ consumption resulted in a significant CIMT reduction, *by up to 30%,* after 1 year." (CX0611_0001 (emphasis added)). No additional improvements in CIMT were seen in the five patients who continued drinking the juice for two additional years. (CX0611_0002). In the nine patients who did not consume pomegranate juice, their mean CIMT increased by 9% over one year when their one year measurement was compared to a baseline measurement. (CX0611_0001-02, 04, 08).

810. The article reports that the pomegranate juice group members' systolic blood pressure was significantly ($p < 0.05$) reduced by *12%* after one year of PJ consumption compared to their baseline values. (CX0611_0005). By contrast, the abstract stated instead that systolic blood pressure was reduced after one year of PJ consumption by *21%* . (CX0611_0001). In the group that did not consume pomegranate juice, blood pressure was unchanged. (CX0611_0005).

811. The CIMT and blood pressure changes described above are all *within-group* analyses. (Sacks, Tr. 1456-57). The article did not provide any *between-group* statistical analysis, that is, analysis of changes in CIMT and blood pressure between the active and control groups at the end of the study. (Sacks, Tr. 1456-57; CX0163_0017 (stating that between group analysis was not performed for any of the outcomes)). Dr. Aviram explained that each subject in the study served as his or her own control. (CX1358 (Aviram, Dep. at 27-28, 32)).

812. The article concludes that, "[c]linical trials are now needed to further prove the beneficial effect of dietary antioxidants in general and of flavonoid-rich antioxidants in particular in patients with cardiovascular diseases." (CX0611_0009).

813. The article identified co-author Dr. Liker as being from the David Geffen School of Medicine. (CX0611_0001). It did not disclose his position as the Medical Director of Respondents Roll and POM. (Liker, Tr. 1930; CX1350 (Heber, Dep. at 92, 98-99)).

(b) Expert Analysis and Respondents' Understanding of the Study

814. Dr. Sacks concluded that, given the lack of a randomized, placebo-controlled group, the fact that the patients in the active and "control" groups received different treatment, the small sample size, and the lack of any between-group statistical analysis, a qualified scientist would not be able to conclude with any credibility that the reported improvements in the treatment group were caused by their consumption of pomegranate juice and not some other factor. (Sacks, Tr. at 1459, 1585 ("the control group did not receive anything . . . there was no placebo or control substance or control agent given"); CX1291 (Sacks, Report at 0019)).

815. Similarly, Dr. Stampfer concluded this study does not support Respondents' heart disease prevention and treatment claims or their lower blood pressure claims. (CX1293 (Stampfer, Report at 0018)).

816. Dr. Ornish generally agreed with Dr. Sacks' assessment of the "many" limitations of the Aviram CIMT/BP Study (2004), which was "not at all conclusive," but he also described its results as "provocative" and "interesting." (PX0025-0010-11); PX0355 (Ornish, Dep. at 107)). Dr. Heber agreed that this study was unblinded and uncontrolled (PX0353 (Heber, Dep. at 173-78)), and opined only that this study was a start leading to a "much larger, controlled trial and also triggered basic mechanistic investigations to provide scientific substantiation." (PX0046 (Heber, Welch Report at 0019)).

817. Respondents were aware of the limited, exploratory nature of the Aviram CIMT/BP Study (2004). According to a *Wall Street Journal* article dated April 5, 2005, and an email to POM staff, the Aviram CIMT Study was "unlikely to impress the scientific community" because "using patients with only severe blockage makes the effects look more significant than they would in normal patients." In the article, POM was quoted as saying that the 10-person study was meant to be only a preliminary test. The article went on to note that POM had "also funded an 18 month study that involves 360 patients with a range of conditions . . . . [P]reliminary results won't be released until December [2005], the company says." (CX0039_0001). The 360-patient study was a reference to the Davidson CIMT Study (2009). (*See* CCFF ¶¶ 875-919).

818. In another example of Respondents' awareness of the limitations of the Aviram study results, the American Botanical Counsel draft monograph circulated to POM employees by Dr. Dreher in December 2007 described the "main limitation of this study is that both

groups were not treated equally . . . there was no placebo, and the PJ group received many more interventions than the control group. The article went on to note that "between group analysis was not conducted of any of the outcomes, only within group analysis." (CX0163_0017).

819. Respondents acknowledge that the relevance of this study to the general population is limited. Dr. Gillespie, Vice President of Clinical Development at POM, told a POM customer that "this study enrolled older patients with severe plaque buildup. Therefore, the results observed in this population may not represent all patients. . . . It's difficult to estimate the long-term effect of pomegranate juice based on this limited sample size." (CX0456_0009-100; *see also* Tupper, Tr. 1054 (agreeing with Dr. Gillespie's characterization of the study's limitations); CX1353 (Tupper, Dep. at 218-19)).

820. Following the completion of the Aviram ACE/BP and CIMT/BP Studies, POM contacted Dr. Ornish in "an effort to confirm and reproduce the . . . carotid IMT data from Israel [Aviram]" and commissioned him to conduct a larger clinical trial, which began in January 2002. (CX0579_0003). The protocols for the Ornish studies describe the Aviram studies as having "a small number of patients or participants and no randomized control group for comparison. Thus, we propose a randomized controlled trial to address these limitations." (*See e.g.,* CX0552_0001 (June 12, 2002 Beverage Study Protocol); CX0613_0006, 17 (June 2003 Beverage I and II protocols)).

821. Despite the acknowledged limitations of this study, from 2004 through 2009, the Aviram CIMT/BP Study (2004) results became the centerpiece of Respondents' marketing claims that science establishes that both POM Juice and POMx can treat, prevent, or reduce the risk of heart disease. (*See* CCFF ¶ 674).

b. Ornish Studies

822. Dr. Ornish conducted two studies for Respondents: (1) Sumner M., et al., *Effects of Pomegranate Juice Consumption on Myocardial Perfusion in Patients with Coronary Heart Disease*, 96 Am. J. Cardiology 810 (2005) ("Ornish MP Study (2005)") (CX1198; *see* JX0003 ¶ B.16); and (2) the Ornish CIMT Study (unpublished, 2005) (CX0754; *see* JX0003 ¶ B.16). These were the only studies ever conducted by Dr. Ornish to consider whether a single food product has health benefits. (Ornish, Tr. 2464).

823. The contract setting forth the terms of the two studies was a September 19, 2003, letter agreement between Stewart A. Resnick and Linda Resnick, as Trustees of the Stewart

and Linda Resnick Revocable Trust, and Dr. Ornish's organization, Preventative Medicine Research Institute ("PMRI"). (CX0613_0001). Attached to the letter agreement were the protocols for the two studies. The Ornish MP Study (2005) was also referred to as "Beverage Study I," and the Ornish CIMT Study was referred to as "Beverage Study II." (CX0613_0001, 0003, 0005, 0016). The Ornish MP Study budget was $708,436, and the CIMT Study budget was $496,390 (together, $1,204,827). (Ornish, Tr. 2431-35).

(1) Ornish MP Study (2005)

(a) About the Study

824. The Beverage Study I had two arms: a "cardiac" group and a "carotid" group. (CX0613_0008 (Beverage Study I protocol, describing the two-arm study)). The results of the 45-person "cardiac" group were published as the Ornish MP Study (2005). (CX1198). The results of the 17-person "carotid" group, which underwent CIMT testing, were not published, but were presented by Dr. Gerdi Weidner, PMRI's Vice President and Director of Research, at the 2004 POM Summit. (CX1306 (Weidner, Decl. at 0001-02). Both arms of the study were randomized, double-blind, and placebo-controlled. (CX0613_0008).

825. The patients in the "carotid" group had documented coronary artery disease. (CX1306 (Weidner, Decl. at 0002)). The results of the 17-person "carotid" group that underwent CIMT testing were negative, in other words, they did not show that POM Juice provided a benefit. (CX1306 (Weidner, Decl. at 0029-32)). Further, in the "cardiac" group, other biomarkers including ACE, Thiobarbituric Acid Reactive Substances ("TBARS"), and paraoxonase ("PON" or "PON1") were measured in the "cardiac" group at baseline and three months. (CX1306 (Weidner, Decl. at 0041-44)). There were no statistically significant effects of pomegranate juice consumption on any of these measures. Thus, the Aviram ACE/BP Study (2001) measures were not replicated by this study. (CX1306 (Weidner, Decl. at 0035-44)). None of these results were published. (*See* CX1198 (published report of Ornish MP Study)).

826. The Beverage Study I results that were published as the Ornish MP Study (2005) (the "cardiac" group) were based on testing to evaluate whether daily consumption of pomegranate juice for 12 months would affect myocardial perfusion, or blood flow to the heart, in 45 patients with CHD and myocardial ischemia. (CX0613_0005, 0009; *see also* PX0025 (Ornish, Report at 0017)). Patients consumed 240 ml (about eight ounces) of POM Juice or a placebo beverage daily. (CX1198_0002). Measurements included before and after imaging of blood flow to the heart, plasma lipids (cholesterol, HDL,

LDL, and triglycerides), body weight, blood sugar, and blood pressure. (CX1198_0003-04; CX1306 (Weidner, Decl. at 0037-44); *see also* CX1291 (Sacks, Report at 0019-24)).

827. The published report provides data on three imaging measures at baseline and *three months* for myocardial perfusion: the summed rest score, or "SRS" (imaging results before the pharmacologic or exercise challenge), the summed stress score, or "SSS" (imaging results after the pharmacologic or exercise challenge) and the summed difference score, "SDS" (calculated by subtracting the SRS from the SSS). (CX1198_0003 (Table 2); CX1291 (Sacks, Report at 0020)). According to the report, after three months there was a significant ($p = 0.05$) improvement of 17% in the SDS score in the POM Juice group, as compared to an average worsening of 18% in the control group. (CX1198_0004). However, there were no statistically significant differences between the two groups in SSS and SRS at the end of the reported three-month period. (CX1198_0003 (Table 2)).

828. The authors concluded that:

> [A]lthough the sample in this study was relatively small, the strength of the design and the clinically significant and statistically significant improvements in myocardial perfusion observed in the experimental group over a rather short period *suggest* that daily consumption of pomegranate juice *may* have important clinical benefits in this population . . . . Further studies appear to be warranted to determine the effects of pomegranate juice on myocardial perfusion in a larger sample of patients over a longer period. In addition, it would be of interest to assess the effects of pomegranate juice on coronary atherosclerosis using methods such as quantitative coronary arteriography and intravascular ultrasound.

((CX1198_0004) (emphasis added)).

829. The published study also reported no significant changes in blood pressure, cholesterol, LDL, HDL, or triglycerides. (CX1198_0003-04, Table 3 (notation below table); CX1291 (Sacks, Report at 0024)).

830. At trial and in his expert report, Dr. Ornish acknowledged that "some problems" occurred during the study that were not "optimal." (Ornish, Tr. 2394; PX0025 (Ornish, Report at 0016)).

831. First, 41 patients completed the study, but the published report provided data on only 39. (Ornish, Tr. 2394; *see* CX1198_0003 (Table 2). Dr. Ornish admitted that this was a mistake. (PX0025, (Ornish, Report at 0015)). In practice, a researcher should publish all patient results, consistent with the "intention to treat" standard. (CX1291 (Sacks, Report at 0022, 24); *see also* Sacks, Tr. 1469; CX664)**.** Alterations in the original sample size may be critical when there is a borderline "*p*" value. (CX1291 (Sacks, Report at 0022)). One of the patients whose data were excluded from the published analysis was in the pomegranate juice group; he had a myocardial infarction (or silent heart attack) while drinking the juice. (Sacks Tr. 1478-79; CX1198_0003). Drinking pomegranate juice did not appear to have prevented his myocardial infarction. (CX1198_0003; CX1339 (Ornish, Dep. at 55-56); Sacks, Tr. 1478-79; CX664_0001).

832. Second, two subjects in the placebo group did not receive a placebo treatment. They were tested at baseline and three months, with no intervention, and their data were included in the final study results. (CX1339 (Ornish, Dep. at 168-70); CX0580, patients' names *in camera*; Sacks, Tr. 1475-77).

833. Third, Dr. Ornish admitted at his deposition that at least eight patients were unblinded before their three-month test dates -- meaning the study patients knew whether they were in the active or placebo groups. (CX1339 (Ornish, Dep. at 146-47); Ornish, Tr. 2403). On two occasions in late 2002, study patients received notices showing what group they were assigned to, and alerted the study staff to their assignments. (CX0555_0001 (22 patients unblinded in September 2002, including six in "cardiac" group and four in "cardiac/carotid" group); CX0560 (four unblinded on Nov. 15, 2002), patients' names *in camera*; *see also* CX0561 (Nov. 18, 2002 PMRI document showing eight patients whose baseline treadmill stress test dates occurred prior to, and three-month test dates occurred after, the unblinding dates), patients' names *in camera*). Dr. Liker and Mr. Resnick were made aware of the unblinding problems. (CX0555_0001).

834. Fourth, Dr. Ornish admits that the Ornish MP Study (2005) was designed as a twelve-month study, not a three-month study. (PX0025 (Ornish, Report at 0017)). Dr. Ornish and the Resnicks had agreed to a twelve-month study, with testing at baseline, three months, and one year, at a cost of $708,437. (*Compare* CX1198 *with* CX591_0001 (May 2003 email); CX613_0010 (Sept. 2003 protocol)). The published report, however, described the Ornish MP Study as a three-month study. (CX1198_ 0001).

835. Documents show that as late as January 26, 2004, the Beverage Study I was expected to include twelve-month test measures. (Ornish, Tr. 2436-38 (regarding Sept. 29, 2003, PMRI email advising a researcher that the Beverage Study I was a twelve-month study);

CX1339 (Ornish Dep. at 139) (regarding Oct. 10, 2003 patient data sheet showing that ten patients had completed their twelve-month testing). On October 10, 2003, PMRI advised Dr. Liker that the three-month testing would be completed in January 2004 and that the one-year testing would be completed in October 2004. (Ornish Tr. 2437-38). On January 26, 2004, a PMRI staff member wrote to Dr. Aviram to say that the 12 month testing for Beverage Study I would be done in November 2004. (Ornish, Tr. 2438 (testifying that "that was our intention at the time")).

836. On February 7, 2004, however, Dr. Michael Sumner, a Ph.D. in Social Psychology and the Ornish MP Study (2005) co-author who conducted the data analysis, provided Dr. Ornish's research team at PMRI with analysis of the MP study patients' three-month test data, showing a statistically significant improvement in the SDS measure. (CX0632; Ornish, Tr. 2438-39).

837. When the interim three-month study results turned out to be positive, minutes for a research team meeting held on February 9, 2004 at Dr. Ornish's PMRI facility reported that "Dean says the good news is, after reviewing the data, the research shows that ischemia is reduced with a sum[med] difference score of 4.33 to 3.63. *Dean wants to quit while we are ahead and wants to call the Resnicks with the news*. . . . Dean will talk with Resnicks . . . after Erin provides him with financials." (CX0633_0001 (emphasis added); Ornish, Tr. 2439-40)). Dr. Ornish wanted cost information from PMRI's financial officer to use in conversations with the Resnicks. (Ornish, Tr. 2440).

838. Although there is no record evidence of those conversations between Dr. Ornish and the Resnicks, on March 12, 2004, Dr. Weidner sent the Beverage Study I data, for both the myocardial perfusion results ("cardiac" results) and the CIMT results ("carotid" results), to Dr. Liker for review. (CX0642_0001, 03-06 (cardiac arm), 09-10 (carotid arm)).

839. Dr. Ornish has repeatedly insisted that he ended the study at three months because his funding got cut. (Ornish, Tr. 2351-52, 2435-36 ("we didn't have the money to do it because our funding got cut")). The documents show that the agreed-to budget for the study was set at $708,437 as early as May 2003, and that this was the amount that PMRI was paid. (*Compare* CX0591_0001 *with* CX1237_0004). It appears that PMRI experienced cost over-runs that it could not afford to absorb. (Ornish, Tr. 2441 ("[t]he cost of the study was significantly higher than" the budget)). As a result, Dr. Ornish and Respondents terminated the study at three months, at a time when the results were statistically significant, rather than at twelve months as originally set forth in the protocol. (*See* CCFF ¶¶ 826, 837).

840. In August 2004, Dr. Ornish advised Dr. Liker that the MP Study abstract had been rejected by the American Heart Association ("AHA"). (CX0672). He asked the AHA's chairman of scientific sessions to reconsider, but the chairman responded that "[m]ultiple qualified, blinded graders scored this abstract below acceptable range." (CX0680).

841. In November 2004, the *Journal of the American Medical Association* ("JAMA") also rejected the Ornish MP Study manuscript. (CX699_0002). In response to Dr. Ornish's request for feedback, the Deputy Editor of JAMA responded that "the study appears very preliminary, with small sample size, apparent baseline imbalances between groups, use of an intermediate endpoint as main outcome measure, and modest differences with large variability." (CX0699_0001-02).

842. Dr. Ornish then submitted the manuscript to the *American Journal of Cardiology*. (CX1339 (Ornish, Dep. at 200)). The editor accepted it without external peer reviews. (CX0715_0001). The editor was a personal friend of Dr. Ornish. (CX0714_0001 (post-script from editor stating "I'm proud to be included as a friend")).

(b) Expert Analysis

843. Dr. Sacks and Dr. Stampfer testified about problems with the design and conduct of the Ornish MP Study (2005). (Sacks, Tr. 1464-79; Stampfer, Tr. 750-51; CX1291 (Sacks, Report at 0019-24)).

844. Drs. Sacks and Stampfer agreed that the MP study did not use a recognized surrogate marker of heart disease. (CX1291 (Sacks, Report at 0020-21); Sacks, Tr. 1464 (myocardial perfusion, a measure of blood flow, is not used as the primary outcome in studies of treatment efficacy for CHD); Stampfer, Tr. 771-72 (blood flow is a research tool but not a recognized surrogate marker); *see also* CCFF ¶ 841 (JAMA editor citing use of intermediate endpoint as a flaw in the study)). Even where blood flow is shown to have been improved, it will not necessarily result in improved cardiovascular health, such as reductions in heart attack and stroke. (CX1291 (Sacks, Report at 0020-21)). Dr. Heber, too, characterizes the blood flow markers as "intermediate" in his expert report. (PX0192 (Heber, Report at 0053)).

845. Another problem was that the primary endpoint measurement reported in the published

study as the main proof of benefit (SDS) was not identified as the primary endpoint in the protocol. The protocol for the Ornish MP Study (2005) provided for measurement of perfusion, but did not identify whether the primary endpoint would be SSS, SRS, SDS or some other imaging measurement. (CX1291 (Sacks, Report at 0021); *see also* CX0613_0009-10). Dr. Ornish conceded that he did not specify that changes in SDS would be the primary endpoint measure. (PX0025 (Ornish, Report at 0014); *see also* Sacks, Tr. 1475)).

846. As previously stated, a study protocol should identify the primary endpoint in advance and set forth the planned statistical analysis, so that the researcher cannot pick and choose among results after the study is done. (CCFF ¶ 772; CX1291 (Sacks, Report at 0021). POM's documents indicate Respondents were advised that the lack of a "detailed statistical analysis plan" was an issue with the Ornish study. (*See* CX0576_0001).

847. Dr. Sumner, arrived at PMRI in January 2004, after the three month testing was done. (CX1344 (Sumner, Dep. at 13, 16-21); CX1136_0003). When Dr. Sumner started working for PMRI, he was told that SSS, SDS, *and* SRS were the "main variables." (CX1344 (Sumner, Dep. at 37-38) (emphasis added)). Dr. Sumner testified that SDS was chosen as the "key variable" based on his review of literature and conferring with cardiologists including Dr. Ornish, and his brother-in-law, a cardiologist researcher. (CX1344 (Sumner, Dep. at 181)).

848. The "35 percent improvement" in myocardial perfusion claimed in the published report pertained only to the SDS scores. It ignored the SRS and SSS data. (Sacks, Tr. 1622-24). Dr. Sacks and Dr. Stampfer both stated that the .05 "*p*" value of the reported SDS improvement is not very persuasive where, as here, there were three possible outcome measures (SSS, SRS, and SDS) and only one just met significance. (CX1198_0003; Sacks, Tr. 1467 ("when there are . . . multiple outcomes . . . then a p-value of .05 . . . doesn't convey the same level of confidence than in a situation where there is one primary outcome"); CX1291 (Sacks, Report at 0021-22); Stampfer, Tr. 751 ("[T]he second reason I don't put a lot of weight on this is that the results were only slightly significant just for one of the three endpoints that was not specified as the primary outcome in advance.")).

849. Moreover, Dr. Sacks made clear that it is not appropriate to focus on the SDS data, and ignore SRS and SSS scores. (CX1291 (Sacks, Report at 0021-24)). Dr. Ornish acknowledged that SSS shows the presence of dead cardiac tissue, thus revealing whether or not a patient has had a silent heart attack; this information is not shown in the SDS measure. (Sacks, Tr. 1468). It also is not clear that the reported change in SDS was

clinically meaningful, because the authors did not show that the patients experienced improvement in their clinical symptoms. (CX1291 (Sacks, Report at 0022)). For example, there was no statistically significant improvement in angina, which is chest pain due to insufficient blood flow to the heart. (CX1198_0003; Sacks, Tr. 1463-64).

850. Another problem with the study was the large discrepancy in the blood flow values between the placebo and active groups at baseline. The baseline SSS for the placebo group was 9.6±6.5, and the baseline SSS of the juice group was 6.4±3.5, meaning that the placebo group was sicker than the juice group when the study started. Similarly, the baseline SRS for the placebo group was 3.8±4.7, and the baseline SRS for the juice group was 1.9±2.6, again showing that the placebo group was sicker at the beginning of the study. (CX1198_0003 (Table 2); CX1291 (Sacks, Report at 0022-23); Sacks, Tr.1469-72, 77; Stampfer, Tr. 750-52). Study documents from Dr. Ornish's clinic files show that the difference between the baseline SSS values of the placebo and juice groups was so large as to be statistically significant. (CX0701_0001 (email from M. Sumner to M. Eller, forwarded to D. Ornish, stating, "[t]here was a baseline difference in SSS between the experimental and the control groups ($p<.04$). We don't have to mention this, but we should keep this in mind.")). This imbalance in baseline values was mentioned by the JAMA Editor as a reason for rejecting the study for publication. (*See* CCFF ¶ 841).

851. This imbalance in baseline values shows that randomization did not produce an active and placebo group that were similar on relevant characteristics. (Stampfer, Tr. 751-52; CX1293 (Stampfer, Report at 0019); CX1291 (Sacks, Report at 0023)). It could be predicted that the control group, having worse coronary perfusion than the POM Juice group at baseline, would have a more accelerated form of the disease and show worsening on follow-up. (CX1291 (Sacks, Report at 0022-23); Sacks, Tr.1469-72, 77; *see also* Stampfer, Tr. 751 ("[H]ere, the placebo group was worse off at the start, and it's easy to imagine that if you're worse off at the start, you are going to get worse faster over time. So, the evidence isn't persuasive.")). Dr. Sacks stated that the baseline difference should have been reported in the publication. (Sacks, Tr. 1477; CX1291 (Sacks, Report at 0023)).

852. According to Dr. Sacks, the errors admitted by Dr. Ornish in the conduct of the study in CCFF ¶¶ 830-34 are inconsistent with widely-accepted standards for conduct of clinical trials. (CX1291 (Sacks, Report at 0023-24)).

853. Also inconsistent with accepted clinical trial conduct standards was the termination of the Ornish MP Study (2005) at a time the *p*-value was considered significant, rather than at the time the trial was originally set to end, as set forth in CCFF ¶¶ 835-39. (Sacks, Tr.

1474-75; CX1291 (Sacks, Report at 0023-24); *see also* Stampfer, Tr. 752-53, 771; CX1293 (Stampfer, Report at 0019)). If a researcher is forced to end a study because of a funding problem, this fact should be reported in the published report. "[I]n a controlled trial, it's essential to state what was the original plan and what was actually done. . . . Otherwise, the study could . . . develop biases." (Sacks, Tr. 1474-75). There is no mention of the 12 month planned study in the published results. (CX1198).

854. The interpretation of the Ornish MP Study (2005) that is most consistent with principles of clinical study design and conduct is that the pomegranate juice treatment had no effect on any measure of cardiac health. (CX1291 (Sacks, Report at 0024)). Experts in the field of cardiovascular disease would not consider the Ornish MP Study to support the proposition that pomegranate juice provides a heart disease benefit, either in terms of prevention or treatment. (Sacks, Tr. 1472, 1526-28). In light of the problems in the design and conduct of the study, and the discrepant results of the SSS, SDS, and SRS measures, the study does not even support the conclusion that pomegranate juice had a favorable effect on coronary perfusion (blood flow to the heart). CX1291 (Sacks, Report at 0024); CX1293 (Stampfer, Report at 0018-19)).

(2) Ornish CIMT Study

(a) About the Study

855. The Ornish CIMT Study (also known as the Beverage Study II) was a randomized, double-blind, placebo-controlled 73-person study that measured CIMT, blood pressure, and other related mechanisms for 12 months. (CX0754_0002). The treatment group drank one cup (eight ounces) of pomegranate juice concentrate daily, and the control group drank one cup of placebo beverage, daily, for one year. (CX0613_0020).

856. The protocol for the Ornish CIMT Study called for measurement of CIMT, cholesterol, LDL, HDL, triglycerides, and systolic and diastolic blood pressure at baseline, six, and twelve months. (CX0613_0019-20). The data analysis section stated that the data would be analyzed for statistical significance using a conventional test. (CX0613_0022).

857. According to the unpublished final report, there were no significant changes in the treatment group relative to the placebo for CIMT thickness or elastic properties. (CX0754_0002) (transmitting "Bev 2 Summary 6-16-05.doc")).

858. There also were no significant differences in the treatment group relative to the placebo group over time for any of the other heart-related measurements, including systolic and diastolic blood pressure, cholesterol, LDL, HDL, or triglycerides. (CX0754_0003,05; CX1291 (Sacks, Report at 0024-25); Stampfer, Tr. 754-55; CX1293 (Stampfer, Report at 0019-20)).

859. An early draft of the Ornish CIMT Study (Beverage II) protocol had called for a sample size of 200 patients. (CX0584_0005; PX0355 (Ornish, Dep. at 178)). Dr. Ornish testified that the decrease in the number of patients was due to the Resnicks cutting his funding. (Ornish, Tr. 2454; *see also* CX1360 (S. Resnick, Dep. at 131) (stating that Dr. Ornish was slow and unable to get enough recruits)). The agreement signed by Dr. Ornish on September 19, 2003, however, called for a sample size of 55 patients. (CX0613_0002). PMRI was actually able to recruit 73 patients, and data on 56 patients were available for analysis. (Ornish, Tr. at 2452).

860. On or about October 21, 2004, PMRI finished its data collection. (CX0697). On or about March 24, 2005, Dr. Sumner provided an analysis of the study data to Dr. Weidner, stating, "very few significant interactions . . . a mixed, but relatively disappointing bag so far." (CX0717_0001; CX1344 (Sumner, Dep. at 151-52)).

861. PMRI made an effort to reexamine the data to identify positive results. On March 24, 2005, Dr. Sumner stated, "I am looking into additional ways to analyze the data" and suggested sending "the CIMT results to [another researcher] to check before [sending] them to Harley [Liker] /the Resnicks." (CX0717_0001; *see also* CX0718_0001). The next day, another PMRI employee suggested having a biostatistician analyze the data "before concluding the juice had a null effect." (CX0719_0001). On April 5, 2005, Dr. Weidner also volunteered to "give Bev II another try . . . feel[ing] pretty confident that if there is something there, [she] can find it[.]" (CX0724_0001).

862. On March 24, 2005, Dr. Ornish told Dr. Sumner that he wanted to "publish results, even if they are non-significant." (CX0717_0001). Dr. Weidner agreed, stating that, "even if there are no effects, we need to report them." (CX0718_0001; CX1344 (Sumner, Dep. at 154)).

863. On March 24, 2005, a PMRI employee emailed Dr. Ornish stating that "Stewart [Resnick] said he was sitting with Harley [Liker] in his office, yelling at him because he wants Bev II results, and he decided to call our office to have someone else to yell at. . . . He said 'you've already been paid, I want the results.'" (CX0718_0001).

864. On or about March 29, 2005, Dr. Sumner ran an analysis on additional data, finding nothing significant but several positive "trends." (CX0720_0001).

865. On April 5, 2005, another PMRI scientist requested more time to reanalyze the data and asked Dr. Ornish to "stall the Resnicks for another week or two." (CX0724_0001). However, on April 20, 2005, in response for another request for more time to analyze the data, Dr. Ornish denied the request, stating that "[t]he Resnicks always punish us for taking more time even when it's to improve the quality of the study." (CX0726_0001).

866. The final analysis for the Ornish CIMT Study results was conducted in approximately June 2005. (CX1344 (Sumner, Dep. at 168-69)). On or about June 16, 2005, the results of the study were provided to Dr. Ornish. (CX0752; CX1344 (Sumner, Dep. at 168-69)).

867. On August 4, 2005, Dr. Ornish sent Respondents the final study results, showing no benefits for patients who drank pomegranate juice on CIMT or any of the other heart related measures including blood pressure and cholesterol. (CX0754; Ornish, Tr. 2457; S. Resnick, Tr. 1682)).

868. Respondents were aware that the Ornish CIMT Study results showed no statistically significant benefit. (*See* CX0756_0001 (email dated August 5, 2005, from Dr. Liker to Mrs. Resnick); CX0837_0001 (email from Dr. Liker to Dr. Dreher transmitting the study results on Sept. 25, 2006); CX0262_0003 (internal POM Wonderful Medical Portfolio dated Dec. 17, 2008 describing Ornish CIMT Study results as showing "no change"); CX1265_0003, *in camera* [redacted]; CX1379_0016, *in camera* (Response to Request for Admissions No. 22)).

(b) Expert Analysis

869. The Ornish CIMT Study appears to have been well-designed and well-conducted. (Sacks, Tr. 1485-88; CX1291 (Sacks, Report at 0026)).

870. Dr. Sacks described the results of this study as "convincingly null, showing that pomegranate juice treatment did not improve CIMT or the other tested parameters" including elasticity of the arteries, blood pressure, or cholesterol. (CX1291 (Sacks, Report at 0026); *see also* CX1293 (Stampfer, Report at 0019-20); Stampfer, Tr. 755).

871. Dr. Sacks further opined that the null results of the Ornish CIMT Study confirm that the purportedly positive results of Dr. Aviram's unrandomized, uncontrolled 19-patient CIMT/BP Study lack credibility. (Sacks, Tr. 1486-88; CX1291 (Sacks, Report at 0026)).

872. Dr. Ornish ignored his own CIMT Study results in reaching his conclusions regarding the effect of pomegranate juice on heart disease. (PX0355 (Ornish, Dep. at 192-93)). He argued that the null results were caused by the fact that the study was underpowered, and stated that this is why he did not publish the study. (CX1339 (Ornish, Dep. at 82); PX0355 (Ornish, Dep. at 188). He hypothesized that if he *had* been provided with sufficient funding to enroll 200 persons, a statistically significant effect *might* have been demonstrated; however, he admitted that this is speculation on his part. (Ornish, Tr. 2352-53, 2457; CX1339 (Ornish, Dep. at 102-04); PX0355 (Ornish, Dep. at 191); *see also* Sacks, Tr. 1486-87; CX1291 (Sacks, Report at 0025-26)).

873. Dr. Sacks stated that Dr. Ornish's willingness to ignore the null results of his study is an inappropriate treatment of the data. (CX1291 (Sacks, Report at 0025)). Dr. Sacks explained that the data are not rendered irrelevant by the fact that the study was smaller than originally planned: "Having conducted the study, the researcher and the sponsor must live with the results." (CX1291 (Sacks, Report at 0025-26); Sacks, Tr. 1487-89).

874. Dr. Heber also did not consider the results of the Ornish CIMT Study in reaching his conclusions, because he had been informed that the study was "incomplete." (PX353 (Heber, Dep. at 180-81); Heber, Tr. 2134). Notably, Respondent Tupper testified that if a study was not published, it was not complete. (CX1353 (Tupper, Dep. at 82-84)).

c. Davidson Studies

875. Dr. Michael Davidson is the Medical Director of Radiant Research, Chicago. (CX1134_0001). He has been involved, in some manner, in over 700 clinical studies over the past 25 years. (JX0003 ¶ B.18). Drs. Sacks and Ornish agree that Dr. Davidson is very highly regarded for his clinical research in the field of cardiovascular disease. (Sacks, Tr. 1490; PX0355 (Ornish, Dep. at 197-98)).

876. In 2003, Dr. Liker approached Dr. Davidson about conducting a CIMT and a brachial artery reactivity testing study for Respondents. (CX1336 (Davidson, Dep. at 92-93); CX0586). From the beginning, Dr. Liker indicated that the study should be randomized, double-blind, and placebo-controlled. (CX1336 (Davidson, Dep. at 92)).

877. Dr. Liker implicitly acknowledged that the Aviram ACE/BP Study (2001), the Aviram CIMT/BP Study (2004), the Ornish MP Study (2005), and the unpublished Ornish CIMT Study collectively did not provide clear evidence of heart health benefits. In a summary of cardiovascular studies sent to a scientific consultant for POM, he described these studies and stated that POM was still exploring its research options "in its efforts to understand whether or not the consumption of pomegranate juice offers cardiovascular benefits." (CX0579_0003-04).

878. Dr. Davidson conducted two studies for Respondents: (1) Davidson MH., *et al.*, *Effects of Consumption of Pomegranate Juice on Carotid Intima-Media Thickness in Men and Women at Moderate Risk for Coronary Heart Disease*, 104 Am. J. Cardiology 936 (2009) ("Davidson CIMT Study") (CX1065; *see* JX0003 ¶ B.17); and (2) Davidson MH, *The Effects of Pomegranate Juice on Flow-Mediated Vasodilation* (unpublished, 2004) ("Davidson BART/FMD Study") (CX0684; *see* JX0003 ¶ B.17). The two studies were covered by a single protocol that was amended over time. (*See* CX0684). The cost for the two studies, sponsored by the Stewart and Lynda Resnick Revocable Trust, was $2,940,494. (CX1134_0001).

(1) Davidson CIMT Study (2009)

(a) About the Study

879. The Davidson CIMT Study (2009) was an 18-month, 289-person randomized, double-blinded, placebo-controlled clinical trial designed to test the effect of pomegranate juice on CIMT progression rates in subjects at moderate coronary heart disease risk. (CX1065_0001; CX1291 (Sacks, Report at 0027)). Subjects were middle-aged men and women with one or more CHD risk factors (high LDL, low HDL, hypertension or use of hypertension medication, or cigarette smoking) and baseline posterior wall CIMT of 0.2 to 2.0 mm without significant stenosis. (CX1065_0001-02; CX1291 (Sacks, Report at 0027)). The study excluded persons with actual CHD or diabetes. (CX1065_0002).

880. Study participants drank eight ounces of pomegranate juice or placebo juice daily. Adherence to study product consumption was assessed at each visit by reviewing daily consumption diaries maintained by the subjects. (CX1065_0002).

881. The study protocol called for ultrasound testing of the carotid artery at baseline, 12 months, and at 18 months. (CX0716_0018-19). The primary outcome variable identified in the protocol was the difference between placebo and pomegranate juice in posterior wall common CIMT progression rate in mm/year, using non-contrast images, and a

secondary outcome measurement was difference between placebo and pomegranate juice in the anterior wall common CIMT progression rate in mm/year, using contrast images. (CX0716_0028). Exploratory endpoints included changes in blood pressure, lipids, and various measures of inflammation and oxidative stress. (CX0716_0011; CX1291 (Sacks, Report at 0027)). The protocol identified the proposed statistical analysis. (CX0716_0012).

882. According to the published results, the 289-person Davidson CIMT Study (2009) showed no significant influence of 18 months of pomegranate juice consumption on CIMT progression in the overall study sample. (CX1065_0006; CX1291 (Sacks, Report at 0028); CX1293 (Stampfer, Report at 0020); PX0025 (Ornish, Report at 0019-20). This included no statistically significant changes in the anterior or posterior wall measurements, or in a "composite" measure that summed the anterior and posterior measurements. (CX1336 (Davidson, Dep. at 54-56); *see* CX1065_0004 (Table 3). Dr. Heber agreed that, on an intent-to-treat analysis, there was no difference between the active and placebo groups at the end of the study. (Heber, Tr. 2132).

883. There also were no statistically significant changes in blood pressure (a validated surrogate marker for heart disease studies) at the end of the Davidson CIMT Study (2009). (CX1065_0003-05; Sacks, Tr. 1492; CX1291 (Sacks, Report at 0028; Stampfer, Tr. 757-59; CX1293 (Stampfer, Report at 0020-21)).

884. The study also evaluated the effect of consuming pomegranate juice on a number of measures of inflammation or oxidative stress, including high sensitivity C-reactive protein, PON1, and two measures of TBARS. (CX1065_0003). There were no statistically significant changes in any of these measures at the end of the study. (CX1065_0003-05; Sacks, Tr. 1492-93; CX1291 (Sacks, Report at 0028); Stampfer, Tr. 757-59; CX1293 (Stampfer, Report at 0020-21); Heber, Tr. 2125-26; CX1336 (Davidson, Dep. at 44-48)).

885. The published report also provides CIMT absolute results at 12 months and 18 months based on a measurement of the "composite" value (*i.e.*, the sum of the posterior and anterior walls) for the pomegranate juice group versus the placebo group. The results indicated a significantly better CIMT *value* for the POM Juice group than the placebo group at 12 months, but not at 18 months. (CX1065_0005-06). The published study does not state, however, what the progression *rate* was, in mm/year, between baseline and 12 months, for the pomegranate and placebo groups; nor does it provide a "*p*" value for the difference in the *change* between those two groups at 12 months. (*See* CX1065_0005; Sacks, Tr. 1495-97, 1611-12 (testifying that he incorrectly stated, in his

expert report, that the composite rate was smaller at 12 months)).

886. In fact, CIMT study data provided to Respondents, but not included in the publication, showed that the difference in CIMT progression *rates* between the active and placebo groups at 12 months was $p = .0544$, a positive trend, but *not* a statistically significant result. (CX0867_0019; CX1336 (Davidson, Dep. at 144-46) (discussing CX0784_0015, Table A.3.8.a)).

887. Dr. Davidson's published report also included a *post hoc* analysis of changes in the CIMT measurements for some of the study subpopulations. The report stated that there were significantly lower anterior and/or composite CIMT progression rates with higher CVD risk factors. (CX1065_0001, 0006; CX1336 (Davidson, Dep. at 57-69)). A *post hoc* analysis is one that is conceived of after the researchers have seen the data and thus is generally a less valid approach than one planned for in the protocol, because it is more subject to bias. (Sacks, Tr. 1500-01). The published article described the subgroup analyses as "post hoc exploratory analyses, which should be interpreted with caution[.]" It stated that, "[b]ecause the decrease in CIMT progression in these subgroups was based on analyses that were not preplanned and had no correction for multiple comparisons (increasing the possibility of type I errors), *these findings will need to be confirmed in future investigations*." (CX1065_0006) (emphasis added). A type I error is a "'false positive'. It is the statistical term [for] a finding that a change has occurred when in fact, it has not." (CX1291 (Sacks, Report at 0028); CX1336 (Davidson, Dep. at 69); Stampfer, Tr. 762-63).

888. Dr. Davidson initially submitted a manuscript of the study to the journal, *Arteriosclerosis, Thrombosis, and Vascular Biology*, in late 2008. That journal rejected the manuscript, however, concluding that it was a negative study. (CX1336 (Davidson, Dep. at 201-02 (discussing CX1016)).

889. In May 2009, Dr. Davidson submitted the manuscript to the *American Journal of Cardiology*. Two expert reviewers provided recommendations and comments. (CX1336 (Davidson, Dep. at 77-78); *see* CX1057_0024-27).

890. One reviewer stated that, given the large number of *post hoc* analyses performed, it would be appropriate to conduct a statistical correction for multiple comparisons. (CX1057_0025; CX1336 (Davidson, Dep. at 80-81)). Dr. Davidson did not do the statistical correction (CX1336 (Davidson, Dep. at 73)), but committed to revise the discussion section to emphasize "[t]he possibility of type I errors, the exploratory nature

of these findings, and caution regarding interpretation of post-hoc subgroup analyses." (CX1057_0024-27).

891. Another reviewer advised that "The study needs to be reported as a negative study as it is." (CX1057_0027). In his response, Dr. Davidson "affirm[ed] that it was a negative study," and committed to revise the manuscript to emphasize that "caution is warranted" with regard to the subgroup findings, and that those findings "should be considered hypotheses that will need to be replicated in future trials designed to assess the efficacy of pomegranate juice consumption" in those subgroups. (CX1336 (Davidson, Dep. at 78-85); CX1057_0027).

(b) Respondents' Reaction to Results

892. Dr. Davidson provided Respondents with the final CIMT study results in February 2006. (CX1336 (Davidson, Dep. at 144)). Those results showed a positive, but not statistically significant, trend at 12 months ($p = .054$); however, this trend was not sustained at 18 months. (CX1336 (Davidson, Dep. at 144-46) (discussing CX0784_0015, Table A.3.8.a)). As further set forth below, Respondents delayed publication of the results for nearly two and a half years. (*See* CCFF ¶¶ 893-98).

893. Respondents' reaction to the study results was "disappointment, bewilderment." (CX1336 (Davidson, Dep. at 146)). Respondents then hired two independent organizations to re-evaluate Dr. Davidson's CIMT scans; those organizations reached the same results as Dr. Davidson had. (CX1336 (Davidson, Dep. at 147-48)).

894. Under the Davidson CIMT protocol, Respondents needed to approve any publication of the results. (CX0716_0036). In October 2006, Dr. Davidson presented the subgroup analysis to Mr. Resnick, and Drs. Heber, Aviram, Liker, and Dreher, requesting permission to publish the results. (CX1336 (Davidson, Dep. at 165-68)). Starting in January 2007, Dr. Davidson worked on various drafts of the manuscript, hoping to obtain Respondents' permission to publish. (CX1336 (Davidson, Dep. at 170-71, 186 ("I was working on . . . various drafts . . . over time.")). As of March 2007, Dr. Dreher had advised one of his colleagues that "Stewart may decide not to publish" the Davidson results. (CX0108_001).

895. In May 2007, Dr. Davidson asked Respondents for permission to publish an abstract of the CIMT study results to the American Heart Association, but Stewart Resnick said no. Dr. Davidson testified that Dr. Liker and Mr. Resnick thought that the study data didn't

show the "true effect" between 12 and 18 months. (CX1336 (Davidson, Dep. at 180-81); Liker, Tr. 1919-20; *see* CX0901 (Liker email transmitting proposed abstract to S. Resnick, Tupper, Dreher, and Heber)).

896. In January 2008, Dr. Aviram wrote Dr. Dreher to say, "I think that we should convince Stewart [Resnick] to agree to publish the Davidson research results, as the results after one year are VERY important to all of us. . . . Just think of a way that it will not harm you." (CX0944_0001) (capitalization in original). Dr. Dreher responded that, "Stewart, as you know, has concerns that the contradictory results of this research between 12 vs 18 months might confound our previous CVD research[.]" (CX0948_0001). Dr. Dreher suggested that Dr. Davidson could demonstrate that "the 12-18 month data can not be trusted[.]" (CX0948_0001).

897. On April 8, 2008, Dr. Liker asked Dr. Kessler to talk to Dr. Davidson about the study, noting that Dr. Davidson thought "that by not publishing the data, POM could be at risk in the future for not being transparent[.]" (CX0962_0001). On April 12, 2008, Drs. Liker and Dreher continued to discuss the possibility of publishing the Davidson CIMT results. Dr. Liker stated that they needed to talk to Mr. Tupper; he said that he had "broach[ed] the disclosure issue with Matt [Tupper] who shares our concerns." (CX0964).

898. On April 14, 2008, Mr. Tupper agreed to meet with Drs. Liker and Dreher about publishing Davidson's research. (CX0965). Dr. Aviram weighed in, urging the importance of the 12 month data and suggesting that "we can convince that the last visit is problematic." (CX0969_0001). In May 2008, Dr. Dreher wrote to Mr. Tupper and Drs. Aviram, Heber, Liker, Kessler and Davidson to suggest "an alternative way to report the POM CIMT results." (CX0977_0001). As noted above, Dr. Davidson submitted the manuscript to one journal in late 2008, where it was rejected (CCFF ¶ 888) and finally to the *American Journal of Cardiology* on May 8, 2009. (*See* CX1057_0003).

899. Thereafter, on May 12, 2009, POM held a cardiovascular advisory board meeting. (*See* CX1063_0001). The meeting was designed to allow Dr. Davidson to present the CIMT research to a group of distinguished cardiologists to see whether they believed that the CIMT data showed sufficient signal of benefit to proceed with a "larger, definitive trial." (CX1336 (Davidson, Dep. at 204-05)). Planned attendees included Stewart Resnick, Tupper, Heber, Gillespie, Aviram, Kessler, Liker, and three outside experts. (CX0538_0001).

900. Subsequently, on July 27, 2009, Mr. Resnick, Mr. Tupper, and Drs. Gillespie, Heber, Kessler, and Liker met to discuss future research. (CX1081_0001). Briefing materials sent to Dr. Liker in advance of the meeting posed the question, "Should POM Wonderful consider a follow up CIMT study in high risk subjects?" (CX1081_0005). According to the briefing materials, "Study would enroll approximately 300 subjects at a cost of about 3 MUSD [*i.e.*, 3 million U.S. dollars]. The probability of success is judged to be between 20-80%." (CX1081_0005).

(CX1349 (Gillespie, Dep. at 87-88), *in camera*).

901.

(CX1084_0002, *in camera* (stating that

). As of 2011, Respondents have not pursued any follow up CIMT studies. (CX1360 (S. Resnick, Dep. at 106)).

902. Respondents' 2009 Medical Research Portfolio Review concluded that the Davidson CIMT Study (2009) showed "no change" in the overall population and that the CIMT result in the "hi-risk" category was only a 2-5% decrease. (CX1029_0003).

(c) Expert Analysis

903. Dr. Sacks noted that the Davidson CIMT Study (2009) is the largest of the heart studies conducted on pomegranate juice. He stated that the Davidson CIMT Study (2009) was carefully designed – the protocol identified the endpoints to be measured, the procedures to be followed, inclusion and exclusion criteria, and the statistical analysis to be conducted. Further, there was no evidence of critical problems in the conduct or analysis of the study (except its over-emphasis on the subgroup results). The Davidson CIMT Study (2009) provides competent and reliable evidence that consumption of pomegranate juice did not improve CIMT in subjects with one or more cardiovascular risk factors. (CX1291 (Sacks, Report at 0029)).

904. Dr. Stampfer provided the opinion that that the main result from the Davidson CIMT Study (2009) provides substantial evidence *against* the hypothesis that pomegranate juice can reduce the progression of CIMT. (CX1293 (Stampfer, Report at 0020-21); Stampfer, Tr. 758-59 ("So it seems clear that this is a null study, and that's what the authors

concluded")).

905. Dr. Ornish agreed with Sacks' conclusion that the Davidson CIMT Study (2009) showed no significant differences in CIMT progression rates between the active and placebo groups. (PX0025 (Ornish, Report at 0019-20)). Dr. Heber acknowledged that "the results suggest that in subjects at moderate coronary heart disease risk, pomegranate juice consumption had no significant effect on overall CIMT progression rate[.]" (PX0192 (Heber, Report at 0039)

906. As for the 12 month data, showing that absolute CIMT measurements were smaller in the pomegranate juice group than those of the placebo group (*see* CCFF ¶¶ 885-86), Dr. Sacks stated that the absolute difference in CIMT values at 12 months is not relevant, because one has to look at the change in the CIMT progression, as the published report did for the primary and secondary endpoint results at 18 months. (Sacks, Tr. 1495-97). The unpublished change rate CIMT data at 12 months was *not* significant although it trended positive. (*See* CCFF ¶ 886).

907. Dr. Ornish argued that a potential reason for lack of a change in the CIMT progression rate at 18 months was that study participants may have stopped drinking the juice after 12 months. (PX0025 (Ornish, Report at 0020-21)). Dr. Davidson, however, evaluated the compliance with product consumption guidelines during the study. (CX1336 (Davidson, Dep. at 151-52); CX0788). He testified that his review of compliance diaries showed high levels of compliance with product consumption. (CX1336 (Davidson, Dep. at 151)).

908. With regard to the *post hoc* subgroup analysis, both Dr. Sacks and Dr. Stampfer agree with the study authors that this exploratory analysis is hypothesis-generating for future research. (CX1293 (Stampfer, Report at 0020-21); Stampfer, Tr. 762; Sacks, Tr. 1504-05). One typically can find subgroups *post hoc* in which results differ from the main in either direction. (CX1293 (Stampfer, Report at 0020)). With each additional subgroup analyzed, the chances increase that one or more will turn out to have a *p*-value of less than .05, by chance alone. (Sacks, Tr. 1505-06; Stampfer, Tr. 760-61).

909. As a result, before it can be considered persuasive, the Davidson subgroup analysis must be evaluated *de novo* in a future study. (CX1291 (Sacks, Report at 0029-30); Stampfer, Tr. 762-63). Dr. Davidson himself stated that *post hoc* studies are very important for hypothesis-generating research, and that they provide "interesting signals of an effect that needs to be confirmed in future research." (CX1336 (Davidson, Dep. at 68)). Dr. Sacks

stated "most subgroup analysis don't turn out to be true, and that's why they have to be confirmed." (Sacks, Tr. 1615). Dr. Ornish agrees that a *post hoc* analysis is "not as rigorous as one stated a priori." (PX0025 (Ornish, Report at 0021)). Dr. Heber has noted that the problem with subgroup analysis is that "one could, you know, randomly continue to divide a group of subjects until you found a positive result without rationale." (Heber, Tr. 2133).

910. Dr. Sacks also noted that the subgroup analysis had not been corrected for multiple comparisons, as stated in Dr. Davidson's published report. (CX1291 (Sacks, Report at 0030)). When multiple endpoints are being measured, the *p*-value needs to be adjusted downward to correct for multiple comparisons. (Sacks, Tr. 1505). This is known as a "Bonferroni correction" in the field of statistics. (CX1336 (Davidson, Dep. at 80)). Without the correction, with each additional subgroup analyzed, the chances increase that one or more will turn out to have a *p*-value of less than .05, by chance alone. (Sacks, Tr. 1505-06; Stampfer, Tr. 760-61). Dr. Davidson never did a correction for multiple comparisons on the subgroup analysis. (CX1336 (Davidson, Dep. at 73)).

911. Because the subgroup data is hypothesis generating only, and has not been corrected for multiple comparisons, a qualified scientist could not rely on the *post hoc* analysis of the subgroup populations as reliable scientific evidence to support claims that POM Juice or POMx prevent, reduces the risk of, or treats heart disease in the subpopulations identified in Figure 3 of the report. (CX1291 (Sacks, Report at 0030)). Correction for multiple comparisons is especially important when you want to recommend that people change their behavior, such as drinking a juice to improve their health. (Sacks, Tr. 1505-06).

(2) Davidson BART/FMD Study

(a) About the Study

912. Dr. Davidson's BART/FMD Study was conducted on a subset of 45 Davidson CIMT Study (2009) participants. (CX0684_0001; CX1336 (Davidson, Dep. at 37, 102-03)). It was a 13-week, randomized, double-blind, placebo-controlled trial to evaluate the effect of consuming POM Juice or placebo on brachial artery reactivity testing ("BART"), also referred to as "flow mediated dilation" ("FMD") testing. BART is a measurement of how much the brachial artery dilates (enlarges) after a blood pressure cuff is inflated, and then released. (JX0003 ¶ A.1). In addition, the study measured blood pressure, lipid parameters, and other vital signs. (CX0684; CX0716_0074-81; Sacks, Tr. 1508-10; Stampfer, Tr. 764-66).

913. While the study was ongoing, Dr. Liker advised Dr. Davidson's group at Radiant that the Resnicks wanted the BART results immediately upon completion "for possible publication." (CX0616_0002; CX1336 (Davidson, Dep. at 113)).

914. At the conclusion of the study, there were no significantant differences between the treatment and placebo groups in BART/FMD. (CX0684_001; CX1336 (Davidson, Dep. at 88-89); Sacks, Tr. 1510-13; CX1291 (Sacks, Report at 0030-31); CX1293 (Stampfer, Report at 0021)). As the results of the BART study were not positive, no written report was prepared. (CX0695_0001; CX1336 (Davidson, Dep. at 125)).

915. Also at the end of the study there were no significant differences between treatment and placebo groups in blood pressure, cholesterol, HDL cholesterol, non-HDL cholesterol, triglycerides, ACE, PON, and two TBARS measurements. (CX1336 (Davidson, Dep. at 86-88; CX0684_0005-13, 19; CX1291 (Sacks, Report at 0031)).

(b) Expert Analysis

916. The study appears to have been properly designed and conducted. (CX1291 (Sacks, Report at 0032)). The protocol identifies the endpoints to be measured, the procedures to be followed, inclusion and exclusion criteria, and statistical analysis to be conducted. There is no evidence of critical problems in the conduct of the study. (CX1291 (Sacks, Report at 0032)).

917. The Davidson BART/FMD Study finding of no statistically significant difference in ACE due to POM Juice consumption contradicts Dr. Aviram's ACE/BP Study (2001) findings. (CCFF ¶ 798; Sacks, Tr. 1512-13; CX1291 (Sacks, Report at 0032); *see also* Heber, Tr. 2140 (agreeing that the ACE result was not replicated in the BART study)).

918. Although, BART/FMD is not a reliable marker of surrogate health, the study does provide information that is relevant to this case. FMD is a measure of nitric oxide production in the brachial artery, a major artery of the arm. (JX0003 ¶ A.2; Sacks, Tr. 1509-12). Brachial artery activity is a factor of nitric oxide activity. (PX0353 (Heber, Dep. at 187)). If pomegranate juice meaningfully affected nitric oxide metabolism and activity, one would have expected to see a positive result in the FMD testing. (Sacks, Tr. 1511-12).

919. In addition, reduction in blood pressure is a valid surrogate marker for cardiovascular health, and this study shows that there was no significant change in blood pressure

between the treatment and placebo groups. (CX1291 (Sacks, Report at 0032)).

3. Additional Biomarker Studies

a. Overweight Studies

920. In 2006, POM sponsored Dr. James Hill, University of Colorado, Denver, to look at the effects of POMx on biomarkers of inflammation and oxidation in overweight people ("Denver Study"). (*See* CX0839 (study protocol)). POM provided the University of Colorado at Denver with a $266,653 gift to cover to cover the conduct of this study, as well as a study on diabetics (further described at CCFF ¶¶ 946-49). (*See* CX1342 (Hill, Dep. at 30-31, 77-79); CX1127_0001).

921. Also in 2006, POM sponsored Dr. David Heber and Accelovance to look at the effect of POMx on biomarkers and inflammation in overweight people ("San Diego Study"). (CX0819_0021-22 (protocol identifying Dr. Heber as Principal Investigator and Accelovance as Investigational Site); CX0859_0001 (Clinical Study Report)). There is no record evidence regarding the cost of this study.

(1) Denver Study

922. Dr. Hill and his colleagues conducted an unblinded, uncontrolled study of POMx capsules in Denver, Colorado. (CX1291 (Sacks, Report at 0032-35); *see* Sacks, Tr. 1514). In the course of protocol development, in May 2006, Dr. Dreher asked Dr. Hill whether it would be better to have a two-arm study, where one arm took a placebo, "to potentially enhance scientific value for a possible publication if we see any interesting trends[.]" (CX0805_0001). Dr. Hill responded that he favored keeping the study as a "quick and dirty," "pilot study to learn how to design a good study that would be publishable." (CX0805_0001; CX1342 (Hill, Dep. at 39-40, 46-47)).

923. The study enrolled 24 adults (19 females, 5 males) ages 40-70 with abdominal adiposity. Subjects took 2 POMx capsules per day for 28 days. (CX0877_0002-10).

924. A "wide range of biomarkers for oxidative stress and inflammation" were measured at baseline and four weeks, including TBARS and PON1 activity. TBARS is a measure of oxidation and PON1 is a measure of anti-peroxidation. Low TBARS and high PON1 are regarded as favorable. Additional measurements included blood pressure, triglycerides, cholesterol, and C-reactive protein. (CX0877_0002-10; CX1342 (Hill, Dep. at 42-44)).

925. Twenty-two subjects completed the study. According to the Preliminary Data Analysis, dated February 15, 2007, the participants gained an average of 1.3 pounds during the study, which Dr. Hill attributed to its conduct during the holiday season. (CX0877_0002-03; CX1291 (Sacks, Report at 0032-33); CX1342 (Hill, Dep. at 99-103)).

926. After adjusting the statistical analysis for the weight change, only two significant results emerged: TBARS decreased and free fatty acids increased. There was no change in PON1. The study statistician stated that the change in TBARS was "of borderline significance [and had] not been adjusted for the number of comparisons made." (CX0877_0002-03, 0008 (TBARS), 0010 (PON1); CX1291 (Sacks, Report at 0033); CX1342 (Hill, Dep. at 97-103, 118-19 (regarding PON1)).

927. In the Denver Study there were no statistically significant changes in blood pressure. (CX0877_0008 (SBP (systolic blood pressure), DBP (diastolic blood pressure); CX1291 (Sacks, Report at 0033); CX1342 (Hill, Dep. at 111-13)).

928. The Preliminary Data Report concluded, "[w]e did not detect any effect of POMx on inflammation but identification of better biomarker assays for inflammation is needed . . . . [T]his pilot project suggests that a larger trial is warranted in abdominally obese subjects who may be at risk for development of metabolic diseases." (CX0877_0002-03; CX1291 (Sacks, Report at 0033)).

(2) San Diego Study (Heber/Accelovance)

929. The protocol for the San Diego Study was titled *A Placebo-Controlled, Randomized, Double-Blind Study to Compare Antioxidant Levels in Normal Subjects with Elevated Waist Circumference When Administered 1 or 2 Pomegranate Dietary Supplement Capsules for 4 Weeks.* (CX0819_0014 (Protocol, July 14, 2006); CX1291 (Sacks, Report 0033-34)).

930. This randomized, double-blind, placebo-controlled study recruited 64 generally healthy male and female subjects who took either two POMx capsules, two placebo capsules, or one placebo and one POMx capsule, per day, for four weeks. (CX0859_0010 (Clinical Study Report); CX1291 (Sacks, Report at 0033-34)).

931. Measurements included blood pressure and various antioxidant and inflammation markers such as oxidized phospholipids, oxidized LDL/HDL, serum nitric oxide, PON, and others. (CX0859_0003; CX1291 (Sacks, Report at 0034)).

932. A portion of the San Diego Study data was presented in a January 11, 2007 Clinical Study Report. (*See* CX0859). This document described the conduct of the study, adverse events, vital signs, and blood pressure data. It stated that "[t]here were no apparent treatment related changes in weight, systolic blood pressure, diastolic blood pressure, pulse rate, respirations, or temperature." (CX0859_0020). The San Diego Study report stated that the efficacy results of antioxidant and anti-inflammatory levels were reported separately. (CX0859_0018).

933. Dr. Heber prepared a slide presentation about efficacy results of the San Diego Study. It stated that, "there were no changes in . . . markers of oxidative stress or inflammation that were studied," including in C-reactive protein, oxidized phospholipids, lipoprotein (a), and nitric oxide. (CX1254_0001, 0006-26; Heber, Tr. 2119-21). He sent this presentation to POM employees Keith Martin, Dr. Dreher, and Pam Saltsman on January 9, 2007. (CX1352 (Heber, Dep. at 107-11) (discussing CX1254). In an accompanying email, he advised Martin and Dr. Dreher that "we have not proved or disproved efficacy at this point." (CX0858_0001). By efficacy, he meant changes in biomarkers of oxidant stress or inflammation. (CX1352 (Heber, Dep. at 110)). Dr. Heber also scheduled a meeting to discuss the San Diego Study "in detail" with Mr. Resnick on February 28, 2007. (Heber, Tr. 2121-22; CX0873_0001).

934. On February 15, 2007, Dr. Dreher advised Dr. Heber that Dr. Hill had agreed to a combined paper relating to the results of the two overweight studies, and he asked Dr. Heber how long it would take to develop a manuscript for a "relatively fast turn time journal." (CX0879_0001).

935. Dr. Heber's article on the San Diego Study results was published in late 2007 as Heber D. et al., *Safety and Antioxidant Activity of a Pomegranate Ellagitannin-Enriched Polyphenol Dietary Supplement in Overweight Individuals with Increased Waist Size*, J. Agric Food Chem., Vol. 55, No. 24 (2007). (*See* CX0934).

936. The published article describes the single-arm Denver Study as the "Antioxidant Activity Study" and the two-arm San Diego Study as the "Safety Study." (CX0934_0003). It states that "[p]reliminary evidence of a reduction in TBARS was seen in the subjects who were studied at the Denver site . . . . TBARS are an important biomarker of oxidative stress. . . . [T]hese pilot studies demonstrate both the safety and efficacy of POMx . . . in humans. However, further studies need to be done to confirm the antioxidant properties of pomegranate ellagitannins administered as a dietary supplement." (CX0934_0003-04).

937. The published article makes no reference to the biomarkers of antioxidant stress or inflammation measured in Dr. Heber's San Diego Study. (*See* CX0934).

938. Dr. Heber acknowledged that the published article did not provide all of the results of his San Diego Study. (Heber, Tr. 2116-18). He testified that the published article contained all of the results "then available." (Heber, Tr. 2116-17). This is not true. According to the publication, the manuscript was received by the journal for review on June 8, 2007. (CX0934_0007). This is several months *after* Dr. Heber provided POM with the slide presentation showing that there were no changes in antioxidant or inflammatory markers in his San Diego Study. (*See* CCFF ¶ 933).

939. On January 7, 2007, POM Marketing staff, including Staci Glovsky, sought confirmation that POMx was an effective antioxidant for the purposes of preparing the POMx brochure. (CX0858_0001). Despite the results of his randomized, double-blinded San Diego Study showing no effect of POMx on numerous heart-related biomarkers, and the fact that the Denver Study was unblinded and uncontrolled, on January 16, 2007, Dr. Heber advised Dr. Dreher that "the marketing people should have their substantiation from this" for efficacy of POMx. (CX0860_0001).

(3) Expert Analysis

940. Drs. Sacks and Stampfer concluded that the methodological shortfalls in the Denver Study – especially the lack of a control group – render its findings unreliable. (CX1291 (Sacks, Report at 0035); *see also* Sacks, Tr. 1519-21; Stampfer, Tr. 768-72).

941. Dr. Heber stated in his report that the Denver Study demonstrated the efficacy of POMx as an antioxidant. (CX0934_0004). At trial, however, he described the Denver Study as a "pilot study . . . not a conclusive demonstration." (Heber, Tr. 2116). Dr. Ornish agreed that there are limitations to the Denver Study. (PX0025 (Ornish, Report at 0024). He also agreed that it was a pilot study, which only provides preliminary findings to justify doing a larger study. (PX0025 (Ornish, Report at 0024)).

942. The San Diego Study appears to have been well-designed. (CX1291 (Sacks, Report at 0035). The study concluded that there were no changes in the groups receiving one or two POMx capsules per day in markers of oxidant stress or inflammation that were studied. (CX1254_0026; CX1222_0001; CX1352 (Heber, Dep. at 100-01); CX0859_0020; CX0934_0003; Sacks, Tr. 1515-19; CX1291 (Sacks, Report at 0032-35); Stampfer, Tr. 768).

943. Dr. Ornish and Dr. Heber both agreed that the San Diego Study did not demonstrate efficacy since there were no significant changes in heart-related biomarkers. (PX0025 (Ornish, Report at 0025); Heber Tr. 2117).

b. Diabetes Studies

(1) Rock Study

944. Dr. Heber relies in part on a study on diabetics conducted by Dr. Rock, a member of Dr. Aviram's team, published as Rock, W., *et al*., *Consumption of Wonderful Variety Pomegranate Juice and Extract by Diabetic Patients Increases Paraoxonase I Association with High-Density Lipoprotein and Stimulates Its Catalytic Activities*, 56 J. Agric. Food Chem. (2008) (PX0127; *see* PX0192 (Heber, Report at 0038)). This study looked at the relationship of PON1 and HDL cholesterol activity in 30 diabetic patients who used pomegranate juice or POMx Liquid for four to six weeks. (*See* PX0127; CX1291 (Sacks, Report at 0036)). It reported a reduction in oxidative stress as measured by TBARS and improved PON. (PX0127). All measurements were comparisons to baseline. (PX0127).

945. This study was unblinded, unrandomized, and uncontrolled. (CX1291 (Sacks, Report at 0036); *see also* CX1358 (Aviram, Dep. at 55) (testifying that each patient served as his own control)). As a result, a qualified scientist cannot conclude whether any changes in measured parameters resulted from pomegranate juice or pomegranate extract consumption, or from some other factor, such as the placebo effect. (Sacks, Tr. 1523; CX1291 (Sacks, Report at 0037)).

(2) Heber/Hill Diabetes Studies

946. Dr. Heber and Dr. Hill conducted two randomized, double-blind, placebo-controlled studies to evaluate the antioxidant effect of pomegranate extract capsule and pomegranate juice, respectively, in diabetic patients. (Heber, Tr. 2048-49, 2054; CX1352 (Heber, Dep. at 124-25); *see* CX0949_0007 (protocol for diabetes extract study); CX1082_0007-21 (protocol for diabetes juice study); CX1284). The POMx protocol called for enrolling 30 diabetics for 12 weeks. (CX949_0013). The POM Juice study protocol called for an enrollment of 40 diabetics for 12 weeks. (CX1082_0012).

947. These two studies were intended to replicate the Aviram/Rock results in diabetic patients. (Heber, Tr. 2138).

948. The two studies were completed, but the results were not published. (CX1352 (Heber, Dep. at 132-33); CX1342 (Hill, Dep. at 157 (last measurement in the diabetes juice study was taken in March 2009)). After Dr. Hill completed his part of the study, he sent the data to Dr. Heber for analysis. (CX1342 (Hill, Dep. at 157-58)). Dr. Hill was not aware that Dr. Heber had analyzed the data. (*See* CX1342 (Hill, Dep. at 157-58)).

949. According to Dr. Heber, the diabetes studies did not show a significant change in malondialdehyde, which is a TBARS measure, or in PON, both of which are heart-related biomarkers. (Heber, Tr. 2124 (malondialdehyde), 2137-38 (PON); CX1352 (Heber, Dep. at 161-70)). Dr. Heber did not include the results of his two diabetes studies in his analysis of available human clinical evidence to substantiate heart benefits of POM products. (PX0192 (Heber, Report at 0052-54)).

4. Analysis of the Challenged Heart Claims in Light of the Scientific Evidence

950. Most of Respondents' marketing pieces from 2003 through 2010 have claimed (1) that a daily serving of POM Juice (eight ounces), POMx (one pill), or POMx Liquid (one teaspoon) prevents, reduces, or treats cardiovascular disease, including by decreasing arterial plaque, lowering blood pressure, and/or improving blood flow to the heart; and (2) that these benefits are established, by showcasing two Aviram studies and one Ornish study and by citing tens of millions of dollars in purportedly completed medical research. (*See* Sections V.D.1, V.D.4, V.E; *see also* CCFF ¶¶ 541-55). As summarized below, Respondents' research fails to support these representations.

a. Arterial Plaque Summary

951. With regard to arterial plaque, Respondents sponsored several studies measuring changes in CIMT. The Aviram CIMT/BP Study (2004), highlighted in Respondents' advertising through at least January 2010, showed a benefit for ten "very sick" heart disease patients compared to their own baseline data. These findings were never replicated (the Davidson study subgroup data pertain to persons who did *not* have CHD and are hypothesis-generating only), and in fact, were contradicted by results from three subsequent RCTs: the Ornish CIMT cardiac arm of 17 patients, the 73-person Ornish CIMT Study, and the large 289-person Davidson CIMT Study (2009), all of which showed no CIMT benefit for patients at mild to moderate risk for coronary heart disease. (CCFF ¶¶ 855-919).

952. At the time the advertisements featuring the Aviram CIMT/BP Study (2004) were run, POM was aware of the subsequent results of the Ornish CIMT Study (2005) and the

Davidson CIMT Study (2009). (CX1029_0003; Tupper, Tr. 960-61; CCFF ¶¶ 406-412, 415-416).

953. Mr. Tupper testified at trial that POM felt comfortable continuing to advertise the results of the Aviram CIMT/BP Study (2004) (*i.e.*, a 30% reduction in arterial plaque) even after learning of Dr. Davidson's CIMT Study results, because POM believes that the Davidson results were reinforcing and consistent with Aviram and the entire body of cardiovascular research. POM felt the Davidson CIMT Study results were consistent with the Aviram results even though the numbers and the percentages were different, and even though the studies involved different populations and therefore were not comparable to each other. (Tupper, Tr. 3006-07).

954. Mrs. Resnick has admitted that Respondents did not have enough science to make the claim that POM Juice "promotes heart health by preventing the build up of plaque in the arteries leading to the progression of atherosclerosis." (CX1375 (L. Resnick, Trop. Dep. at 105)).

b. Blood Pressure Summary

955. Respondents sponsored numerous studies involving blood pressure data. Two of Dr. Aviram's studies -- the ACE/BP Study (2001) and CIMT/BP Study (2004) – showed small improvements in blood pressure. These were unblinded, uncontrolled studies, however, and they reported only within-group data. (CCFF ¶¶ 796-820).

956. Five subsequent RCTs sponsored by Respondents showed no benefit to blood pressure. These include the Ornish MP Study (2005) (CCFF ¶ 829); the Ornish CIMT Study (CCFF ¶ 858); the Davidson BART/FMD study (CCFF ¶ 915); the Davidson CIMT Study (2009) (CCFF ¶ 883); and the San Diego Study (CCFF ¶ 932).

957. Nevertheless, POM ran the "Decompress" advertisement (which depicted a blood pressure cuff around a POM bottle), after it was aware of these five subsequent studies, which showed POM products had no effect on blood pressure. (CCFF ¶¶ 357-58; Tupper, Tr. 976). POM also continued to cite to the Aviram studies on its website until at least October 2009. (CX0473 (Oct. 2009, pomwonderful.com at 02:45-02:52)).

958. Mr. Resnick has admitted that Respondents do not have enough substantiation to support a claim that POM Juice lowers blood pressure. (CX1376 (S. Resnick, OS Dep. at 310-11)).

c. Blood Flow Summary

959. Respondents frequently cited the Ornish MP Study (2005) in their advertising. (CCFF ¶¶ 415, 419). Respondents were aware, however, of significant problems with this study, including the lack of a statistical analysis in the protocol; the fact that the published report reflected only three-month interim data; that only one out of three primary measures showed any benefit; and the fact that there were two separate instances of unblinding. (CCFF ¶¶ 830-38). Indeed, the published report itself acknowledged that the study was small and needed replication. (CCFF ¶ 828). In any event, myocardial perfusion measures are not recognized surrogate markers for the purpose of heart disease prevention and treatment studies. (CCFF ¶ 844).

d. Biomarkers

960. Many of Respondents' studies collected data on biomarkers related to heart health such as ACE, C-reactive protein, oxidized phospholipids, TBARS, and nitric oxide. (*See* CCFF ¶¶ 796-801 (Aviram ACE/BP Study (2001)), 912-919 (Davidson BART/FMD Study), 920-43 (Denver and San Diego studies), 944-49 (Heber/Hill and Rock Diabetes studies)). The heart-related biomarker data in Respondents' studies were on the whole, unsupportive of the proposition that the POM Products benefit heart health.

961. Nevertheless, Respondents touted the Aviram ACE/BP Study (2001) data until at least 2009 (*see, e.g.*, CCFF ¶¶ 455-56), even though the ACE data from the Davidson BART/FMD Study, which was an RCT, contradicted this result. (CCFF ¶ 917). Although the TBARS data from the uncontrolled Denver Study were positive (CCFF ¶ 926), there were no significant changes in the numerous antioxidant/inflammatory markers measured in the Davidson CIMT Study (2009), the San Diego Study, and the Heber Diabetes Study, all of which were RCTs. (CCFF ¶¶ 884, 933, 949).

e. Summary Analysis

962. In considering whether a product – whether a conventional food, drug, or dietary supplement – is likely to have an effect on the risk or treatment of a disease, it is important to first look at the individual items of evidence, to determine whether they are reliable and probative. Then, it is important to look at the evidence as a whole. (CX1291 (Sacks, Report at 0038)).

963. There is no reliable evidence that POM Juice reduces or delays the development of

arterial plaque; reduces blood pressure; increases blood flow to the heart (or other blood vessels); or that it produces statistically significant reductions in LDL, HDL, triglycerides, or cholesterol. (CX1291 (Sacks, Report at 0038-39)). The current data do not support the claims for heart disease prevention or treatment. (CX1293 (Stampfer, Report at 0022)). Further, clinical studies, research and/or trials do not prove that drinking POM Juice, daily, prevents or reduces the risk of heart disease, including by decreasing arterial plaque, lowering blood pressure, and/or improving blood flow to the heart. (CX1291 (Sacks, Report at 0010); CX1293 (Stampfer, Report at 0017)).

964. Further, Respondents' research provides no evidence that POMx Pills or POMx Liquid will treat, prevent, or reduce the risk of heart disease, through any mechanism. (CX1291 (Sacks, Report at 0038); CX1293 (Stampfer, Report at 0017)). Similarly, the establishment claims for POMx Pills and POMx Liquid are not supported. (CX1291 (Sacks, Report at 0010); CX1293 (Stampfer, Report at 0017)). POM Juice and POMx are not identical products. POM Juice contains anthocyanins and pomegranate sugars (PX0192 (Heber, Report at 0016) (POM Juice contains anthocyanins); CX1358 (Aviram, Dep. at 60-61) (POM Juice contains sugar)). The extract products do not. (CX1426_00042) (POMx contains no sugar); CX1352 (Heber, Dep. at 358 (anthocyanins are not part of any pomegranate extract)).

965. Research by Dr. Heber showed that POM Juice has greater antioxidant activity than the extracts (Heber, Tr. 2187), and he testified that the anthocyanins in POM Juice "undoubtedly" contribute to its antioxidant activity. (PX0192 (Heber, Report at 0017); *see also* CX1352 (Heber, Dep. at 273-74 (antioxidant components of pomegranate juice due in part to anthocyanins)). Dr. Aviram attributes the benefits of POM Juice in part to its sugars. (CX1358 (Aviram, Dep. at 60-61)). Dr. Aviram testified that much less research has been done on POMx and that he is not confident that POMx will work in the same manner as POM Juice. (CX1358 (Aviram, Dep. at 48)). Respondents' own internal documents recognize that research on POM Juice cannot be used to support claims for POMx. (CX0266_0003).

f. Respondents' Awareness of Inadequate Evidence

966. In January 2009, Mr. Tupper and Dr. Dreher prepared a medical research portfolio review. These portfolio reviews were updated from time to time and used during meetings with Mr. Resnick and other scientific advisors when discussing POM's current research and making decisions on future research. (Tupper, Tr. 941-42; CX1029).

967. POM's January 2009 Medical Research Portfolio Review summarized POM's medical

research to that point on various conditions (including heart disease, prostate cancer, and erectile dysfunction/sexual function). It also contained a section meant to facilitate a discussion about options looking forward, including end game scenarios and assessments. (CX1029_0003-04, 0013; Tupper, Tr. 951, 976-77).

968. The heart disease summary clearly shows that respondents knew they did not have enough science to make treat, prevent, or reduce the risk of heart disease claims, including claims about lowering blood pressure. (CX1029_0003).

969. For example, the summary noted that claims of "prevent heart disease" or "lower blood pressure" must be based on death/heart attack data and systolic BP data, respectively, for the pills. POM deemed the claims "too expensive and too risky" since such claims would require FDA approval. (CX1029_0003).

970. POM further deemed the idea of seeking FDA approval for a health claim for juice or pills (*e.g.*, "reduced risk of heart disease" or "reduced risk of hypertension") as "[p]robably not worth pursuing" because, in part, its heart disease (CIMT) and blood pressure data may not have been strong enough. (CX1029_0003).

971. POM's summary assessment at the time noted that its heart disease research "has holes" and that its "current body of research [was] only viewed as a '3' on a scale of 1-10 by MDs[.]" (CX1029_0003). Respondents' "End Game Scenarios" listed for heart disease research, as well as for other research areas, included doing "[a]dditional, targeted research for Marketing/PR/Medical Outreach purposes" or "[n]o more clinical research – publicize what we already have[.]" (CX1029_0003; *see also* CX1029_0004).

972. Despite POM's own assessment in January 2009 that doctors would consider POM's cardiovascular science as three out of ten, Mr. Tupper testified at trial that he would grade POM's cardiovascular science an eight out of ten. (Tupper, Tr. 3011-12).

973. Dr. Heber testified that he did not tell Mr. Resnick or Mr. Tupper that there was scientific agreement that POM Juice or POMx could prevent or treat cardiovascular disease. (CX1352 (Heber, Dep. at 244-45)).

D. Analysis of Respondents' Research Related to Prostate Cancer

1. Background Information

974. To substantiate a claim that a food or a diet supplement is effective in preventing or reducing the risk of prostate cancer, experts in the field of prostate cancer would require at least one well-designed, randomized, double-blind, placebo-controlled clinical trial (RCT) involving an appropriate sample population and endpoint. (CX1287 (Eastham, Report at 0012-15); CX1293 (Stampfer, Report at 0009-10); CCFF ¶ 771).

975. Prostate cancer prevention clinical trials study the effect of a product in a healthy population to determine whether the product will prevent disease occurrence in the future. (Eastham, Tr. 1270; CX1287 (Eastham, Report at 0012)). In a prostate cancer prevention trial, prevalence or the incidence of prostate cancer in the population studied is the endpoint generally accepted by experts in the field. (Eastham, Tr. 1273; CX1287 (Eastham, Report at 0014)).

976. PSADT (PSA doubling time) is not a relevant surrogate marker for prostate cancer prevention trials because it is not used by urologists to predict whether or not a healthy patient will end up getting prostate cancer, nor is it used as a screening tool for prostate cancer. (*See generally* CX1287 (Eastham, Report at 0006-08) (explaining the use of PSA in screening for prostate cancer)). In fact, Dr. Heber noted that PSA is "an imperfect surrogate marker when the prostate is intact." (PX0192 (Heber, Report at 0026)).

977. To substantiate a claim that a food or dietary supplement is an effective treatment for prostate cancer, experts in the field would require a similar RCT trial with an appropriate sample population of patients with the stage of the disease targeted by the study, and measuring a proper endpoint. (CX1287 (Eastham, Report at 0015)). In a prostate cancer treatment trial, overall survival or prostate cancer-specific mortality is the endpoint generally accepted by experts in the field. (Eastham, Tr. 1280; CX1287 (Eastham, Report at 0009); CX1293 (Stampfer, Report at 0025)).

978. Experts in the field of prostate cancer agree that PSADT is not an accepted surrogate endpoint for survival or prostate cancer-specific mortality in prostate cancer treatment clinical trials. (Eastham, Tr. 1297; Stampfer, Tr. 782-83; deKernion, Tr. 3096; CX1287 (Eastham, Report at 0010); CX1293 (Stampfer, Report at 0025); CX1340 (Carducci, Dep. at 88-90); CX1341 (Pantuck, Dep. at 253-54)). Many men with increases in PSA after initial therapy do not die of prostate cancer. (Stampfer, Tr. 783; Eastham, Tr. 1258;

deKernion, Tr. 3088). On the other hand, some men succumb to prostate cancer without an increase in PSA. (Stampfer, Tr. 783).

979. Prostate specific antigen or PSA is a protein produced exclusively by the prostate gland, which is used as a biomarker for detecting prostate cancer incidence and recurrence. After initial treatment for prostate cancer, PSA values fall to zero or near zero. (CX1293 (Stampfer, Report at 0025); CX1287 (Eastham, Report at 0008)). If PSA rises rapidly after initial treatment, it is a sign that the cancer may not have been sufficiently eliminated by treatment or that it had spread to other organs prior to surgical removal of the prostate. (CX1293 (Stampfer, Report at 0025); CX1287 (Eastham, Report at 0008)). A rise in PSA after treatment is called a "biochemical recurrence." (Eastham, Tr. 1257-58; deKernion, Tr. 3053-54). For example, approximately, one-third of prostate cancer patients treated by radical prostatectomy will develop a biochemical recurrence. (CX0815_0001; Eastham, Tr. 1257-58; PX0163-0002).

980. PSADT is used by clinicians as a prognostic tool at the time of biochemical recurrence of prostate cancer to predict the odds of clinical progression of the disease in prostate cancer patients who have undergone initial treatment. (Eastham, Tr. 1260; PX0351 (deKernion, Dep. at 93)). PSADT is a mathematical calculation of how rapidly PSA is increasing. (Eastham, Tr. 1259-60; CX1340 (Carducci, Dep. at 57); CX1341 (Pantuck, Dep. at 75); deKernion, Tr. 3050)).

981. As a prognostic tool, the most clinically meaningful PSADT value is a doubling time of less than three months. (Eastham, Tr. 1262; CX1287 (Eastham, Report at 0008); CX1293 (Stampfer, Report at 0026)). The vast majority of men with a PSADT of less than 3 months after being treated with radiation and/or surgery will develop metastatic disease and ultimately die of prostate cancer. (Eastham, Tr. 1262; CX1293 (Stampfer, Report at 0026); deKernion, Tr. 3084)).

982. In contrast, men with a long PSADT of 15 months after having been treated with radiation and/or surgery will have a lower risk of clinical progression. (Eastham, Tr. 1263; deKernion, Tr. 3085; Stampfer, Tr. 784). Few prostate cancer deaths occur in men with long PSADT. (deKernion, Tr. 3085).

983. There are no studies demonstrating that modulating PSADT (*i.e.,* changing the rate of the PSA doubling time) changes the natural history of prostate cancer by delaying the development of metastases or death from the disease. (Eastham, Tr. 1261; CX1287 (Eastham, Report at 0011, 0019); PX0161 (deKernion, Report at 0004); PX0351

(deKernion, Dep. at 52-53)).

984. Respondents have been researching prostate cancer since 1999 and spent approximately $12 million, or one third of their research dollars, in this area. (*See* CX1263) (calculating this amount by adding the prostate cancer expenditures by the 1988 Trust and POM for the years 1999 through 2010 listed on pages CX1263_ 0003-06).

985. Respondents, however, have just one human study completed and published. It is not an RCT. Respondents also conducted four *in vitro* studies and four animal studies relating to prostate cancer, according to their January 13, 2009 summary of their prostate cancer research to date. (CX1029_0004). Complaint Counsel's experts reviewed the available *in vitro* and animal research, and concluded that RCTs with proper endpoints are needed to confirm the potential antioxidant effect on prostate cancer observed in a test tube or laboratory setting. (CX1293 (Stampfer, Report at 0022); CX1287 (Eastham, Report at 0021)). Thus, Respondents do not have support for their prostate cancer advertising claims, as further explained below.

2. Prostate Cancer Studies

a. Pantuck Phase II Prostate Cancer Study (2006)

(1) About the Study

986. Dr. Allan J. Pantuck is a urologist in the Department of Urology at the UCLA Medical Center in Los Angeles, California and, at the time of the study, reported to Respondent's expert, Dr. deKernion, Chairman of the Department. (deKernion, Tr. 3114; CX1090_0004).

987. The *Phase II Study of Pomegranate Juice for Men with Rising Prostate-Specific Antigen following Surgery or Radiation for Prostate Cancer* ("Pantuck Phase II Prostate Cancer Study (2006)") [redacted] involving POM Juice and men with prostate cancer. (CX1379_0019, *in camera*). Dr. Pantuck conducted the study for, and it was sponsored by, Respondents. (CX0815_0001; CX1128_0001). The Pantuck Phase II Prostate Cancer Study (2006) cost $479,236.50. (CX1128_0001).

988. In 2001, Dr. Allan J. Pantuck wrote a letter to Dr. Dornfeld and Dr. Liker (Respondents' scientific advisors) setting forth his protocol concepts for two clinical studies studying the benefits of pomegranate juice in populations of men with prostate cancer. (CX0544_0001). According to the letter, "these pilot studies are designed to provide

preliminary data to justify further development of pomegranate juice as a chemopreventative agent for prostate cancer." (CX0544_0001). One of the two proposed protocol concepts became the Pantuck Phase II Prostate Cancer Study (2006). (CX1341 (Pantuck, Dep. at 57)).

989. The Pantuck Phase II Prostate Cancer Study (2006) commenced in 2003. (CX1128_0001). According to the protocol, the study was a single-center, three-year study in which approximately 40 patients with prostate cancer treated by radical prostatectomy or radiotherapy with a rising PSA would receive eight ounces of pomegranate juice daily. (CX0666_0004-05).

990. By 2006, the Pantuck Phase II Prostate Cancer Study (2006) was complete and ready for publication. Dr. Pantuck first submitted the manuscript for the study to the *Journal of Clinical Oncology*. (CX1341 (Pantuck, Dep. at 107)). It was rejected. (CX1341 (Pantuck, Dep. at 107)). He subsequently submitted it to *Clinical Cancer Research*. (CX1341 (Pantuck, Dep. at 107)). One peer reviewer called the manuscript "excessively advocatory of pomegranate juice as a treatment for prostate cancer." (CX0790_0001). Dr. Pantuck addressed this concern and other comments by making various changes to the manuscript. (CX0790; CX0786). The results of the Pantuck Phase II Prostate Cancer Study (2006) were published in the journal *Clinical Cancer Research* in July 2006. (CX0815).

991. Dr. Liker, an author of the Pantuck Phase II Prostate Cancer Study (2006), indicated his academic affiliation with UCLA in the published study article, but did not disclose his affiliation as the Medical Director for Respondents. (Liker, Tr. 1931).

992. According to the published study report, the Pantuck Phase II Prostate Cancer Study (2006) was "an open-label, single-arm clinical trial," meaning it was not a RCT and did not have a placebo group. (CX0815_0002). The Pantuck Phase II Prostate Cancer Study (2006) included 46 patients who were evaluated for a treatment response. (CX0815_0003). All the patients in the Pantuck Phase II Prostate Cancer Study (2006) had been diagnosed with prostate cancer. (*See* CX0815_0001). The majority of the patients (68%) in the Pantuck Phase II Prostate Cancer Study (2006) had been previously treated for prostate cancer by undergoing radical prostatectomy. (CX0815_0003). The remainder had been treated by radiation (10%), brachytherapy (10%), a combination of surgery and radiation (7%), or cryotherapy (5%). (CX0815_0003).

993. All 46 patients drank eight ounces of pomegranate juice daily until meeting disease

progression endpoints. (CX0815_0002). Patients had their blood drawn every three months to have their PSA determined. (CX0815_0002). Disease progression was defined as either a greater than 100% increase in PSA (with a minimum value of 1.0 ng/mL) compared with the best response observed or any documentation of metastatic or recurrent disease. (CX0815_0002). The primary endpoint for the Pantuck Phase II Prostate Cancer Study (2006) was the effect on PSA variables, such as change in PSADT. (CX0815_0002). The average pretreatment PSADT before intervention was approximately 15 months, and after 33 months, the average post-treatment PSADT was 54 months. (CX0815_0004).

994. The men treated with POM Juice in the study experienced a significant statistical increase in PSADT when compared to their own baseline pre-treatment PSADT. Dr. Pantuck stated in the published report that "[i]t remains controversial whether modulation of PSA levels represents an equally valid clinical endpoint." (CX0815_0008). According to Dr. Pantuck, "PSA has not been validated prospectively as a surrogate endpoint for a meaningful prostate cancer outcome." (CX1080_0001). Dr. Pantuck has stated that "although PSA changes are thought to be prognostically important, it is based on level 2 evidence, and nobody had ever shown conclusively that changes in PSA kinetics arising from therapeutic intervention is meaningful." (CX1080_0001).

995. Dr. Pantuck stated in the published report that "further research is needed to . . . determine whether improvements in such biomarkers [including PSADT] are likely to serve as surrogates for clinical benefit." (CX0815_0008). He also indicated in the published report that the results of the Pantuck Phase II Prostate Cancer Study (2006) need to be tested further in a randomized, double-blind, placebo-controlled study, in which the ability of pomegranate juice to produce an alteration in PSA kinetics is compared with the change observed in a control group. (CX0815_0008).

996. Dr. Pantuck testified that the greatest limitation of the Pantuck Phase II Prostate Cancer Study (2006) was the lack of a blinded control arm. (CX1341 (Pantuck, Dep. at 110)). In the published study report, Dr. Pantuck specifically pointed to the published study *Rosiglitizone versus Placebo for Men with Prostate Carcinoma and a Rising Serum Prostate-Specific Antigen Level after Radical Prostatectomy and/or Radiation Therapy*, Cancer 2004: 101:1569-74 ("Rosiglitizone Study") as a reason for the need of confirmatory study with a blinded control arm. (CX0815_0008).

997. The Rosiglitazone Study was a randomized, double-blind placebo-controlled study examining the effect of rosiglitazone in a population of men similar to the patients studied in the Pantuck Phase II Prostate Cancer Study (2006), namely men who had been

treated by radical prostatectomy or radiation with a rising PSA. (PX0172-0001; CX0815_0001; deKernion, Tr. 3069). The Rosiglitazone Study found that 40% of the placebo group and 38% of the treatment group experienced a prolongation in PSADT. (PX0172-0001; deKernion, Tr. 3071). Although the patients in the Rosiglitizone Study had a higher risk of clinical progression than the patients in the Pantuck Phase II Prostate Cancer Study (2006), they still experienced improvement in their PSADT. (deKernion, Tr. 3072-73; PX0172-0004).

998. The Rosiglitizone Study authors -- including Dr. Kantoff (with whom Respondents consulted and who testified as a rebuttal witness for Complaint Counsel) -- stated that "[t]he discordance between baseline and posttreatment PSADT in our placebo group suggests caution is required when using changes in PSADT as an outcome in uncontrolled trials and reinforces the value of randomized, placebo-controlled trials in this setting." (PX0172-0006). Dr. Pantuck stated that the Rosiglitazone Study "highlights the potential limitations of PSA variables in monitoring patients and the need for confirmatory prospective studies using a blinded control arm." (CX0815_0008).

999. When the Pantuck Phase II Prostate Cancer Study (2006) report was released in 2006, Dr. Pantuck stated "[w]e don't believe we are curing anyone from prostate cancer." (CX0816_0002). He pointed out that "although a third of patients experienced a decrease in PSA during the study, nobody's PSA went to zero." (CX0816_0002).

1000. Dr. Pantuck testified that the Pantuck Phase II Prostate Cancer Study (2006) did not prove that pomegranate juice prevents or reduces the risk of prostate cancer. (CX1341 (Pantuck, Dep. at 108)). He also refused to state that the Pantuck Phase II Prostate Cancer Study (2006) proved that pomegranate juice treats prostate cancer. (CX1341 (Pantuck, Dep. at 108)). Instead, Dr. Pantuck summarized the findings of the Pantuck Phase II Prostate Cancer Study (2006) as follows: "pomegranate juice was given to men with prostate cancer, to measure . . . how their PSA levels were affected" and "what [the study] showed is that the doubling time was prolonged." (CX1341 (Pantuck, Dep. at 108)).

1001. In 2008, Dr. Pantuck released the following abstract: Pantuck, AJ, *et al*., *Long term follow up of pomegranate juice for men with prostate cancer and rising PSA shows durable improvement in PSA doubling times*, American Society of Clinical Oncology (2008 Genitourinary Cancers Symposium) ("Pantuck Phase II Follow-Up Results"). (CX0955). The abstract summarized follow-up results for the Pantuck Phase II Prostate Cancer Study (2006). (CX0955). According to the abstract, the mean post-treatment PSADT of the active group (17 men) increased to 68.57 months and in the non-active

group to 51.2 months. (CX0955). All of the men who had dropped out of the study did so because their PSA had increased. (CX0918_0001). As of June 2010, only 12 patients remained active in the study. (CX1128_0001).

(2) Expert Analysis

1002. Complaint Counsel's experts testified that the Pantuck Phase II Prostate Cancer Study (2006) fails to provide support for prostate cancer treatment claims for two major reasons: the lack of a placebo control group and the lack of an accepted endpoint marker. (Eastham, Tr. 1295-97; CX1287 (Eastham, Report at 0018-19); CX1293 (Stampfer, Report at 0024-25); Stampfer, Tr. 782-83).

1003. According to Dr. Stampfer, without a placebo control group in the Pantuck Phase II Prostate Cancer Study (2006), it is not possible to know whether the same change in PSADT would have been observed in this patient group if they had never received POM Juice. (Stampfer, Tr. 870; CX1293 (Stampfer, Report at 0024)).

1004. According to Dr. Eastham, if the Pantuck study had included a control group, it is possible that *no* statistical difference between groups would have been observed. (Eastham, Tr. 1295-97; CX1287 (Eastham, Report at 0018)). Without a placebo, there is no way to eliminate confounding factors that may have impacted PSADT -- such as changes in diet, exercise, or the reduction of stress. (Eastham, Tr. 1295-96).

1005. Respondents' expert, Dr. deKernion, acknowledged during his testimony that the purpose of a placebo control group is to limit confounding factors. (deKernion, Tr. 3066-67). Dr. deKernion agreed with Dr. Eastham that there are variables such as exercise and a low-fat diet which may affect prostate cancer growth and that without a placebo control arm in a clinical study it is impossible to control for confounding factors. (*See* deKernion, Tr. 3067).

1006. Dr. deKernon believes that a placebo arm is a good thing for a study when it is feasible. (*See* deKernion, Tr. 3081). He agreed with Dr. Stampfer that it would have been ethical to use a placebo in the Pantuck Phase II Prostate Cancer Study (2006), because there is no "standard of care" for men of the type studied in the Pantuck Phase II Prostate Cancer Study (2006). (Stampfer, Tr. 872; deKernion, Tr. 3083).

1007. Dr. Eastham testified that there is evidence in the scientific literature showing that a patient's PSADT can be prolonged even without treatment. (Eastham, Tr. 1300). Dr. Eastham and Dr. deKernion testified that both the treatment and placebo groups in the Rosiglitazone Study (CCFF ¶¶ 997-98) experienced a lengthening of PSADT. (Eastham, Tr. 1299-1300; CX1287 (Eastham, Report at 0018); deKernion, Tr. 3071). Dr. Eastham and Dr. deKernion testified that another randomized, double-blind, placebo-controlled study examining the effect of celecoxib (an anti-inflammatory drug) on prostate cancer in a patient population similar to that of the Pantuck Phase II Prostate Cancer Study (2006) also found that men in both the treatment and placebo groups experienced a lengthening in PSADT. (Eastham, Tr. 1300; deKernion, Tr. 3071).

1008. At trial, Dr. Heber argued that it is not possible to conduct a placebo-controlled study because PSA is so variable. (Heber, Tr. 2150-51). However, Dr. Heber is not an expert in the clinical treatment of prostate cancer. (Heber, Tr. 2034-35). His view strains credulity because he co-authored the Pantuck Phase II Prostate Cancer Study (2006) report, which stated that a confirmatory study with a blinded control arm was needed. (CX0815_0008). In addition, Dr. Pantuck consulted with Dr. Heber when designing the protocol for the Pantuck Phase III Study (*see* CCFF ¶ 1026), which includes a placebo control group. (CX1341 (Pantuck, Dep. at 44-46); *see also* CX0740).

1009. Another issue in weighing the assessment of benefit for POM Juice observed in the Pantuck Phase II Prostate Cancer Study (2006) is the patient population studied. The average pretreatment PSADT for the study participants in the Pantuck Phase II Prostate Cancer Study (2006) was 15 months. (CX0815_0001). These patients are considered to have a far lower risk of clinical progression and thus, it is unclear whether the increase in PSADT observed in the Pantuck Phase II Prostate Cancer Study (2006) is clinically significant. (Eastham, Tr. 1297-98; Stampfer, Tr. 785; *see also* CX1287 (Eastham, Report at 0019); CX1293 (Stampfer, Report at 0026); PX0351 (deKernion, Dep. at 94)).

1010. Also, the Pantuck Phase II Prostate Cancer Study (2006) was designed as a treatment study (*i.e.*, study was conducted in men with prostate cancer) and does not provide any evidence that POM Juice is a prostate cancer preventative. (CX1293 (Stampfer, Report at 0025); Eastham, Tr. 1294-99). Complaint Counsel's and Respondents' experts agree that Respondents have not conducted a prevention clinical study on prostate cancer. (CX1287 (Eastham, Report at 0025); CX1293 (Stampfer, Report at 0025); *see also* deKernion, Tr. 3062-63). More importantly, Respondents acknowledge that they have "no data on prostate cancer prevention, prior to radiation or prostatectomy." (CX1029_0004).

1011. Complaint Counsel's experts also state that the Pantuck Phase II Prostate Cancer Study (2006) on POM Juice cannot provide reliable evidence to support claims about POMx Pills' or POMx Liquid's benefit for prostate cancer. (Eastham, Tr. 1306; CX1293 (Stampfer, Report at 0025); CX1287 (Eastham, Report at 0020)). According to Dr. Eastham, POM Juice is not identical to POMx Pills and POMx Liquid. (CX1287 (Eastham, Report at 0020)). POM Juice has more than one active ingredient. Processing may result in eliminating a needed ingredient. (Eastham, Tr. 1306-07). Even if the active ingredient is known and the alternate compound contains the same amount of active ingredient, the alternate compound may contain some other as yet unknown compound that might counter-act the benefit of the active agent. (CX1287 (Eastham, Report at 0020)).

1012. Finally, Dr. Eastham concluded that the Pantuck Phase II Follow-up Results did not provide support for prostate cancer prevention and treatment claims because the results flow from the original Pantuck Phase II Prostate Cancer Study (2006) and suffer from the same flaws, namely, there was no placebo and PSADT is not accepted as a surrogate endpoint. (CX1287 (Eastham, Report at 0020-21); Eastham, Tr. 1304-05).

b. Carducci Dose Study

(1) About the Study

1013. Respondents have also sponsored a human study looking at POMx use in men who have already been treated for prostate cancer. The study is completed and an abstract summarizing the results has been published. *See* M.A. Carducci, et al., *A Phase II Study of Pomegranate Extract for Men with Rising Prostate-Specific Antigen Following Primary Therapy* ("Carducci Dose Study"), J Clin Oncol 29: 2011 (suppl 7; abstr 11). (PX0175; *see also* CX1174). A final, peer-reviewed study report has not been published, however. (*See* Nonparties Johns Hopkins University and Michael A. Carducci, M.D.'s Motion for *In Camera* Treatment, at 5).[3] The Carducci Dose Study was conducted by Dr. Carducci, a urologist and oncologist at Johns Hopkins University in Baltimore, Maryland. (CX1120). It cost at least $97,000 to conduct. (CX1138_0003).

1014. In 2006, Dr. Michael A. Carducci began working with Respondents to design the Carducci Dose Study. (CX0806). [redacted]

[3] http://www.ftc.gov/os/adjpro/d9344/110420hopkinscarduccimoincam.pdf

(CX0064_0002, *in camera*).

(CX0064_0002, *in camera*).

1015. Dr. Carducci submitted a proposed protocol for the Carducci Dose Study to Respondents for a larger randomized study with a placebo arm. (CX1340 (Carducci, Dep. at 28-29)). Respondents conducted a feasibility and cost analysis and decided that the study proposed by Dr. Carducci was too costly. The placebo arm was dropped from the study. (CX1340 (Carducci, Dep. at 28-29)).

1016. In 2007, Dr. Carducci approached Dr. Kessler, a consultant to Respondents, to discuss the Carducci Dose Study design and to lobby for the original placebo-controlled study. (CX1340 (Carducci, Dep. at 36-38)). Dr. Carducci approached Dr. Kessler because "it was [his] sense that [Kessler] was a more effective counsel to POM and what decisions they were making." (CX1340 (Carducci, Dep. at 38)). Despite his appeal to Dr. Kessler, Respondents did not approve a placebo arm and Dr. Carducci proceeded to conduct the study with no placebo arm. (CX1340 (Carducci, Dep. at 38)). Dr. Liker testified that decisions about the size of a study are "more of a business decision than a scientific decision." (CX1350 (Liker, Dep. at 188-89)).

1017. The Carducci Dose Study commenced in January 2008. (CX1138_0002). According to the protocol, the Carducci Dose Study was an 18-month, multi-center, randomized, double-blind, dose-finding study of the effect of two doses of POMx capsules (1 or 3 capsules) on PSADT in men who had received initial therapy for prostate cancer. (CX1110_0007). [redacted] (*See* CX1088, *in camera*; CX1102, *in camera*). [redacted] (CX1146, *in camera*).

1018. Dr. Carducci testified that without a placebo, he cannot be sure that the effect on PSADT observed in the Carducci Dose Study is attributable to POMx. (CX1340 (Carducci, Dep. at 95); *see also* CX1175_0002 (article stating "Dr. Carducci acknowledged that the study was limited by the lack of placebo, and that a number of reports in literature . . . have shown that placebo can slow PSADT"). According to Dr. Carducci, the Carducci Dose Study was never designed to prove that POMx prevents, reduces the risk of, or treats prostate cancer. (CX1340 (Carducci, Dep. at 87-88)).

1019. Dr. Carducci presented an abstract summarizing the Carducci Dose Study findings in February 2011 at the American Society of Clinical Oncology ("ASCO") Genitourinary Cancers Symposium. (PX0175; CX1175_0001; *see also* CX1174). According to the

abstract, one-hundred and four (104) men were enrolled and treated for up to six (92%), 12 (70%) and 18 months (36%). There was no significant treatment difference (p=.920) in PSADT between the one capsule and three capsule dose groups. Median PSADT lengthened from 11.9 months at baseline to 18.5 months after treatment (p<.001), a within group measurement. (PX0175; CX1174_0001).

1020.

(CX1145_0001, *in camera*).

1021. According to a published report of the symposium, invited discussant Dr. Michael J. Morris of Memorial Sloan-Kettering Cancer Center reportedly said that the study's endpoint (PSADT) has never been prospectively validated to show anything in terms of clinical outcome. (CX1175_001). Dr. Morris further stated, "[i]f you believe that prolonged PSA doubling time is clinically beneficial, what do we say about patients whose disease appears to *accelerate* as a result of taking the pomegranate extract . . . . Do we say or suggest that a third to 40% of patients might be done some harm . . . ? I don't know, but I think that's an issue of concern." (CX1175_0001 (emphasis added)).

(2) Expert Analysis

1022. The Carducci Dose Study evaluated the effect of POMx in men who had prostate cancer. (PX0175; CX1174_0001). As a result, the Carducci Dose Study cannot provide support for prevention claims. (Eastham, Tr. 1309-10; *see also* CX1293 (Stampfer, Report at 27)).

1023. Complaint Counsel's experts stated that the Carducci Dose Study cannot provide support for treatment claims because it lacked a placebo-control group. (Eastham, Tr. 1310; Stampfer, Tr. 789-90). Without a placebo-control group, it is not possible to conclude that POMx caused the change in the patients' PSADT. (Eastham, Tr. 1310; CX1287 (Eastham, Report at 0022); Stampfer, Tr. 789-90; CX1293 (Stampfer, Report at 0028)).

1024. Complaint Counsel's experts also stated that the Carducci Dose Study cannot provide support for treatment claims because the primary endpoint in the study is PSADT, which has not been accepted by experts in the field as a surrogate for overall survival. (Eastham, Tr. 1310; CX1287 (Eastham, Report at 0022); CX1293 (Stampfer, Report at

0028)).

1025. As previously noted, the Carducci Dose Study was designed as a "dose finding" study, but in fact showed no difference between a one pill and three pill dose. (*See* CCFF ¶ 1019). The lack of a dose response despite a three-fold difference in dosage does not support a causal relationship between POMx and change in PSADT. (Stampfer, Tr. 789; CX1293 (Stampfer, Report at 0028)).

3. Respondents' Ongoing Prostate Cancer Research

1026. [redacted]

1027. Because of the time it took to fully enroll the study, a Data Safety Monitoring Board ("DSMB") at UCLA was established for the Pantuck Phase III Study sometime in 2009. (CX1097_0001; CX1350 (Liker Dep. at 239-40); JX0003 ¶ A.6). The DSMB was established to avoid sponsor bias and maintain study integrity for analysis purposes. (CX1094_0001). It is an independent group of individuals charged with reviewing the blinded data to ensure that it is safe to continue with a study. (CX1349 (Gillespie, Dep. at 164)).

1028.

1029.

1030. [redacted]

1031. [redacted]

1032. [redacted]

1033. The Pre-Surgical Study commenced in 2008 and patient enrollment stopped in May 2009 when the Johns Hopkins IRB determined that an IND (investigational new drug application) was needed to conduct the study. (CX1138_0002; CX1340 (Carducci, Dep. at 169-70)). An IND is one of the applications submitted to the FDA in the development cycle of a drug. (CX1377 (Gillespie, OS Dep. at 42-44)).

1034. Johns Hopkins told Respondents that it would shut down the Pre-Surgical Study and the Carducci Dose Study unless they agreed to file an IND. (CX1350 (Liker, Dep. at 249-50; CX1340 (Carducci, Dep. at 157-60)). Respondents committed to filing an IND in order to keep their studies open. (CX1081_0003). Data from the Pre-Surgical Study were not available when fact discovery closed in February 2011. (*See* CX1340 (Carducci, Dep. at 27-28) (Dr. Carducci testifying that data may be available in March or April 2011)).

4. Analysis of the Challenged Prostate Cancer Claims in Light of the Scientific Evidence

1035. Respondents advertised that drinking eight ounces of POM Juice or taking one POMx Pill or one teaspoon of POMx Liquid daily is not only effective in treating, preventing or reducing the risk of prostate cancer, including by prolonging PSADT, but that their research establishes that its products are effective for these purposes. (*See supra* Sections V.D.2, V.D.4, V.E, V.F).

1036. Respondents' substantiation for these claims at the time they were made consisted of sponsored *in vitro* and animal studies and the Pantuck Phase II Prostate Cancer Study (2006) (which was not placebo controlled and did not use a validated endpoint). (*See, e.g.,* CCFF ¶ 373) (Mrs. Resnick testifying that basis for prostate claim was Pantuck's study and the basic science).

a. Expert Analysis

1037. Based upon their review of the totality of the evidence, Complaint Counsel's experts stated that there is not enough valid scientific evidence to claim that drinking eight ounces of POM Juice or taking one POMx Pill or one teaspoon of POMx Liquid daily is effective in treating, preventing or reducing the risk of cancer, including by prolonging PSADT, and certainly no clinical studies, research and/or trials establish these claimed benefits. (CX1287 (Eastham, Report at 0024-26); Stampfer, Tr. 790-91; CX1293 (Stampfer, Report at 0029-30); *see also* Eastham, Tr. 1317-19)).

1038. Agreeing with Complaint Counsel's experts, Dr. deKernion testified that there is no clinical study, research, or trial proving that POM Juice, POMx Pills, or POMx Liquid treats, prevents or reduces the risk of prostate cancer. (deKernion, Tr. 3062-63; *see also* PX0161 (deKernion, Report at 0011)).

1039. Dr. Pantuck testified at his deposition that the current level of scientific evidence would not support a public health statement that everyone should drink pomegranate juice. (CX1341 (Pantuck, Dep. at 273); *see also* CX0063). According to Dr. Pantuck, pomegranate juice is not the standard of care for prostate cancer. (CX1341 (Pantuck, Dep. at 270-71)). He would not recommend pomegranate juice to patients with end stage cancer that are refractory to hormones, and to chemotherapy, and having bone pain. (CX1341 (Pantuck, Dep. at 269-70)).

1040. Dr. Pantuck testified that it is reasonable to discuss pomegranate juice with patients like the ones he has studied in the Pantuck Phase II Prostate Cancer Study (2006). These are patients who have had some primary treatment for prostate cancer, who have had a biochemical recurrence of prostate cancer that is asymptomatic, who have no evidence of clinical disease on X-rays, and who would not be a candidate for other immediate treatment. (CX1341 (Pantuck, Dep. at 270)).

1041. Dr. deKernion stated that although he recommends the POM Products to his prostate cancer patients, it is not the only thing he recommends. He recommends exercise, weight control, and restricting their intake of fatty foods to improve their chances of preventing or controlling a tumor. (deKernion, Tr. 3104-05; PX0161 (deKernion, Report at 0012)). Most notably, Dr. deKernion emphasizes to his patients that the POM Products have not been proven to prevent prostate cancer or prolong their lives. (deKernion, Tr. 3105-06).

1042. Respondents' expert Dr. Heber testified that there was a consensus among prostate cancer experts at POM's scientific advisory board meetings that the body of scientific evidence shows that the POM Products can help to treat, prevent, or reduce the risk of prostate cancer. (Heber, Tr. 2155-56). However, Complaint Counsel's rebuttal witness Dr. Philip Kantoff, Chief of the Genitourinary Oncology Division at the Dana-Farber Cancer Institute at Harvard Medical School, testified that he attended these meetings and told the group assembled that although the data was "very encouraging . . . more work needs to be done in order to demonstrate that [POM Products] have effectiveness." (Kantoff, Tr. at 3265).

1043. Dr. Heber acknowledges that he is not an expert in the clinical treatment of prostate

cancer. (Heber, Tr. 2034-35).

b. Respondents' Awareness of Inadequate Evidence

1044. Respondents have always known that PSADT is not an acceptable endpoint to support claims that their products will treat, prevent, or reduce the risk of prostate cancer. Dr. Liker, POM's Medical Director, testified that he became aware that PSADT is not an accepted biomarker for drug approval as early as 2002 or 2003. (CX1350 (Liker, Dep. at 173)). The Pantuck Phase II Prostate Cancer Study (2006) published report clearly stated that PSADT is not an accepted clinical endpoint for prostate cancer treatment trials. (CX0815_0008).

1045. POM's analysis in the January 2009 Medical Research Portfolio Review was that it was most likely not worth pursuing an approval for a botanical drug claim for POMx Pills (*e.g.*, prevent/treat prostate cancer) because it was "risky": POM had no clinical data beyond PSA and PSA would not be accepted as an endpoint. (CX1029_0004).

1046. Similarly, POM concluded that it was probably not worth pursuing an approval for a health claim for the juice or pills (*e.g.*, reduced risk of prostate cancer), because PSA alone was not sufficient; it would require another study using an endpoint of active surveillance of cancer progression via biopsy. (CX1029_0004).

1047. In its 2009 Medical Research Portfolio Review, POM also recognized that it had a "research gap: no data on prostate cancer prevention, prior to radiation or prostatectomy." (CX1029_0004).

1048. Even after this analysis in early 2009, POM continued to try to use PSA or PSADT results to support its position that its prostate cancer studies did not need a placebo control or a different endpoint to establish efficacy for prostate cancer. For example, in July 2009, Mr. Tupper asked Mr. Liker to obtain further explanation of PSADT, stating that he thought Mr. Resnick "was looking for any published data around this latter concept: ie, once established, does PSADT shift on its own. He seemed to want to understand this in the context of 'pitching' FDA on the concept that not having a placebo is irrelevant." (CX1080_0002).

1049. In response to Mr. Tupper's question, Dr. Pantuck told Dr. Liker (in a July 2009 email that was forwarded to Mr. Tupper and Dr. Gillespie) that PSA "has not been validated

prospectively as a surrogate endpoint for a meaningful prostate cancer outcome. . . . [A]lthough PSA changes are thought to be prognostically important, it is based on level 2 evidence, and nobody has ever shown conclusively that changes in PSA kinetics arising from therapeutic intervention is meaningful." (CX1080_0001).

1050. Dr. Pantuck also told POM that if it "want[ed] to ask for an approval based on PSA kinetic changes in a single arm study without a placebo comparison, I think your odds of being successful are approaching infinitely remote. . . . You could never definitively make the case that a single arm study does not just reflect the biology of the patients." (CX1080_0001).

1051. In 2010, POM acknowledged in an internal research summary that "[t]o date, all POM Wonderful clinical evaluations of pomegranate-derived products in prostate cancer have used PSADT as the primary endpoint" and conceded that "it is unclear whether PSADT is acceptable as a registrational endpoint" for a drug approval. (CX1104_0004).

1052. Undeterred, POM convened meetings of prostate cancer experts to continue to "discuss how to best position PSADT for acceptance as a primary endpoint." (CX1104_0001; *see also* CX1265_0001, *in camera* [redacted]

1053. Nevertheless, POM has continued to advertise the POM Products from 2007 to as late as 2010, citing Dr. Pantuck's study, touting the "statistically significant prolongation of PSA doubling times" and claiming that the study showed "hopeful results for prostate health," among other things. (*See, e.g.*, CCFF ¶¶ 368-84, 397-434, 439-41, 446, 524).

1054. With respect to helping healthy people with prostate conditions and helping people with prostate cancer, Mr. Tupper testified at trial that he would rate POM's science an eight out of ten. (Tupper, Tr. 3012-13).

E. Analysis of Respondents' Research Related to Erectile Dysfunction

1. Background Information

1055. To substantiate a claim that pomegranate juice or any other food or supplement prevents, reduces the risk of, or treats erectile dysfunction, one needs data from at least one well-designed, human RCT involving several investigation sites. The RCT should use an

appropriate sample population, large enough to produce a statistically significant ($p < .05$) result. It also must show a clinically significant result, meaning that the participant is able to achieve an erection hard enough to engage in sexual intercourse and have sexual satisfaction. (Melman, Tr. 1092-1105; CX1289 (Melman, Report at 0008-11)).

1056. Both Complaint Counsel's and Respondents' erectile dysfunction experts agree that experts in the field would use a validated tool when conducting a human clinical trial investigating whether a product treats, prevents, or reduces the risk of erectile dysfunction. (Melman, Tr. 1099; CX1289 (Melman, Report at 0010); Burnett, Tr. 2266 (agreeing that experts would rely on a validated tool when conducting a human clinical trial investigating whether a product treats erectile dysfunction)). Experts in the erectile dysfunction field would not rely on data from a nonvalidated measure alone to show efficacy of a product in treating, preventing, or reducing the risk of erectile dysfunction in humans. (Melman, Tr. 1101; *see also* Burnett, Tr. 2268).

1057. A validated tool is "established as measuring erectile dysfunction through rigorous assessments involving reliability testing, validity testing, construct validity, and other criteria[,]" unlike a non-validated measure. (Burnett, Tr. 2266; *see also* Melman, Tr. 1100 (stating that validation means that a measure has been shown to have statistical reliability)). Validation is important because, as Respondent's expert Dr. Goldstein has written, "[r]igorous assessment of patient-reported outcomes is necessary to ensure reliability, responsiveness, and discriminant and predictive validity. These attributes ensure that the instrument measures what it states it measures, and that the results are reproducible and sensitive to change." (PX0352a02-0002; PX0352 (Goldstein, Dep. at 55-56)).

1058. The International Index of Erectile Function ("IIEF") is a validated measure for evaluating change in erectile function. (JX0003 ¶ A.9; Melman, Tr. 1099; CX1289 (Melman, Report at 0010); Burnett, Tr. 2293; PX0352 (Goldstein, Dep. at 65); CX1193_0002; *see also* CX1240_0003, *in camera* [redacted]). The IIEF questions that evaluate change in erectile function are referred to as the erectile function domain. (Melman, Tr. 1099-1101; CX0686_0026-27; CX1193_0002 (stating that the "IIEF is a validated questionnaire whose erectile function domain score has been demonstrated to correlate with ED [erectile dysfunction] intensity")).

1059. Dr. Goldstein described the IIEF as "cross-culturally valid, psychometrically sound, and

relatively easy to administer with a high degree of sensitivity and specificity to the effects of treatment across all five domains in patients with ED." (PX0352 (Goldstein, Dep. at 66-67)).

1060. The Global Assessment Questionnaire ("GAQ") is not a validated measure for assessing erectile function. (Melman, Tr. 1118; Burnett, Tr. 2294; PX0352 (Goldstein, Dep. at 73)). Dr. Goldstein testified that the GAQ is a single-sentence question that has not been systematically reviewed for sensitivity, reliability, and specificity. (Goldstein, Tr. 2634; *see also* Melman, Tr. 1120 (testifying that the GAQ has not been tested for statistical reliability)). As a nonvalidated measure, the GAQ does not measure the degree of improvement, indicate how often a study participant experienced improved erections, or show whether he was able to complete sexual intercourse. (Melman, Tr. 1120, 1122; CX1289 (Melman, Report at 0014)). Without the ability to show meaningful change of erectile function, the GAQ does not provide clinically significant information. (Melman, Tr. 1120, 1122; CX1289 (Melman, Report at 0014)).

1061. Dr. Burnett testified that experts would not consider the GAQ, by itself, to be a sufficient endpoint in a clinical study evaluating a treatment for erectile dysfunction. (Burnett, Tr. 2294-95) (agreeing that the GAQ was more vague and nonspecific than a validated tool in measuring whether a therapy had an effect on the ability to achieve and maintain erections).

1062. Respondents have conducted at least six *in vitro* and animal studies looking at nitric oxide metabolism in an effort to identify a potential erectile dysfunction benefit from pomegranate. (PX0051-0001; PX0056-0001; PX0057-0001; PX0059-0001; PX0004-0001; PX0058-0001). In addition, Respondents have sponsored two human studies looking at erectile dysfunction-related endpoints. (CX1193_0001; CX0716_0029). These studies are discussed in CCFF ¶¶ 1063-81.

2. Erectile Dysfunction Studies

a. Forest Erectile Dysfunction Study (2007)

(1) About the Study

1063. POM sponsored a study by Mr. Christopher Forest, Dr. Harin Padma-Nathan, and Dr. Harley Liker, *Efficacy and Safety of Pomegranate Juice on Improvement of Erectile Dysfunction in Male Patients with Mild to Moderate Erectile Dysfunction: A Randomized, Placebo-Controlled, Double-Blind, Crossover Study* ("Forest Erectile

Dysfunction Study (2007)"). (CX1147_0004; CX1193_0001, 0004). The Forest clinical trial was conducted in 2004 to 2005, and the results were later published in the *International Journal of Impotence Research* in 2007. (CX1193_0001; CX1147_0004). POM spent approximately $100,000 to $300,000 for the Forest Erectile Dysfunction Study (2007). (CX0626_0001).

1064. The Forest Erectile Dysfunction Study (2007) was a randomized, double-blinded, placebo-controlled pilot study that examined the efficacy of POM Juice versus placebo in improving erections in 53 men with mild to moderate erectile dysfunction. (CX1193_0001; CX1289 (Melman, Report at 0012-13)). A pilot study is designed to investigate whether there is any evidence of a treatment effect. (CX1338 (Padma-Nathan, Dep. at 87-88, 155) (describing a pilot study as a proof of concept study); *see also* CX1193_0001; Melman, Tr. 1116 (stating that the study was a pilot study, which is a small or exploratory study)).

1065. The Forest Erectile Dysfunction Study (2007) used a crossover design, and the fifty-three participants who completed the study received a different beverage during the two twenty-eight-day treatment periods. (CX1289 (Melman, Report at 0012-13); CX1193_0002-03). Participants in cohort one drank POM Juice in period one and then switched to the placebo beverage in period two. (CX1193_0002-03). Participants in cohort two consumed the placebo beverage in period one and POM Juice in period two. (CX1193_0002-03).

1066. The Forest Erectile Dysfunction Study (2007) used the GAQ as the primary outcome measure and the IIEF as the secondary outcome measure. (CX1337 (Forest, Dep. at 84); CX1193_0002; Melman, Tr. 1120; CX0686_0008). The Forest Erectile Dysfunction Study (2007) hypothesized that treatment of the participants with POM Juice would produce: 1) statistically significant positive GAQ scores when compared to placebo-controlled patients, and 2) changes in the erectile function domain of the IIEF when the values are compared with the baseline and between the two groups. (CX0686_0008).

1067. The Forest Erectile Dysfunction Study (2007)'s GAQ asked participants the following yes or no question: "While using the study beverage, did you feel that your erections improved?" (CX0686_0025). Dr. Padma-Nathan, the lead researcher, testified that the GAQ is not a validated measure for measuring erectile function. (CX1338 (Padma-Nathan Dep. at 90-91) (stating that validation was not appropriate for a single-question questionnaire)). In developing the Forest Erectile Dysfunction Study (2007)'s protocol, POM was aware that the GAQ was not a validated measure. (CX0655_0003) (questioning by Germaine Tupper, Respondent Tupper's wife, who reviewed the protocol

for POM, about whether the GAQ was a validated tool)).

1068. The IIEF's erectile function domain questions have graded response scales and ask specific questions relating to erectile function, such as "Over the last month, when you attempted sexual intercourse, how often were you able to penetrate (enter) your partner?" and "Over the last month, during sexual intercourse, how often were you able to maintain your erection after you had penetrated (entered) your partner?" (CX0686_0026-27; *see also* Melman, Tr. 1123). Dr. Padma-Nathan stated that the IIEF was a validated measure and the "gold standard." (CX1338 (Padma-Nathan, Dep. at 90)).

1069. The Forest Erectile Dysfunction Study (2007) authors, Dr. Padma-Nathan and Mr. Forest, testified that neither the erectile function domain of the IIEF nor the GAQ had statistically significant results. (CX1338 (Padma-Nathan, Dep. at 183-84); CX1337 (Forest, Dep. at 162)).

1070. Dr. Liker, POM's medical director, was involved with the Forest Erectile Dysfunction Study (2007)'s design, conduct, and statistical analysis of the data. (CX0626_0001; CX0637_0001; CX0622_0001; CX0704_0001; CX0644_0001-02; CX0834_0001-02). Dr. Liker also reviewed and approved changes to the article prior to publication. (CX0881_0001-02; *see also* CX0856_0001) (sending revised draft of manuscript to Dr. Liker)).

1071. Respondents underpowered the Forest Erectile Dysfunction Study (2007) in order to stay within their budget despite Dr. Padma-Nathan's belief that the population should have been larger. (CX0626_0001; CX1350 (Liker, Dep. at 188-89); Liker, Tr. at 1882-83, 1886, 1914; CX1338 (Padma-Nathan, Dep. at 108)). Mr. Forest stated that Dr. Liker "would like to keep the cost of the trial in the $100K to $300K range . . . [and] would rather under-power the study than go out of this range." (CX626_0001).

1072. After the Forest Erectile Dysfunction Study (2007) was submitted for publication, a peer reviewer for the *International Journal of Impotence Research* stated that it was "a negative study, not a positive study, and should be presented that way." At this time, Dr. Liker was informed that the study was "negative." (CX0856_0001 (noting that Mr. Forest sent the peer reviewers' comments to Dr. Liker)).

1073. A published review by Dr. Jacob Rajfer, Professor of Urology at UCLA, *Pomegranate Juice: Is It the New, All-Natural Phosphodiesterase Type 5 Inhibitor?*, 10 Rev. Urol. 168-69 (2008), stated that the Forest Erectile Dysfunction Study (2007) had negative

results. Dr. Rajfer's review also stated that the study "highlights the fact that not all bench findings prove clinically efficacious and demonstrates the necessity of randomized, double-blind, placebo-controlled studies." (CX1290 (Melman, Report at Ex. C); Melman, Tr. 1128-29; CX1289 (Melman, Report at 0016)).

1074. The Forest Erectile Dysfunction Study (2007) authors testified that their study did not conclude that POM Juice treats, prevents, or reduces the risk of erectile dysfunction. (CX1338 (Padma-Nathan, Dep. at 157-58); CX1337 (Forest, Dep. at 165-66)). In fact, the authors stated that "[f]urther studies are warranted to clarify the efficacy and clinical role of POM [Juice] on male ED." (CX1193_0004; *see also* CX1338 (Padma-Nathan, Dep. at 184)).

1075. In the Forest Erectile Dysfunction Study (2007) article, Dr. Liker indicated his academic affiliation with UCLA, but did not disclose his affiliation with POM as its Medical Director. (Liker, Tr. 1931-32).

(2) Expert Analysis

1076. All the erectile dysfunction experts in this case agree that the Forest Erectile Dysfunction Study (2007)'s IIEF erectile function domain results achieved a *p* value of 0.72, *i.e.*, not statistically significant. (Melman, Tr. 1120-21; Burnett, Tr. 2297 (agreeing that a *p* value of 0.72 is "nowhere near approaching statistical significance"); PX0352 (Goldstein, Dep. at 65); CX1193_0003; CX1213_0001 (comparing the change from baseline for the treatment group versus the control group)).

1077. All the erectile dysfunction experts in this case also agree that the Forest Erectile Dysfunction Study (2007)'s GAQ results achieved a *p* value of 0.058 and were not statistically significant. (Melman, Tr. 1120-21; Burnett, Tr. 2298; PX0189 (Goldstein, Report at 0013); *see also* CX1193_0003). Nearly achieving statistical significance is insufficient to prove a product's efficacy in treating, preventing, or reducing the risk of erectile dysfunction in humans. (Melman, Tr. 1103, 1121).

1078. As the Forest Erectile Dysfunction Study (2007) report noted, the treatment period was a limitation because it might not have been long enough to allow for a clinical response. (CX1193_0004). Dr. Melman testified that the study was not conducted over a sufficient duration to show a sustained clinically significant effect on erectile function. (Melman, Tr. 1125, 1127; CX1289 (Melman, Report at 0014)). Experts in the erectile dysfunction field would require that a study be conducted over an appropriate duration because, even

if there is improvement in the quality of erection, a treatment is not efficacious when the participant is still unable to complete intercourse. (CX1289 (Melman, Report at 0011-12)).

b. Davidson IIEF Study

1079. A subset of 27 participants from the Davidson BART/FMD Study, a randomized, double blind, and placebo-controlled cardiovascular study funded by Roll (discussed in CCFF ¶¶ 879-911), also completed the IIEF. (CX1065_0001; CX0716_0029; CX0684_0001, 0014). This analysis was planned for in the protocol for the Davidson Study. (CX0716_0029).

1080. The unpublished IIEF results from the Davidson BART/FMD Study were not statistically significant for the intent to treat population. (Melman, Tr. 1130-31; CX1289 (Melman, Report at 0017; CX1336 (Davidson, Dep. at 88-89)). The *p* value was 0.7887 when comparing the intent to treat population's change in IIEF erectile function domain scores for the treatment group versus the control group. (CX0684_0014). These results do not show that drinking eight ounces of POM Juice daily treats, prevents, or reduces the risk of erectile dysfunction in humans. (Melman, Tr. 1130-31; CX1289 (Melman, Report at 0017)).

1081. Neither Dr. Burnett nor Dr. Goldstein reviewed the IIEF data from the Davidson BART/FMD Study. (PX0352 (Goldstein, Dep. at 142); PX0349 (Burnett, Dep. at 170)).

c. Nitric Oxide Studies

1082. Respondents have sponsored at least six *in vitro* and/or animal studies investigating the effects of pomegranate juice on nitric oxide levels, including:

- *Oxidative Stress in Arteriogenic Erectile Dysfunction: Prophylactic Role of Antioxidants* by Dr. Azadzoi (animal study);
- *Effects of a Pomegranate Fruit Extract Rich in Punicalagin on Oxidation-Sensitive Genes and eNOS Activity at sites of Perturbed Shear Stress and Atherogenesis* by Dr. De Nigris (*in vitro* and animal study);
- *The Influence of Pomegranate Fruit Extract in Comparison to Regular Pomegranate Juice and Seed Oil on Nitric Oxide and Arterial Function in Obese Zucker Rats* by Dr. De Nigris (animal study);
- *Beneficial Effects of Pomegranate Juice on Oxidation-Sensitive Genes and Endothelial Nitric Oxide Synthase Activity at Sites of Perturbed Shear Stress* by Dr. de Nigris (*in*

vitro study);

- *Pomegranate Juice Consumption Reduces Oxidative Stress, Atherogenic Modifications to LDL, and Platelet Aggregation: Studies in Humans and in Atherosclerotic Apolipoprotein E-Deficient Mice* by Dr. Aviram (animal study in part); and
- *Pomegranate Juice Protects Nitric Oxide Against Oxidative Destruction and Enhances the Biological Actions of Nitric Oxide* by Dr. Ignarro (*in vitro* study).

(PX0051-0001; PX0056-0001; PX0057-0001; PX0059-0001; PX0004-0001; PX0058-0001).

1083. Both Drs. Burnett and Goldstein describe such studies as basic research. (PX0149 (Burnett, Report at 0005-06); PX0189 (Goldstein, Report at 0010-13 (describing the De Nigris, Aviram, Ignarro, and Azadzoi studies as *in vitro* or *in vivo*); CX0982_0011-14 (describing the De Nigris, Aviram, Ignarro, and Azadzoi studies as "pre-clinical" studies)).

1084. While nitric oxide plays an important role in erectile function, nitric oxide alone does not produce erections. Many types of cells and molecules, in addition to nitric oxide, participate in the erection process. (CX1289 (Melman, Report at 0005-07); Melman, Tr. 1088-90; *see also* Burnett, Tr. 2274-75 (agreeing that the erection process involves many different molecules and pathways)). Diagnosis of erectile dysfunction does not necessarily mean that there is a corresponding loss of nitric oxide production. (Burnett, Tr. 2276-77).

1085. Basic research studies about antioxidants' effects on nitric oxide levels may relate to the biochemical process for erectile function. (CX1289 (Melman, Report at 0017-18)). However, such studies do not directly involve erectile function in humans and cannot alone prove that POM Juice treats, prevents, or reduces the risk of erectile dysfunction in humans. (CX1289 (Melman, Report at 0017-18)).

3. Analysis of the Challenged Erectile Dysfunction Claims in Light of the Scientific Evidence

a. Expert Analysis

1086. Dr. Melman concluded that neither the Forest Erectile Dysfunction Study (2007) nor the unpublished data from the Davidson BART/FMD Study support a claim that drinking eight ounces of POM Juice daily treats, prevents, or reduces the risk of erectile dysfunction in humans. (Melman, Tr. 1118-19; CX1289 (Melman, Report at 0016-18)).

1087. Dr. Melman stated that aside from the Forest Erectile Dysfunction Study (2007), he did not find any other published human clinical study investigating the efficacy of POM Juice, or any other pomegranate product, in treating, preventing, or reducing the risk of erectile dysfunction in humans. (Melman, Tr. 1129; CX1289 (Melman, Report at 0016)).

1088. Respondents' experts, Dr. Burnett and Dr. Goldstein, do not believe that POM Juice treats erectile dysfunction. Dr. Burnett would be concerned about relying on the Forest Erectile Dysfunction Study (2007) to conclude that POM Juice is efficacious in treating erectile dysfunction and would want additional data. (Burnett, Tr. 2298). Dr. Burnett agreed with Dr. Melman that there was insufficient evidence to conclude that drinking eight ounces of POM Juice daily treats, prevents, or reduces the risk of erectile dysfunction in humans. (Burnett, Tr. 2274 (agreeing that prevention is the same as reducing the risk)).

1089. Likewise, Dr. Goldstein did not testify that the Forest Erectile Dysfunction Study (2007) proves that POM Juice treats erectile dysfunction. (Goldstein, Tr. 2611 (stating that he does not propose that pomegranate juice is a treatment for erectile dysfunction); *see also* Goldstein, Tr. 2627-28 (noting that he was an author of an article published in 2011 evaluating the results of randomized clinical trials on the use of ginseng and yohimbine to treat erectile dysfunction)).

1090. Dr. Goldstein considered the Forest Erectile Dysfunction Study (2007) to be "suggestive evidence that use of pomegranate juice would benefit the patient with erectile dysfunction," but does not recommend POM Juice as a treatment for erectile dysfunction. (Goldstein, Tr. 2607, 2611 (stating also that he would "not suggest[] that pomegranate juice is going to replace Viagra or is consistent with the pharmaceutical evidence for treatment of erectile dysfunction"); PX0352 (Goldstein, Dep. at 34, 120) (noting that the Forest Erectile Dysfunction Study (2007) was the only human clinical study investigating the effects of pomegranate juice in treating erectile dysfunction he relied on)).

1091. Both Dr. Goldstein and Dr. Burnett distinguished between erectile dysfunction and erectile health. (Burnett, Tr. 2259-61; PX0352 (Goldstein, Dep. at 31-32); PX0189 (Goldstein, Report at 0008)). Erectile dysfunction is the recognized clinical disorder while erectile health refers to interventions that have a benefit to erectile function. (Burnett, Tr. 2260-61; PX0352 (Goldstein, Dep. at 31-32); PX0189 (Goldstein, Report at 0008)).

1092. Dr. Burnett believes that POM Juice can be a complimentary therapy for erectile health,

but does not endorse POM Juice as a "primary intervention." (Burnett, Tr. 2298, 2313 (stating that he would support patients' use of pomegranate juice as a complement to conventional erectile dysfunction treatments); PX0149 (Burnett, Report at 0006) (stating that although pomegranate juice has a "potential benefit for vascular blood flow and vascular health of the penis[,] . . . drinking pomegranate juice is not advocated as an alternative to following medical advice")).

1093. As part of an overall strategy to promote erectile health, Dr. Goldstein recommends POM Juice along with exercise and the Mediterranean diet, which is a low fat diet based on eating fruits, vegetables, fish, nuts, whole grains, and wine, for two specific subpopulations: 1) people who have erectile dysfunction, but for whom PDE-5 inhibitors (such as Viagra, Levitra, and Cialis) do not work and do not want more invasive therapies, and 2) people who do not have erectile dysfunction, but have experienced a loss in erectile health. (Goldstein, Tr. 2608-09, 2637-40; PX0189 (Goldstein, Report at 0008, 0014-15)).

1094. Dr. Goldstein testified that his recommendation of pomegranate juice to promote erectile health would be made in the context of the doctor-patient relationship only. (Goldstein, Tr. 2638-39; PX0352 (Goldstein, Dep. at 158) (stating that "the use of pomegranate juice in this context requires dialogue with a healthcare provider")). In the doctor-patient relationship, the doctor can evaluate the patient's overall health, monitor progress, and provide guidance on any side effects. (Goldstein, Tr. 2638).

1095. As Dr. Goldstein so aptly stated: "[T]he use of pomegranate juice in this context requires dialogue with a healthcare provider. This is not somebody who just goes to . . . a supermarket and just drinks pomegranate juice for no reason. This would be done in a context of a dialogue with the patient and a physician who understood the sexual issues of that person." (PX0352 (Goldstein, Dep. at 158); Goldstein, Tr. at 2639).

b. Respondents' Awareness of Inadequate Evidence

1096. POM's 2009 Medical Research Portfolio Review on erectile dysfunction clearly shows Respondents knew they did not have enough science to make treat, prevent, or reduce the risk of erectile dysfunction claims. The summary listed only one published human study in the erectile dysfunction / sexual function area, the Forest Erectile Dysfunction Study (2007). The summary acknowledged that the study "has limitations: it was small (n=53) and just missed statistical significance (p=0.058)" and that POM's results compared to placebo in its small study of 53 patients (under 50% improvement) paled in comparison to drug benchmarks (*e.g.*, Cialis and Viagra studies of between 200 and 500 patients

showed a nearly 300% improvement over placebo). (CX1029_0013; *see also* CX0128_0003 (POM press release stating that the Forest Erectile Dysfunction Study (2007) "did not achieve overall statistical significance")). Respondents posited that they could "explore 1 larger ED clinical study to achieve statistical significance and stronger marketing value." (CX1029_0013).

1097. In July 2009, Respondents' Vice President of Clinical Development, Dr. Gillespie, prepared discussion points and brief summaries of POM's past research efforts, for a medical research review meeting. (CX1081_0001). Dr. Gillespie's July 2009 research summary acknowledged that although results from one endpoint in the Forest Erectile Dysfunction Study (2007) "trended towards improvement" versus the placebo, in the end, "the primary endpoints were not met in this trial" and "the study failed to meet its objectives." (CX1081_0006). Dr. Gillespie also noted that "the design of this study may have been flawed" and that a consultant had identified problems with the study's crossover design, population, questionnaire, and duration. (CX1081_0006; *see also* CX1039_0002 (summary assessment of study)).

1098. Dr. Gillespie concluded in his July 2009 research summary: "It will be difficult to further publicize existing [erectile dysfunction] data as it is relatively weak, and not fresh." (CX1081_0006).

1099. [redacted] (CX1152_0005, 0021, *in camera*). As of January 2011, POM had not finished planning this study. (CX1349 (Gillespie, Dep. at 182)).

1100. Despite the internal assessment from Dr. Gillespie, Mr. Tupper testified that with respect to erectile dysfunction, he would give POM's science an eight out of ten, moving to ten out of ten. POM would not be pursuing a drug registration with FDA if it didn't feel its science was extraordinarily strong and positive. (Tupper, Tr. 3013-14).

1101. POM has continued to advertise erectile dysfunction claims for POMx and POM Juice from at least April 2009 to as late as July 2010, citing efficacy data from the Forest Erectile Dysfunction Study (2007). (CCFF ¶¶ 425, 447).

F. Competent and Reliable Scientific Evidence Consisting of Well Conducted Randomized Clinical Trials (RCTs) Is the Appropriate Level of Substantiation for Respondents' Disease Benefit Claims and Respondents Lack This Level of Evidence

1. Experts in the Disease Disciplines at Issue and in the Field of Food Science Adopt the View That RCTs Are Required to Substantiate Disease Treatment or Prevention Claims for the POM Products

1102. According to experts in the fields of nutrition, cardiovascular disease, prostate cancer, and erectile function, claims that a food or supplement treats, prevents, or reduces the risk of heart disease, prostate cancer, or erectile dysfunction must be supported by data from well-designed, well-conducted, randomized, placebo-controlled, and double-blinded human clinical trials. (Sacks, Tr. at 1430-31; CX1291 (Sacks, Report at 0010-11) (heart disease); Stampfer, Tr. at 706-07, 718 (cardiovascular disease and prostate cancer; stating that "most scientists in the field of clinical trials, epidemiology, and the prevention of cardiovascular disease and prostate cancer would agree" that RCTs are required, because it "is what we teach in medical schools and schools of public health [and] write about in journals"); CX1293 (Stampfer, Report at 0009); Eastham, Tr. 1265-66 (prostate cancer; stating that this is the opinion shared by the bulk of the scientific community, based on his work on safety monitoring, scientific committees, and expert panels); and CX1287 (Eastham, Report at 1002) (prostate cancer); Melman Tr. 1092-1110; CX1289 (Melman, Report at 0008, 0012) (erectile dysfunction); Burnett, Tr. 2264 (RCTs are the standard of evidence for evaluating erectile dysfunction treatment); Goldstein, Tr. 2612-15 (articles that he has authored state that RCTs are the criterion standard for determining causality)).

1103. Respondents' disease claims are founded in large part on the premise that POM products contain high levels of antioxidants, which may play a role in the prevention or treatment of disease, as illustrated in some of their *in vitro* and *in vivo* testing. (*See, e.g.,* PX0004 (Aviram 2000 study); CX0543 (Aviram 2001 study); CX0765 (Rosenblat 2006 study); CX1188 (Seeram 2005 study)). This preliminary basic research fails, however, to substantiate claims that POM's products will prevent or treat heart disease, prostate cancer, or erectile dysfunction. (CX1293 (Stampfer, Report at 0015, 0029-30)).

1104. High levels of antioxidants shown in *in vitro* tests may or may not translate to increased antioxidant levels in the human body. (CX1291 (Sacks, Report at 0015-16); Stampfer, Tr. 736-37, 725-26, 773; CX1293 (Stampfer, Report at 0016-17)). Respondents' expert, Dr. Heber, concedes that *in vitro* testing does not show how an antioxidant will work in

the body. (CX1352 (Heber, Dep. at 183, 277) (no "standardized method" to evaluate how pomegranate acts as an antioxidant in humans; difficult to show antioxidant activity in humans). He explained, "we know that we have antioxidants in the test tube, and we know it's a very potent antioxidant in a test tube. But once it gets in the body, it gets metabolized, it has to interact with all the other antioxidant defense mechanisms, and what do you have? . . . Still not sure." (CX1352 (Heber, Dep. at 186)).

1105. In his report, Dr. Stampfer explains that "[i]t has been hypothesized that diets high in [antioxidant] nutrients may prevent or treat chronic diseases, such as [cardiovascular disease] or cancer, by neutralizing free radicals," which may be responsible for cellular damage in the human body. (CX1293 (Stampfer, Report at 0010-11)). However, according to Dr. Stampfer, "there is conflicting scientific evidence on the benefits of specific nutrients with antioxidant activity in preventing or treating diseases." (CX1293 (Stampfer, Report at 0011)). Dr. Stampfer states that "[a]lthough observational and laboratory studies suggest that these nutrients have beneficial effects, several randomized controlled clinical trials have found no consistent benefit for specific nutrient antioxidants." (CX1293 (Stampfer, Report at 0011)).

1106. For example, several antioxidant nutrients have been associated with reduced risk of prostate cancer in *in vitro* and observational studies. (CX1293 (Stampfer, Report at 0015)). The data from these studies, along with secondary analyses or randomized trials, was strongest for vitamin E and selenium, which prompted the Selenium and Vitamin E Cancer Prevention Trial ("SELECT") RCT. (CX1293 (Stampfer, Report at 0015)). SELECT terminated early because an initial review of the data showed that neither supplement prevented cancer and that there were slightly more cases of prostate cancer in men taking vitamin E. (CX1293 (Stampfer, Report at 0015); CX1287 (Eastham, Report at 0002, fn. 1); Eastham, Tr. 1210-11)). Although Vitamin E and selenium worked in *in vitro* studies, these nutrients did not have the same effect when studied in humans. (Eastham, Tr. 1286; CX1293 (Stampfer, Report at 0015)). Therefore, randomized, double-blind, placebo-controlled trials are needed "before drawing firm conclusions regarding causality[.]" (CX1293 (Stampfer, Report at 0015)). Complaint Counsel's experts point to the SELECT trial as demonstrating the need for randomized clinical trials. (Eastham, Tr. 1286-87; CX1293 (Stampfer, Report at 0015).

1107. Similarly, "[b]oth observational and *in vitro* studies suggest that vitamin E can prevent or delay coronary heart disease" but randomized clinical trials have failed to demonstrate the same association. (CX1293 (Stampfer, Report at 0012)).

1108. Thus, to demonstrate that the POM Products treat, prevent, or reduce the risk of heart

disease, prostate cancer, and erectile dysfunction, well conducted RCTs are the type of competent and reliable science required before such a claim can be made. (CCFF ¶¶ 784, 974, 1055). As established through the detailed analysis of Respondents' research in each relevant disease area, Respondents lack the necessary competent and reliable evidence in the form of RCTs for their claims. (*See supra* CCFF Sections VII.C.4, VII.D.4, and VII.E.4).

2. Respondents' Experts' Argument That Disease Benefit Claims for Food Products Do Not Need RCTs to Establish Such Efficacy Is Unpersuasive

1109. In his testimony and expert report, Dr. Heber has stated that RCTs do not work well for studying nutrients, are infeasible, and are too expensive. (Heber, Tr. 1948-50; PX0353 (Heber, Dep. at 98-99 (placebo-controlled trials are not the gold standard for nutritional research)).

1110. This assertion, however, is inconsistent with his conduct over the past decade. In fact, Dr. Heber designed, solicited Respondents' funding for, and conducted several randomized, controlled human clinical studies with the purpose of proving health benefits for POM products on endpoints such as cognitive function, sports performance, and heart disease. (Heber, Tr. 2016-17, 2045-50, 2053-57; CX1352 (Heber, Dep. at 94-95); *see* CX0859_0003 (identifying Heber as primary investigator in San Diego Study RCT); CX0949_0007-13 (identifying Heber as principal investigator in RCT evaluating the effect of POMx on heart-related endpoints in diabetics); CX0659 (RCT to test pomegranate extract sports drink on sports performance)). Dr. Heber never told Respondents that randomized, controlled human clinical trials were not appropriate or necessary to study the effects of POM products on various areas of health. (Heber, Tr. 2053-57). Dr. Heber also has previously testified in federal court that randomized, placebo-controlled clinical trials were necessary to support advertising claims that a dietary supplement causes weight loss. (Heber, Tr. 2041-45).

1111. Moreover, in his report, Dr. Heber points out that his research led to the initiation of a Phase III placebo-controlled, randomized study "to determine" whether intake of POM Juice can lengthen PSA in a certain group of prostate cancer patients. (PX0192 (Heber, Report at 0031-32)). He also states in his report that Respondents followed up the Aviram heart studies with "larger [human] studies," implying that this is the right thing to do. (PX0192 (Heber, Report at 0052)). Dr. Heber is also one of the investigators taking part in the [redacted] an RCT. (CX1118_0002, *in camera*; *see* CCFF ¶ 1030).

1112. Dr. Miller testified in this matter that a claim that fruit juice treated prostate cancer would not need to be supported by a randomized clinical trial. (Miller, Tr. 2201). This is directly contrary to his 2009 testimony in *Daniel Chapter One* : "Dr. Miller explained that in order to constitute competent and reliable scientific evidence that a product treats, cures, or prevents cancer, the products' efficacy and safety must be demonstrated through controlled clinical studies (tests on humans)." *In re Daniel Chapter One and James Feijo*, No. 9329, Commission Opinion at 18 (Dec. 24, 2009)[4]; *see also In re Daniel Chapter One and James Feijo*, No. 9329, Initial Decision at 55 (Aug. 5, 2009) (Dr. Miller's report stated that "[o]nly data from well-designed, controlled, clinical trials will substantiate a claim that a new therapy is safe and effective to treat, cure, or prevent cancer.")[5] Dr. Miller testified in *Daniel Chapter One* that such a cancer treatment claim for orange juice, for example, would require scientific evidence. (Miller, Tr. 2226).

1113. Dr. Miller conceded in his report that "[t]he regulatory requirements are much more rigorous when crossing the boundary between making a general health benefit claim (low fat diets are healthier than high fat diets) and taking a general statement to the next level and claiming efficacy in the treatment of a specific type of cancer." (PX0206 (Miller, Report at 0006)).

1114. Dr. Miller also agreed that the claim being made about a product is relevant to the level of substantiation required, but he did not actually evaluate any of the advertising claims made regarding the health benefits of POM's products. (Miller, Tr. 2195, 2210).

1115. Although Dr. Miller testified that his views have "evolved" since testifying in *Daniel Chapter One*, the only citation in his expert report for his opinion that the level and rigor of substantiation for a food is quite different from that for a drug is a paper that he concedes is not a medical article or review. The paper is entitled, "In Defense of the Pfizer Factors," by Howard Beales, Timothy Muris, and Robert Pitofsky ("Beales paper"). (Miller, Tr. 2221; PX0206 (Miller, Report at 0015, 0019-20)). Dr. Miller did not know the background of the authors or whether they had medical backgrounds. (Miller, Tr. 2222).

1116. The Beales paper that Dr. Miller relied upon is in fact a legal advocacy paper urging the application of a different substantiation standard for foods versus conventional treatments. Dr. Miller concedes this describes the entire scope of his opinion. (PX0209; Miller, Tr. 2222). Dr. Miller was not familiar with the Beales paper before he was asked

4 http://www.ftc.gov/os/adjpro/d9329/091224commissionopinion.pdf
5 http://www.ftc.gov/os/adjpro/d9329/090811dcoinitialdecision.pdf

to give his opinion in this matter, had not come across the paper in his independent literature review in this case, and was provided the Beales paper by Respondents. (Miller, Tr. 2223).

1117. Dr. Miller is not an expert in the role of foods in prevention and treatment of disease; nor is he a nutritionist or a lawyer. (Miller, Tr. 2215, 2222; CCFF ¶ 757).

1118. Dr. Heber and Dr. Miller's attempts to minimize the necessity of RCTs to support claims that a product will treat, prevent, or reduce the risk of a specific disease are not credible; Respondents' own heart expert, Dr. Ornish, directly contradicts Dr. Heber and Dr. Miller in this regard. Dr. Ornish testified that not only did he *not* recall telling the Resnicks that they did not need to sponsor randomized, controlled human trials before they could claim that pomegranate juice helps reduce the risk of heart disease, but that he was the "one who actually encouraged the Resnicks to do these studies when the Resnicks first proposed them. I thought it was a wonderful idea. I think that's the kind of behavior that the FTC should be encouraging[.]" (Ornish, Tr. 2386; *see also* CCFF ¶ 822 (Ornish conducted two RCTs on Respondents' behalf attempting to link pomegranate juice to a preventative for heart disease)).

3. Respondents' Own Statements About and Use of RCTs Establish Their Important Role

1119. Mr. Resnick stated that human research is the most important type of study. (CX1360 (S. Resnick, Dep. at 93, 116, 121-22) (acknowledging early mechanistic research is different from human trials); *see also* S. Resnick, Tr. at 1758 (human research needed to reinforce *in* vitro and animal studies); CX1372 (S. Resnick, Trop. Dep. at 90) (Respondents conducted human research to reinforce *in* vitro and animal studies)).

1120. Mr. Resnick testified that Respondents' human research distinguished POM from its competitors. (CX1360 (S. Resnick, Dep. at 94-95)).

1121. Mr. Tupper stated in the "POM's Health Benefits: Fact or Fiction?" section of the www.pomwonderful.com website, that "[w]hen you look at the medical research that has been conducted on POM and compare it to research that's been done on other foods and beverages, what's been done on POM is . . . more akin to research being done on pharmaceutical drugs." (CX0336_0001; Tupper, Tr. 918).

1122. Mr. Tupper further explained on the website that this "is why we go beyond the test tube

and do all this clinical research. It isn't until you see an effect in humans with measurements that are medically meaningful that you know you've got something going on." (CX0336_0010; Tupper, Tr. 918, 1041; *see also* CCFF ¶ 272, ("[I]t really comes down to what happens in the human body.")).

1123. Mr. Tupper reiterated this position when he testified in federal court that Respondents worked with scientists to explore health benefits of POM and "pursued a very rigorous approach to science" starting with test tube research, then animal studies, followed by human clinical trials, which was the "gold standard in the scientific research community." (CX1406 (Tupper, Trop. Tr. at 130); *see also* CX1406 (Tupper, Trop. Tr. at 34-35) (Respondents' research on various areas of health "included very basic lab science, test tube science, and progressed over time into human studies[.]")).

1124. Steve Henig, one of POM's in-house scientific advisors, stated in an email that was copied to Mr. Tupper and Ms. Resnick that "we [POM] and our collaborators are using a proven process to test [sic] health benefits of naturally occurring active components. A process that test the hypothesis in vitro first, then scales it up to a biological model using test animals . . . and then to human clinical. This process is used for functional foods, nutritional supplements, and medical drugs." (CX0038_0001; *see also* CX0780_0001 (outside scientists suggesting that "the juice must be tested in a large placebo-controlled trial . . . [to] finally answer the pomegranate question in a fashion that would be publishable in a major journal and sufficiently powered to convince clinicians and the media.")).

1125. Mrs. Resnick testified that the company protocol was to require animal studies as prerequisites to human studies, which were essential for the company to make marketing claims about heart or prostate health. (L. Resnick, Tr. 276-77).

1126. Mrs. Resnick states in her book, "[W]e had invested millions in medical research to understand the efficacy of Wonderful pomegranates in treating a host of medical issues. Animal tests were necessary for the kind of rigorous, peer-reviewed science we were financing. Animal studies are generally a prerequisite for human studies and human studies are considered essential. (We didn't invent this protocol; but for the science to be considered sound, we had to follow it.)" (CX0001_0033).

1127. Indeed, Respondents have commissioned at least ten randomized, controlled human trials to study the effects of pomegranate products on endpoints relating to heart disease, prostate cancer, and erectile dysfunction. (*See* CCFF ¶¶ 822, 855, 879, 912, 929-30, 946,

1026, 1063-64)).

1128. In addition, Respondents have sponsored various human clinical trials on pomegranate products related to other diseases and areas of health, including two large unpublished RCTs on cold and flu, urinary tract infection, an RCT on cognitive function, an RCT on sports health, and skincare. (S*ee, e.g.,* CX01029_0008-09, 0011, 0015-16). For example, Respondents' Research Portfolio describes an RCT on the effect of POM Juice/POMx Beverage on 80 HIV/AIDS patients. (CX1029_0009). This document indicates that the "end game scenario" of the HIV/AIDS research was to "[p]ublicize results of current study (if positive)." (CX1029_0009).

1129. Given the overwhelming evidence of Respondents' understanding and use of RCTs, they are well aware that their randomized, controlled human clinical trials have failed to support their treatment, prevention and reduction of risk claims for heart disease, prostate cancer, or erectile dysfunction. (*See* CCFF ¶¶ 966-73, 1044-51, 1096-99). Nevertheless, POM continues to maintain that anything it has said in any of its ads is more than adequately backed up by published research over the past 10 to 15 years. Mr. Tupper testified that POM is comfortable that every advertisement it has run, with one or two exceptions, have been more than adequately supported by the body of science. (Tupper, Tr. 2985-86, 3015).

1130. Respondents' expert testimony dismissing the need for RCTs to support Respondents' claims is revisionist history, as best exposed by Mrs. Resnick's trial testimony when she attempted to distance herself from her own prior statements about the proper scientific method, such as in CCFF ¶ 1126. (L. Resnick, Tr. 276-77). She testified: "I've recently been educated to the fact that" studies on fruits were better done in test tube studies rather than human studies. (L. Resnick, Tr. 277).

VIII. COMPLAINT COUNSEL'S PROPOSED CONCLUSIONS OF LAW

A. Burden of Proof

1. The parties' burdens of proof are governed by Federal Trade Commission ("FTC") Rule 3.43(a), Section 556(d) of the Administrative Procedure Act ("APA"), and case law. FTC Rules of Practice, Interim rules with request for comments, 66 Fed. Reg. 17,622, 17,626 (Apr. 3, 2001). Pursuant to Commission Rule 3.43(a), "[c]ounsel representing the Commission . . . shall have the burden of proof, but the proponent of any factual proposition shall be required to sustain the burden of proof with respect thereto." 16 C.F.R. § 3.43(a).

2. "It is well established that the preponderance of the evidence standard governs FTC enforcement actions." *Daniel Chapter One*, Docket No. 9329, 2009 FTC LEXIS 157, at *134-35 (Aug. 5, 2009) (initial decision) (citing *Telebrands Corp.*, 140 F.T.C. 278, 426 (2004) (initial decision), *aff'd.*, 140 F.T.C. 278 (2005), *aff'd.*, 457 F.3d 354 (4th Cir. 2006); *Automotive Breakthrough Sciences, Inc.*, 126 F.T.C. 229, 306 n.45 (1998)) (other citations omitted), *aff'd*, FTC Commission Decision (Dec. 24, 2009), *available at* http://www.ftc.gov/os/adjpro/d9329/091224commissionopinion.pdf, *aff'd.*, 405 F. App'x. 505 (D.C. Cir. 2010), *cert. denied*, 131 S. Ct. 2917 (2011).

B. Jurisdiction

1. Jurisdiction over Respondents

3. The acts and practices charged in the Complaint in this matter took place in or affecting commerce within the meaning of the Federal Trade Commission Act, as amended. 15 U.S.C. § 41 *et seq*. (2012); (PX0364-0002 (Answer ¶ 8)). Nationwide advertising, marketing, or sales activity of the sort that Respondents engaged in constitutes "commerce" under the FTC Act. *See, e.g.*, *P.F. Collier & Son Corp. v. FTC*, 427 F.2d 261, 272 (6th Cir. 1970); *Ford Motor Co. v. FTC*, 120 F.2d 175, 183 (6th Cir. 1941) (noting that commerce also includes the actions, communications, and other acts or practices that are incident to those activities).

4. The Commission has jurisdiction over persons, partnerships, and corporations. 15 U.S.C. § 45(a)(2). A "corporation" is defined in Section 4 of the FTC Act as "any company . . . which is organized to carry on business for its own profit or that of its members[.]" 15 U.S.C. § 44. If individuals direct and control the acts and practices of a corporation amenable to the FTC's jurisdiction, then they too may be made subject to the FTC's jurisdiction. *Ohio Christian Coll.*, 80 F.T.C. 815, 845 (1972); *see also FTC v. Amy Travel Serv., Inc.*, 875 F.2d 564, 573 (7th Cir. 1989) (holding that an individual who either participated directly in or had the authority to control deceptive acts or practices

may be held liable under the FTC Act for the violations of his corporation). Therefore, the Commission has jurisdiction over Corporate Respondents POM and Roll and Individual Respondents Stewart Resnick, Lynda Resnick, and Matthew Tupper.

5. The Complaint charges Respondents with violating Sections 5 and 12 of the FTC Act. Section 5(a) provides that "unfair or deceptive acts or practices in or affecting commerce are hereby declared unlawful." 15 U.S.C. § 45(a)(1). Section 12 prohibits the dissemination of "any false advertisement" in order to induce the purchase of "food, drugs, devices, services, or cosmetics." 15 U.S.C. § 52(a)(2). For the purposes of Section 12, the POM Products are "food" or "drugs." 15 U.S.C. § 55(b), (c) (defining "food" as, among other things, "articles used for food or drink for man," and defining "drug" as, among other things, "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man"). For the purposes of Section 12, "false advertisement" is defined as "an advertisement, other than labeling, which is misleading in a material respect[.]" 15 U.S.C. § 55(a).

2. All of Respondents' Challenged Marketing Is Advertising Subject to the FTC Act

6. "Advertisement" is not defined in the FTC Act and the "ordinary meaning of the word is: The act or process of calling something to the attention of the public; or a public notice, especially one published in the press or broadcast over the air." *Daniel Chapter One*, 2009 FTC LEXIS 157, at *168 (initial decision). Respondents promoted the POM Products through various means, including print advertisements in magazines, freestanding inserts in newspapers, out of home media such as billboards and bus shelters, posters in health clubs and doctors' offices, advertising on prescription drug bags, Internet websites, online banner advertisements, medical outreach, radio advertisements, television advertisements, press releases, and press interviews. (*See* CCFF ¶¶ 175-77).

7. Neither Section 5 nor 12 limits the FTC's reach to a specific type of advertising or even to paid-for advertising. *See* 15 U.S.C. § 55(a)(1) (defining "false advertisement" without requiring that the ad be paid for); *see also Daniel Chapter One*, 2009 FTC LEXIS 157, at *168 (initial decision). Rather, the Commission's authority to regulate advertising is circumscribed only by its statutory authority and the limits of the commercial speech doctrine. *See R.J. Reynolds Tobacco Co., Inc.*, 111 F.T.C. 539, 542 (1988) ("The more limited protection accorded commercial speech permits the FTC to act when necessary to challenge false or deceptive advertising.") (citing *Thompson Med. Co. v. FTC*, 791 F.2d 189 (D.C. Cir. 1986); *Sears, Roebuck & Co. v. FTC*, 676 F.2d 385 (9th Cir. 1982); *Warner-Lambert Co. v. FTC*, 562 F.2d 749 (D.C. Cir. 1977); *Beneficial Corp. v. FTC*, 542 F.2d 611 (3d Cir. 1976)). Public relations was a critical component of POM's marketing scheme and Respondents' challenged promotional materials include press

releases and press interviews. (*See* CCFF ¶¶ 175-77, 261-80, 541-78). Respondents admitted in their Answer that the Lynda Resnick and Matthew Tupper interviews excerpted in the Complaint were "advertisements and promotional materials" that they disseminated or caused to be disseminated. (*See* CCFF ¶ 578).

8. Although the Commission observed in *R.J. Reynolds Tobacco Co*. that "commercial speech *frequently* takes the form of paid-for advertising" and that "paid-for advertising [] is *typical* of commercial speech," it did not declare that payment is a necessary element of commercial speech. *R.J. Reynolds Tobacco Co., Inc.*, 111 F.T.C. at 545, 547 (emphasis added). The Commission merely pointed to payment as one of five non-dispositive indicia of commercial speech. *Id.* at 544. The other four were whether the speech (1) "contain[s] a message promoting the demand for a product;" (2) "refers to a specific product or service;" (3) conveys "information about attributes of a product or service offered for sale, such as type, price, or quality" or "health effects associated with the use of a product;" and (4) "benefit[s] or seek[s] to benefit the economic interests of the speaker by promoting sales of its products." *Id.* at 544-56. POM's challenged public relations carried the latter four indicia of commercial speech and fit comfortably into the commercial speech factors that the Commission considered in *R.J. Reynolds Tobacco Co.*

9. Respondents' challenged public relations materials, as well as Respondents' other challenged forms of marketing, constitute "advertisements" within the scope of Section 12 of the FTC Act, 15 U.S.C. § 52, and alleged deceptive acts or practices within the scope of Section 5 of the FTC Act, 15 U.S.C. § 45.

C. Respondents' Advertising is Deceptive or Misleading

1. Respondents' Advertisements Make the Claims Alleged in the Complaint

10. As alleged in Paragraphs 12 through 18 of the Complaint, Respondents' challenged advertisements make false and misleading representations that clinical studies, research, and/or trials prove that daily use of the POM Products treats, prevents, and/or reduces the risk of heart disease, prostate cancer, and/or erectile dysfunction ("establishment claims"). As alleged in Paragraphs 19 through 21 of the Complaint, Respondents' challenged advertisements make false and misleading representations that Respondents had substantiation that daily use of the POM Products treats, prevents, and/or reduces the risk of heart disease, prostate cancer, and/or erectile dysfunction ("efficacy claims"). These deceptive misrepresentations violate Sections 5 and 12 of the FTC Act.

11. An "advertisement is deceptive under the FTC Act if it is likely to mislead consumers, acting reasonably under the circumstances, in a material respect." *Daniel Chapter One*, 2009 FTC LEXIS 157, at *173 (initial decision) (quoting *Kraft, Inc. v. FTC*, 970 F.2d 311, 314 (7th Cir. 1992)); see also *FTC v. Direct Mktg. Concepts, Inc.*, 569 F. Supp. 2d

285, 297 (D. Mass. 2008), *aff'd*, 624 F.3d 1 (1st Cir. 2010); *Telebrands Corp.*, 140 F.T.C. at 290; *Thompson Med. Co.*, 104 F.T.C. 648, 788 (1984), *aff'd*, 791 F.2d 189 (D.C. Cir. 1986); *Cliffdale Assocs., Inc.,* 103 F.T.C. 110, 164-66 (1984); *Federal Trade Commission Policy Statement on Deception*, 103 F.T.C. 174, 175-76 (1984) (*appended* to *Cliffdale Assocs., Inc.*) ("*Deception Policy Statement*").

12. "The primary evidence of the claims an advertisement conveys to reasonable consumers is the advertisement itself." *Daniel Chapter One*, 2009 FTC LEXIS 157, at *176 (initial decision) (citing *Telebrands Corp.*, 140 F.T.C. at 290; *Novartis Corp.*, 127 F.T.C. 580, 680 (1999), *aff'd,* 223 F.3d 783 (D.C. Cir. 2000); *Kraft, Inc.*, 114 F.T.C. 40, 121 (1991), *aff'd,* 970 F.2d 311 (7th Cir. 1992)).

13. The FTC may use its own reasoned analysis to determine what claims an advertisement conveys. *See Kraft, Inc. v. FTC*, 970 F.2d at 318 ("[i]n determining what claims are conveyed by a challenged advertisement, the [FTC] relies on . . . its own viewing of the ad"); *FTC v. Colgate-Palmolive Co.*, 380 U.S. 374, 385 (1965).

14. In determining whether an advertisement conveys a claim, the Commission looks to the overall, net impression created by the advertisement, through the interaction of different elements in the advertisement, rather than focusing on the individual elements in isolation. *See Am. Home Prods. Corp. v. FTC*, 695 F.2d 681, 687-88 (3d Cir. 1982); *Stouffer Foods Corp.*, 118 F.T.C. 746, 798-99 (1994); *Kraft, Inc.*, 114 F.T.C. at 122; *Deception Policy Statement*, 103 F.T.C. at 179; *see also FTC v. Sterling Drug, Inc.*, 317 F.2d 669, 674 (2d Cir. 1963) ("The entire mosaic should be viewed rather than each tile separately. 'The buying public does not ordinarily carefully study or weigh each word in an advertisement. . . .'") (quoting *Aronberg v. FTC*, 132 F.2d 165, 167 (7th Cir. 1942)).

15. This Court has the authority to rule as to the conveyed meaning of advertisements and promotional materials based on a facial analysis of these advertisements or promotional materials. *Auto. Breakthrough Scis., Inc.*, Docket Nos. 9275-77, 1996 FTC LEXIS 252, at *44, (partial summary decision May 22, 1996) (citing *Kroger Co.*, 98 F.T.C. 684, 726, 729 n.12 (1981); *Ford Motor Co.*, 87 F.T.C. 756, 794-97 (1976)).

16. Assessing the overall net impression of an advertisement includes examining the interaction of such elements as language and visual images. *See Kraft, Inc. v. FTC*, 970 F.2d at 322; *Telebrands Corp.*, 140 F.T.C. at 290; *see also Thompson Med. Co.,* 104 F.T.C. at 793, 811-12.

17. Advertising claims may be express or implied. *See Kraft, Inc. v. FTC*, 970 F.2d at 318. Express claims directly state the representation at issue, while implied claims make representations without direct statements. *Id.* at 319 n.4; *Thompson Med. Co.*, 104 F.T.C. at 788-89.

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

19. "If the advertisement explicitly states or clearly and conspicuously implies a claim, the court need not look to extrinsic evidence to ascertain whether the advertisement made the claim." *FTC v. Nat'l Urological Group, Inc.*, 645 F. Supp. 2d 1167, 1189 (N.D. Ga. 2008), *aff'd*, 356 F. App'x 358 (11th Cir. 2009); *see also FTC v. Colgate-Palmolive Co.*, 380 U.S. at 391-92 (stating that the FTC is not required to conduct consumer surveys before determining that a commercial has a tendency to mislead); *Kraft, Inc. v. FTC*, 970 F.2d at 320 ("[W]hen confronted with claims that are implied, yet conspicuous, extrinsic evidence is unnecessary because common sense and administrative experience provide the Commission with adequate tools to make its findings. [citations omitted]. The implied claims Kraft made are reasonably clear from the face of the advertisements, and hence the Commission was not required to utilize consumer surveys in reaching its decision.").

20. "[R]eferences to clinical testing, research and case studies are express claims that the respondents' representations are supported by scientific evidence." *Removatron Int'l Corp.*, 111 F.T.C. 206, 298 (1988), *aff'd*, 884 F.2d 1489 (1st Cir. 1989). *See also Thompson Med. Co.*, 104 F.T.C. at 814 (finding that "references to tests by a medical specialist, or 'clinical tests,' are an express reference to the type of test acceptable to the medical scientific community" and it would be "reasonable for consumers to expect that the claims . . . would be substantiated in a manner acceptable to the medical scientific community.")

21. "Common examples of establishment claims include statements such as 'tests prove,' 'doctors recommend,' or 'studies show.'" *Daniel Chapter One*, 2009 FTC LEXIS 157, at *225-26 (initial decision) (citing *FTC v. Direct Mktg. Concepts*, 569 F. Supp. 2d at 298-99).

22. "Although an establishment claim may be made by such words and phrases as 'established,' 'here's proof' and 'medically proven' …, it may also be made through the use of visual aids (such as scientific texts or white-coated technicians) which clearly suggest that the claim is based upon a foundation of scientific evidence." *Bristol-Myers*

Co., 102 F.T.C. 21, 321 (1983) (internal citations omitted), *aff'd*, 738 F.2d 554 (2d Cir. 1984). The net impression of such advertisements is that "respondents' claims were based on competent scientific proof." *Removatron Int'l Corp.*, 111 F.T.C. at 298 (citing *Bristol-Myers Co.*, 102 F.T.C. at 321; *Porter & Dietsch, Inc.*, 90 F.T.C. 770, 865 (1977), *aff'd* 605 F.2d 294 (7th Cir. 1979)).

23. The following are examples of the types of advertising statements from which courts have found "clinically proven" claims to have been made either expressly or by implication:

- *FTC v Nat'l Urological Group, Inc.*, 645 F. Supp. 2d at 1201 (finding challenged claim that "Spontane-ES is clinically proven to be effective in treating 90% of men with erectile dysfunction" was made by the combination of an advertising statement that "in preliminary testing, Spontane-ES's active components have been shown to be effective in nearly 90% of all men who have taken it" combined with a reference to "research and development" conducted by "pharmacological staff at Warner Laboratories" and a letter from a doctor positively reviewing the product).

- *Bristol-Myers Co.*, 102 F.T.C. at 32, 322-23 (finding a challenged establishment claim that "tests or studies prove claims that Bufferin is twice as fast . . . as aspirin in relieving pain" from statements that "[s]cientific tests show," "[t]ests show," and "Bufferin laboratory tests show" faster relief than aspirin and noting that although "[n]one of Bristol-Myers' ads actually uses the word 'established' . . . this is immaterial because the ads create the impression that the claims have been established.");

- *FTC v. QT, Inc.*, 448 F. Supp. 2d 908, 929-32 (N.D. Ill. 2006) (finding the challenged establishment claim that "tests proved the Q-Ray bracelet relieves pain" from an ad in which a medical doctor said the bracelet worked for him, that he "did a little bit more research on it and then I decided to give the bracelet a try on some of my patients . . . and I was absolutely amazed at the response"; finding it from infomercials which emphasized the connection between the Q-Ray bracelet and alternative treatments such as acupuncture; finding it from a brochure in which a doctor described before and after thermographic imaging of one person as "a convincing piece of evidence for it's [sic] effectiveness"; and finding it from another brochure "that included the following statements: 'Only Q-Ray has Passed the Critical Yin-Yang Test; No other bracelets can pass these Natural Power tests.'"), *aff'd*, 512 F.3d 858 (7th Cir. 2008);

- *Metagenics, Inc.*, Docket No. 9267, 1996 FTC LEXIS 459, at *39-41 (Oct. 11, 1996) (initial decision) (finding challenged claim that "scientific research proves

that Bone Builder or MCHC halts, prevents or treats osteoporosis" was made by an ad which stated, "Important and exciting research demonstrates that osteoporosis can safely and effectively be treated with a specially processed bone concentrate from young cattle . . ." and by an ad which stated, "[w]here there is evidence [of osteoporosis risk to an individual] [t]his safe, reliable, inexpensive, scientifically tested preventive is his/hers to take as they choose and not dependent upon the whim of another;" also finding challenged claim that "scientific research proves that Bone Builder or MCHC reduces or eliminates pain associated with bone ailments" from an ad which stated, "MCHC has been reported to improve fracture healing and relieve back pain in women with post menopausal bone loss").

24. Here, the vast majority of Respondents' challenged advertisements contain indicia of "clinically proven" claims: express language (*e.g.*, "Medical studies have shown" that POM Juice "minimizes factors that lead to atherosclerosis"; "Pomegranate juice consumption resulted in significant reduction in IMT (thickness of arterial plaque) by up to 30% after one year"), references to specific clinical studies, bold headlines (*e.g.*, "24 SCIENTIFIC STUDIES NOW IN ONE EASY-TO-SWALLOW PILL," "Real Studies. Real Results."; "Science, not fiction"), statements touting their medical research expenditures (*e.g.*, "backed by $32 million in medical research at the world's leading universities"), and/or medical imagery (*e.g.*, a picture of POM Juice bottle used as an intravenous bottle, hooked to an electrocardiogram; or enclosed in a blood pressure cuff). (*See, e.g.*, CCFF ¶¶ 326, 344, 357, 368, 398, 415, 419, 425, 468).

25. "Disclaimers or qualifications in any particular ad are not adequate to avoid liability unless they are sufficiently prominent and unambiguous to change the apparent meaning of the claims and to leave an accurate impression. Anything less is only likely to cause confusion by creating contradictory double meanings." *Daniel Chapter One*, 2009 FTC LEXIS 157, at *213 (initial decision) (quoting *Removatron Int'l Corp. v. FTC*, 884 F.2d 1489, 1497 (1st Cir. 1989)).

26. Qualifier words such as "can help" that appear in some of the challenged ads do not negate the net impressions of those ads that daily use of the POM Products prevents, and/or reduces the risk of heart disease, prostate cancer, and/or erectile dysfunction. Similarly, words such as "preliminary" and "pilot" that appear in some of the challenged ads do not negate the establishment claims in those ads. *See Daniel Chapter One*, 2009 FTC LEXIS 157, at *204 (initial decision) ("Even though the language of the product description . . . attempts to relegate GDU's claimed effectiveness to a supporting role in 'helping' or 'aiding' the body, . . . the entire mosaic of the advertisement belies a merely 'supporting' role for GDU.").

27. Small print disclaimers at the bottom of advertisements are insufficient as disclaimers.

See FTC v. Medlab, Inc., 615 F. Supp. 2d 1068, 1077 (N.D. Cal. 2009) ("Defendants cannot innoculate [sic] themselves from the representations that appear in the body of the text by including cautionary statements at the foot of the advertisements."). To be effective, disclosures must be clear and conspicuous. *See, e.g., Thompson Med. Co.*, 104 F.T.C. at 842-43.

28. Moreover, "persons reading a print ad often will read only the headline, and will take their sole impression of the ad from it. The special significance of headlines has previously been recognized in Commission cases, which hold that even an express disclosure in the text of an ad may not be enough to change the ad's net impression upon consumers." *Thompson Med. Co.*, 104 F.T.C. at 799. Here, some of Respondents' bold headlines and sub-headlines conveyed specific health benefit claims, *e.g.,* "Floss your arteries. Daily," "Heart Therapy," "Drink to prostate health," "I'm off to save PROSTATES!", "One small pill for mankind. 'Findings from a small study suggest that pomegranate juice may one day prove an effective weapon against prostate cancer,'" "NEW RESEARCH OFFERS FURTHER PROOF OF THE HEART-HEALTHY BENEFITS OF POM WONDERFUL JUICE. . . . 30% DECREASE IN ARTERIAL PLAQUE . . . 17% IMPROVED BLOOD FLOW . . . PROMOTES HEALTHY BLOOD VESSELS," and "NEW POMEGRANATE RESEARCH OFFERS HOPE TO PROSTATE CANCER PATIENTS." (capitalization in originals). (*See* CCFF ¶¶ 336, 363, 368, 372, 397, 435-37, 440).

29. In considering the net impression of an advertisement, the Commission does "not require that all consumers reading or viewing it be sophisticated experts in interpreting the nuances of the English language." *Thompson Med. Co.*, 104 F.T.C. at 792 ("We look at how such individuals actually interpret advertisements in a real-life situation, not at how they would if they had sufficient time and incentives attentively to review the ads so as to come up with the most semantically correct interpretation of them.").

30. If an ad is targeted at a particular audience, the Commission analyzes ads from the perspective of that audience. *See Telebrands Corp.,* 140 F.T.C. at 291-92 ("Different target audiences come to an ad with different perceptions. Consumers cannot understand an ad – or any communication – without applying their own knowledge, associations, or cultural understandings that are external to the ad itself. For that reason, the purpose of ad interpretation is to determine the claims that consumers – particularly the target audience – take away from an ad, whether or not an advertiser intended to communicate those claims."); *Deception Policy Statement*, 103 F.T.C. at 179. Here the target audiences for ads for the POM Products were consumers who were very concerned about health or who already have health problems. (*See* CCFF ¶¶ 302-05).

31. Commission law recognizes that advertisements may be susceptible to more than one reasonable interpretation. *Kraft, Inc.*, 114 F.T.C. at 120-21 n.8; *Thompson Med. Co.,* 104

F.T.C. at 789 n.7. "[S]tatements susceptible of both a misleading and a truthful interpretation will be construed against the advertiser." *FTC v. Bronson Partners, LLC*, 564 F. Supp. 2d at 127 n.6 (quoting *Country Tweeds, Inc. v. FTC*, 326 F.2d 144, 148 (2d Cir. 1964)).

32. "Moreover, an ad need not mislead a majority of reasonable consumers. An ad is misleading if at least a significant minority of reasonable consumers are likely to take away the misleading claim." *Telebrands Corp.*, 140 F.T.C. at 291 (citing *Kraft, Inc.*, 114 F.T.C. at 122; *Deception Statement*, 103 F.T.C. at 177 n.20).

33. The Bovitz Survey provides evidence that at least a significant minority of consumers took away relevant health messages from the headlines and images used in several of the challenged ads. For example, a significant minority of consumers took from the images and headlines of the challenged "Decompress" print ad a message that drinking POM Juice lowers blood pressure; from the image and headline/subheadline of the challenged "I'm off to save PROSTATES!" print and banner ads a message that drinking POM Juice is good for prostate health; and from the headline "Holy Health! $25 million in medical research!" a message that "$25 million [was] spent on research/research based." (*See* CCFF ¶ 588). It also shows that a significant minority of those who saw the image and headline of the challenged "Heart Therapy" print and banner ads, together with the headlines of other challenged print ads, took away a message that a benefit of drinking POM Juice is that it is good for the heart. (*See* CCFF ¶ 590).

34. These conclusions are based upon responses to open-ended questions. (*See* CCFF ¶¶ 587, 589). The Commission has held that credible evidence as to advertising communication can be obtained from responses to open-ended questions without controls. *See Telebrands Corp.,* 140 F.T.C. at 318 ("Marketing experts have found that credible evidence can be obtained from the responses to open-ended questions. We agree with the ALJ that it is appropriate to consider the open-ended responses without netting out any controls.") (citation omitted).

35. In fact, the Commission has held that results from open-ended ad communication questions understate communication. *Telebrands Corp.,* 140 F.T.C. at 318-19. In *Telebrands Corp.*, survey respondents were asked, "[w]hat did the commercial say, show, or imply about" the product at issue followed by, "[a]nything else?" to elicit additional responses, and the Commission held that this "likely understated the consumer take-away because consumers are unlikely to volunteer all of the messages they glean from an ad." *Id.*; *see also Stouffer Foods Corp.*, 118 F.T.C. at 805 (noting that "even . . . one of Stouffer's experts testified that often a researcher must rely on open-ended responses in the magnitude of 8 percent to 10 percent as being meaningful"); *Thompson Med. Co.,* 104 F.T.C. at 697 (initial decision) ("[O]pen-ended questions lead most respondents to play back only one theme or point. They do not draw out a complete or exhaustive list of all

the things respondents may have on their minds. Rather, respondents will play back the dominant theme or primary impression and, having done that, will probably stop.").

36. In the Bovitz Survey, a majority of consumers exposed to the images and headlines of POM print ads, one of which referred to $25 million in medical research," said in response to a closed-ended question that, based on the ads they saw, POM Juice had "proven health benefits." (*See* CCFF ¶ 592-93). Even after using another attribute as a control for noise and yea-saying, 43% or more thought that POM Juice had "proven health benefits." (*See* CCFF ¶ 594).

37. "Marketing experts also rely upon the results to closed-ended questions as indicative of consumer responses to ads. Closed-ended questions, however, have the potential to direct participants to certain aspects of an ad. Consequently, participants may respond to such questions based upon yea-saying, inattention, pre-conceptions, or other 'noise.' Thus, closed-ended questions require the use of some type of control mechanism. An appropriate control can involve the use of a control ad, or a control question. The use of both is not required." *Telebrands Corp.,* 140 F.T.C. at 319-20 (citations omitted).

38. "The Commission does not require methodological perfection before it will rely on a copy test or other type of consumer survey, but looks to whether such evidence is reasonably reliable and probative." *Stouffer Foods Corp.*, 118 F.T.C. at 799. Thus, the Bovitz Survey provides additional reliable evidence of how consumers interpreted various elements of Respondents' challenged ads.

39. There is abundant evidence in the record that Respondents intended to communicate the Challenged Claims. (*See, e.g.,* CCFF ¶¶ 281-318, 334, 337-38, 350, 354, 359-60, 369, 373-74). Making the specific health claims at issue was the business strategy for Respondents from the outset. (*See* CCFF ¶¶ 153-57; 159-60). Respondents have highlighted the medical research in POM Product advertising and marketing materials because the research lends credibility to the claims and gives consumers a "reason to believe." (*See* CCFF ¶ 306). Although intent is not required to find liability, a showing of intent is powerful evidence that the alleged claims in fact were conveyed to consumers. *See Telebrands Corp.*, 140 F.T.C. at 304; *Novartis Corp.*, 127 F.T.C. at 683; *see also Thompson Med. Co.,* 104 F.T.C. at 791.

40. Respondents' challenged advertisements convey expressly or strongly imply the challenged claims:

    a. Clinical studies, research, and/or trials prove that daily use of POM Juice treats, prevents, and/or reduces the risk of heart disease. (*See* CCFF ¶¶ 328, 335, 340, 348, 361, 367, 388, 414, 418, 424, 429, 434, 441, 471, 494, 500, 535, 548, 555, 562, 573).

b. Clinical studies, research, and/or trials prove that daily use of POM Juice treats, prevents, and/or reduces the risk of prostate cancer. (*See* CCFF ¶¶ 371, 376, 384, 388, 405, 414, 418, 424, 429, 434, 441, 471, 494, 500, 535, 562, 573, 575, 577).

c. Clinical studies, research, and/or trials prove that daily use of POM Juice treats, prevents, and/or reduces the risk of erectile dysfunction. (*See* CCFF ¶¶ 388, 429, 471, 494, 500, 535, 567, 577).

d. Clinical studies, research, and/or trials prove that daily use of POMx Pills or POMx Liquid treats, prevents, and/or reduces the risk of heart disease. (*See* CCFF ¶¶ 414, 418, 424, 429, 434, 441, 535, 562).

e. Clinical studies, research, and/or trials prove that daily use of POMx Pills or POMx Liquid treats, prevents, and/or reduces the risk of prostate cancer. (*See* CCFF ¶¶ 405, 414, 418, 424, 429, 434, 441, 535, 562).

f. Daily use of POM Juice treats, prevents, and/or reduces the risk of heart disease. (*See* CCFF ¶¶ 328, 335, 340, 343, 348, 356, 361, 367, 388, 414, 418, 424, 429, 434, 441, 471, 494, 500, 535, 538, 548, 555, 562, 573).

g. Daily use of POM Juice treats, prevents, and/or reduces the risk of prostate cancer. (*See* CCFF ¶¶ 371, 376, 384, 388, 405, 414, 418, 424, 429, 434, 441, 471, 494, 500, 535, 540, 562, 571, 573, 575, 577).

h. Daily use of POM Juice treats, prevents, and/or reduces the risk of erectile dysfunction. (*See* CCFF ¶¶ 388, 429, 471, 494, 500, 535, 567, 577).

i. Daily use of POMx Pills or POMx Liquid treats, prevents, and/or reduces the risk of heart disease. (*See* CCFF ¶¶ 414, 418, 424, 429, 434, 441, 535, 562).

j. Daily use of POMx Pills or POMx Liquid treats, prevents, and/or reduces the risk of prostate cancer. (*See* CCFF ¶¶ 405, 414, 418, 424, 429, 434, 441, 535, 562).

k. Daily use of POMx Pills or POMx Liquid treats, prevents, and/or reduces the risk of erectile dysfunction. (*See* CCFF ¶¶ 429, 535).

2. Respondents' Advertising Claims Are Material

41. A "material" misrepresentation is one that involves information important to consumers and that is therefore likely to affect the consumer's choice of, or conduct regarding, a product. *Deception Policy Statement*, 103 F.T.C. at 182.

42. To be material, "a claim does not have to be the *only* factor or the *most* important factor likely to affect a consumer's purchase decision, it simply has to be *an* important factor." *Novartis Corp.*, 127 F.T.C. at 695.

43. Materiality is a test of the likely effect of the claim on the conduct of a consumer who has been reached by the claim. *Novartis Corp.*, 127 F.T.C. at 691 ("Materiality turns upon whether those consumers who have drawn the claim from the advertisement" are "likely to have their conduct affected by the [alleged] misrepresentation."); *Deception Policy Statement*, 103 F.T.C. at 182.

44. Certain categories of information are presumptively material. Claims significantly involving health are presumptively material. *Kraft, Inc. v. FTC*, 970 F.2d at 323; *accord Novartis Corp. v. FTC*, 223 F.3d 783, 786 (D.C. Cir. 2000) (quoting *Deception Policy Statement*, 103 F.T.C. at 182; *see also Daniel Chapter One*, 2009 FTC LEXIS 157, at *245 (initial decision) ("Health-related efficacy claims are consistently held to involve information that is important to consumers"); *FTC v. Direct Mktg. Concepts, Inc.,* 569 F. Supp. 2d at 300 (holding that claims that dietary supplements could prevent or treat cancer and other diseases were health-related efficacy claims which were "clearly material"); *FTC v. Nat'l Urological Group, Inc.,* 645 F. Supp. 2d at 1190-91 (applying presumption of materiality to claims that dietary supplements were effective to treat weight loss and sexual dysfunction); *FTC v. QT, Inc.*, 448 F. Supp. 2d at 965-66 (stating that claims that the Q-Ray bracelet provides immediate, significant, or complete relief from various types of pain were "[w]ithout question" medical, health-related claims that were material to consumers).

45. Express representations are presumed material because "the willingness of a business to promote its products reflects a belief that consumers are interested in the advertising." *Deception Policy Statement*, 103 F.T.C. at 182 (quoting *Cent. Hudson Gas & Elec. Co. v. Pub. Serv. Comm'n*, 447 U.S. 557, 567 (1980)); *see also FTC v. 1st Guar. Mortg. Corp.*, No. 09-cv-61840, 2011 U.S. Dist. LEXIS 38152, at *46 (S.D. Fla. Mar. 30, 2011); *FTC v. Nat'l Urological Group, Inc.*, 645 F. Supp. 2d at 1190; *Medical Billers Network, Inc.*, 543 F. Supp. 2d 283, 304 (S.D.N.Y. 2008). Also presumed as material are implied claims that are made "by such strong implication that they are the functional equivalent of an express claim." *See FTC v. Bronson Partners, LLC*, 564 F. Supp. 2d at 135.

46. "The Commission presumes that claims are material if . . . they pertain to the 'central characteristics of a product * * * such as those relating to its purpose * * * [or] efficacy.'" *Telebrands Corp.*, 140 F.T.C. at 292 (quoting *Thompson Med. Co.*, 104 F.T.C. at 816-17) (alteration in original); *see also Novartis Corp.*, 127 F.T.C. at 687 (agreeing with the ALJ that "the challenged superior efficacy claim relates to central characteristic of the product, that is, Doan's ability to relieve back pain."); *Brake Guard Prods., Inc.*, 125 F.T.C. 138, 210-11 (1997) (initial decision) ("The Commission also

presumes claims to be material if they pertain to the 'central characteristics of a product . . . such as those relating to its purpose . . . [or] efficacy,' or to safety. The majority of the challenged claims made for the product directly involved its purpose, efficacy and safety. The central theme of respondents' ads was that the Brake Guard device was an antilock brake system that provided certain braking and stopping distance improvements, and that installing an antilock brake system like Brake Guard would make the vehicle safer.") (alteration in original) (citation omitted), *aff'd.*, 125 F.T.C. 138 (1998).

47. The Commission will also infer materiality where the record shows that Respondent intended to make an implied claim. *Novartis Corp.*, 127 F.T.C. at 686-89 (explaining that the ALJ correctly presumed implied superior efficacy claims were material because Novartis had intended to make such claims) (citing *Deception Policy Statement*, 103 F.T.C. at 182); *see also FTC v. 1st Guar. Mortg. Corp.*, 2011 U.S. Dist. LEXIS 38152, at *46 ("[D]eliberately-implied claims used to induce the purchase of a product or service are presumed to be material to consumers as a matter of law."); *FTC v. Bronson Partners, LLC*, 564 F. Supp. 2d at 135 ("The underlying rationale for finding [an intended] claim to be presumptively material . . . is 'the assumption that the willingness of a business to promote its product reflects a belief that the consumers are interested in the advertising.'"); *FTC v. Nat'l Urological Group, Inc.*, 645 F. Supp. 2d at 1190 ("[D]eliberately made implied claims, used to induce the purchase of a particular product or service are presumptively material.").

48. In this case, Respondents' challenged claims unquestionably relate to health concerns. (*see* CCFF ¶ 625), were often made expressly or so strongly implied as to be virtually express (*see* CCFF ¶ 627), and were intended (*see* CCFF ¶ 628), so they are presumed material. The claims are also presumptively material because they relate to the central characteristic and purpose of using POMx Pills or POMx Liquid and a central characteristic of POM Juice as it was advertised. (*See* CCFF ¶ 626).

49. The Commission has also relied upon other evidence of materiality. Studies Respondents commissioned in the ordinary course of business demonstrate the importance of the challenged claims. (*See* CCFF ¶¶ 639-50). In the 2009 A&U study, 85% of then-current POM Juice drinkers said they personally drank pomegranate juice because it is "healthy/good for my health." (*See* CCFF ¶¶ 640-41). "[H]elps promote heart health" (57%), and "helps protect against prostate cancer" (47% of males) were the second and third ranked of nine or ten specific health benefits motivating drinkers of POM Juice. (*See* CCFF ¶¶ 642-43). Heavy pomegranate drinkers in the August 2007 Zoomerang online study ranked cardiovascular health and prostate health as the top two (out of six) health benefits of drinking pomegranate juice in importance to them. (*See* CCFF ¶¶ 648-49). Among a larger sample population, which included drinkers of other juices, 18% of males ranked erectile dysfunction as the first or second most important health benefit to them. (*See* CCFF ¶ 650).

50. In *Kraft*, the Commission relied upon the responses to a similar closed-ended survey question as evidence of materiality. *Kraft, Inc.*, 114 F.T.C. at 135. In that matter, survey respondents were asked to rate the importance of nine factors in the decision to buy a challenged product. *Id.* at 86. The critical factor at issue was ranked only seventh out of nine characteristics, but the Commission still viewed the survey as evidencing materiality because a high percentage rated the factor as "extremely" or "very important." *Id.* at 138 n.30. *See also Novartis Corp.,* 127 F.T.C. at 690 (relying upon the closed-ended ratings of characteristics of pain relief products).

51. The survey conducted by Respondents' marketing expert, Dr. Reibstein, also shows the importance of health benefits to past POM purchasers. (*See* CCFF ¶ 655).

52. Moreover, Dr. Reibstein testified that consumers in POM's target audience who were concerned about heart disease, prostate cancer, or erectile dysfunction would likely find the challenged claims to be important. (*See* CCFF ¶ 638). Expert testimony that a challenged claim would motivate the target audience to purchase a product has been a basis for finding materiality. *Novartis Corp.*, 127 F.T.C. at 689-90.

53. Materiality is also shown by a willingness to pay a price premium for a product with a claimed attribute. *Deception Policy Statement*, 103 F.T.C. at 183 & n.57 ("there is a reason to believe consumers are willing to pay a premium for a product believed to contain a special analgesic ingredient, but not for a product whose analgesic is ordinary aspirin") (quoting *Am. Home Prods. Corp.*, 98 F.T.C. 136, 369-70 (1981), *aff'd as modified,* 695 F.2d 681 (3d Cir. 1982)). Respondents' marketing strategy for the POM Products was premised on convincing consumers that the claimed health benefits are the reason to buy their expensive products. (*See* CCFF ¶ 629).

54. Materiality is also shown by evidence that the challenged advertising led to increased sales. *Kraft, Inc. v. FTC*, 970 F.2d at 324 (Kraft's "increase in sales corresponded directly with the ad campaign . . . . [and] Kraft's increase in market share came at a time when Singles were priced roughly 40% higher than imitation slices. Thus, the Commission reasonably inferred that the [challenged] imitation superiority message, as a central theme in the ads, contributed to increased sales and market share."). Here, Respondents, themselves, assert that through their investment of millions of dollars to research and promote the health benefits associated with pomegranate juice, they largely created the market for pomegranate juice. (*See* CCFF ¶ 176). Sales went from nothing to $165 million in just four years. (*See* CCFF ¶ 137).

55. Another basis to infer materiality is persistence in using challenged claims in the face of warnings that a deceptive message is conveyed. *Kraft, Inc. v. FTC*, 970 F.2d at 323; *Kraft, Inc.*, 114 F.T.C. at 137. Here, Respondents persisted in conveying the challenged claims despite numerous third parties warning them of the deceptive nature of their claims. (*See* CCFF ¶ 685).

56. In order to rebut the presumption of materiality Respondents must come forward with sufficient evidence to support a finding that the claim at issue is not material. *Novartis Corp.*, 127 F.T.C. at 686. Materiality is a test of the likely effect of the claim on the conduct of a consumer who has been reached by the claim. *Deception Policy Statement*, 103 F.T.C. at 182-83; *Novartis Corp.*, 127 F.T.C. at 691 ("Materiality turns upon whether those consumers who have drawn the claim from the advertisement" are "likely to have their conduct affected by the [alleged] misrepresentation."). Respondents' rebuttal evidence, the Reibstein Survey, fails to provide such evidence. (*See* CCFF ¶¶ 654-55, 657-59). *See Kraft, Inc. v. FTC*, 970 F.2d at 323 (concluding that Respondent's consumer surveys were insufficient to rebut the presumption of materiality that had properly been presumed because the challenged calcium content and benefit claims involved a significant health concern to consumers).

57. The Reibstein survey should have but did not ask survey respondents to evaluate the importance of the challenged claims in terms of whether those claims were likely to have an effect on their decision to purchase or to use POM Juice. (*See* CCFF ¶ 658). The survey failed to even expose consumers to the challenged ads or the challenged claims, so it did not provide a proper measure of materiality. (*See* CCFF ¶¶ 654-55, 657-59).

58. In *Novartis Corp.*, the Commission concluded that a study by respondents' expert "understated the number of respondents to whom the [challenged] superiority claims were material by failing to ask directly whether the superiority claim was important to them." *Novartis Corp.*, 127 F.T.C. at 695; s*ee also Kraft, Inc.,* at 90 (initial decision) (faulting Respondent's survey for not mentioning that the ads made the challenged claim and that "therefore it did not provide a basis for a conclusion as to the impact of the claims on consumer behavior").

59. Even as a study of the purchase motivations of past purchasers, the Reibstein survey was flawed by its reliance on broad open-ended questions with no probing as to what survey respondents who said they bought POM Juice because it was "healthy" meant. (*See* CCFF ¶¶ 660-61). In *Novartis Corp.*, even when survey respondents had been exposed to a challenged ad, the Commission found that responses to an open-ended question about materiality were "almost certainly understated" because Respondents' expert "failed to ask follow-up questions to determine *all* of the aspects of the commercial that made consumers more likely to buy Doan's in the future." *Novartis Corp.*, 127 F.T.C. at 695.

60. Even if the Court were to give the Reibstein survey some weight, the predicate facts that gave rise to the presumption of materiality are not negated and remain evidence from which materiality can be inferred. *Novartis Corp.*, 127 F.T.C. at 686-89. The vast, overwhelming evidence on this issue in the record supports a finding that the challenged claims are material. (*See* CCFF ¶¶ 625-61).

3. Respondents' Advertising Claims Are Deceptive or Misleading

61. The Commission may prove an advertisement is deceptive or misleading by showing that a claim is false, or by showing that a claim is unsubstantiated because Respondents lacked a reasonable basis for asserting that the claim was true. *FTC v. Pantron I Corp.*, 33 F.3d 1088, 1096 (9th Cir. 1994); *FTC v. Sabal*, 32 F. Supp. 2d 1004, 1007 (N.D. Ill. 1998). The Complaint in this case makes allegations under both theories. (*See* Complaint ¶¶ 12-21).

62. To prevail under the "falsity" theory, Complaint Counsel must prove that the express or implied claims conveyed by an advertisement are false. *Daniel Chapter One*, 2009 FTC LEXIS 157, at *222 n.4 (initial decision).

63. In an advertising case, "the advertiser has the burden of establishing the substantiation it relied on for its claim." *Daniel Chapter One*, 2009 FTC LEXIS 157, at *137 (initial decision) (citing *FTC v. QT, Inc.*, 448 F. Supp. 2d at 959). The Commission then has the burden of proving that Respondents' purported substantiation is inadequate, but is not required to conduct or present clinical studies showing that the products do not perform as claimed. *See FTC v. QT, Inc.*, 448 F. Supp. 2d at 959 (citing *FTC v. Sabal*, 32 F. Supp. 2d at 1008-09).

64. The vast majority of Respondents' challenged advertisements contain establishment claims, referencing clinical testing or medical research or otherwise suggesting that Respondents' claims are based upon a foundation of scientific evidence. (*See* CCFF ¶¶ 328, 335, 340, 348, 361, 367, 371, 376, 384, 388, 405, 414, 418, 424, 429, 434, 441, 471, 494, 500, 535, 548, 555, 562, 567, 573, 575, 577; CCCL ¶ 40).

65. "If an advertisement represents that a particular claim has been scientifically established, the advertiser must possess a level of proof sufficient to satisfy the relevant scientific community of the claim's truth." *Removatron Int'l Corp.*, 111 F.T.C. at 297. In other words, the advertiser must possess "competent scientific proof." *Id.* at 298-99.

66. In affirming the Commission's *Removatron* decision, the 1st Circuit stated that "a 'reasonable basis,' when one makes establishment claims, means well-controlled scientific studies. Without such a study, petitioners could not, as a matter of law, have a reasonable basis for their establishment claims." *Removatron Int'l Corp. v. FTC*, 884 F.2d 1489, 1498 (1st Cir. 1989).

67. Moreover, if advertisements "expressly or impliedly promise a scientific level of substantiation," then a *Pfizer* analysis is not required and the ads' claims must be supported by scientific proof. *Removatron Int'l Corp.,* 111 F.T.C. at 297-98, 306 (when evaluating ads "the net impression" of which was "that respondents' claims were based on competent scientific proof . . . . we need not apply the *Pfizer* analysis in determining

the reasonable basis for respondents' claims.").

68. Courts have consistently found or upheld that double-blind, placebo-controlled studies are required to provide adequate substantiation for the truthfulness of the health-related efficacy claims challenged by the Commission. *See FTC v. Direct Mktg. Concepts, Inc.*, 569 F. Supp. 2d at 303 ("While it seems well-accepted that double-blind, placebo-controlled studies are necessary to substantiate health-related efficacy claims, it is not firmly accepted how many such studies must be offered"; requiring double-blind, placebo controlled human studies for claims of multiple health benefits for coral calcium supplement); *see also Removatron Int'l Corp. v. FTC*, 884 F.2d at 1499-1500 (upholding requirement for double-blind clinical test to substantiate performance claims for hair removal device); *Schering Corp.*, 118 F.T.C 1030, 1080, 1115-16 (1991) (initial decision) (weight-loss and generalized health benefit claims for a high fiber supplement required "substantiation by two well controlled clinical trials," which were described as double-blind, placebo controlled); *FTC v. Nat'l Urological Group, Inc.*, 645 F. Supp. 2d at 1202-03 (accepting undisputed expert testimony that erectile dysfunction claims require well-designed, placebo-controlled, randomized, double-blind clinical trials for substantiation); *FTC v. Braswell*, CV 03-3700 DT, 2005 U.S. Dist. LEXIS 42976, at *35 (C.D. Cal. Sept. 26, 2005) (by offering unrefuted evidence that the standard to substantiate claims for various health-related products should be double-blind, placebo-controlled tests, Commission offered sufficient evidence to withstand summary judgment); *FTC v. SlimAmerica, Inc.*, 77 F. Supp. 2d 1263, 1274 (S.D. Fla. 1999) ("Scientific validation of the defendants' product claims requires a double blind study of the combination of ingredients used in" the defendants' weight loss product); *FTC v. Sabal*, 32 F. Supp. 2d at 1008-09 (rejecting a study as inadequate substantiation, in part, because it was not blinded or placebo-controlled); *FTC v. Pantron I Corp.*, 33 F.3d at 1097-98 (finding that use of a placebo-control is required to substantiate efficacy claims for a hair growth product); *FTC v. Cal. Pac. Research, Inc.*, No. CV-N-88-602, 1991 U.S. Dist. LEXIS 12967, at *12-13 (D. Nev. Aug. 27, 1991) (only placebo-controlled, double-blind clinical studies meet "the most basic and fundamental requirements for scientific validity and reliability").

69. The need for double-blind, placebo-controlled studies is even clearer in cases which involve establishment claims. *See FTC v. QT, Inc.*, 448 F. Supp. 2d at 962 ("[W]ith medical, health-related claims, a well-conducted, placebo-controlled, randomized, double-blind study, the gold standard, should have been conducted. . . . Defendants would not be required to have a gold-standard study to substantiate the Q-Ray bracelet if they did not make such a strong, medical claim"). Here, Respondents, themselves, have asserted that one does not know that an antioxidant product is efficacious until one finds "measurements that are medically meaningful" through clinical testing on humans. (*See* CCFF ¶¶ 491, 1122).

70. A well-conducted, placebo-controlled, randomized, double-blind clinical trial:

> must (a) include patients who fulfill criteria for the type of pain to be treated; (b) be randomized so that each individual has the same probability of being in either the treatment or the placebo group; (c) be a double-blind study so that neither the investigator conducting the study nor the participants know who is receiving the placebo; (d) utilize [an endpoint, e.g.,] a pain rating instrument that has been demonstrated to be valid, reliable, and responsive for that disease and population; (e) subject its data to appropriate statistical analysis; and (f) show a statistically significant and clinically significant improvement in the treatment group, when compared to the control group, at the end of the trial.

FTC v. QT, Inc., 448 F. Supp. 2d at 938 (citing the Federal Judicial Center *Reference Guide on Statistics* and the Federal Judicial Center *Reference Manual on Scientific Evidence*).

71. "Randomized controlled experiments are ideally suited for demonstrating causation. . . . A good study design compares outcomes for subjects who are exposed to some factor (the treatment group) with outcomes for other subjects who are not exposed (control group). . . . In summary, data from a treatment group without a control group generally reveal very little and can be misleading." Federal Judicial Center, *Reference Manual on Scientific Evidence* 218-20, (3d ed. 2011); *see also id.* at 230 ("It is randomness in the technical sense that provides assurance of unbiased estimates from a randomized controlled experiment or a probability sample.")

72. One court has noted that "[i]n a randomized, placebo-controlled, clinical study, the appropriate statistical analysis is one that statistically compares the change observed in the treatment group to the change in the same measure observed in the placebo group" and that "it is not scientifically appropriate to rely on a 'within group' statistical analysis; that is, an analysis of only the change in a measured parameter in the treatment group from the beginning to the end of the study, because the result may be due to other factors such as regression to the mean or the placebo effect." *See FTC v. QT, Inc.*, 448 F. Supp. 2d at 939.

73. "If statistical significance is not achieved, [a] treatment cannot be said to have had an effect." *FTC v. QT, Inc.*, 448 F. Supp. 2d at 939 (citing the Federal Judicial Center *Reference Guide on Statistics*, the court wrote that "statistical significance is achieved if the statistical analysis shows that there is a 0.05 or less likelihood that the difference measured is due to chance ($p \leq 0.05$)").

74. Clinical studies, research, and/or trials do **not** prove that:

a. Daily use of POM Products treats, prevents, and/or reduces the risk of heart disease. (*See* CCFF Section VII.C, ¶¶ 784-973).

b. Daily use of POM Products treats, prevents, and/or reduces the risk of prostate cancer. (*See* CCFF Section VII.D, ¶¶ 974-1054).

c. Daily use of POM Products treats, prevents, and/or reduces the risk of erectile dysfunction. (*See* CCFF Section VII.E, ¶¶ 1055-1101).

Accordingly, Respondents' challenged establishment claims are false and misleading and Respondents did not possess competent and reliable scientific evidence for the challenged efficacy claims presented in these advertisements.

75. A minority of the challenged ads only make non-establishment, efficacy claims. (*See* CCFF ¶¶ 343, 356, 538, 540, 571; CCCL ¶ 40). For those advertisements, the Court must determine the appropriate level of substantiation.

76. "For non-establishment claims, what constitutes sufficient substantiation may depend on multiple factors, such as the type of claim, the type of product, the consequences of a false claim, the benefits of a truthful claim, the cost of developing substantiation for the claim, and the amount of substantiation that experts in the field believe is reasonable." *Daniel Chapter One*, 2009 FTC LEXIS 157, at *226-27 (initial decision) (citing *FTC v. Direct Mktg. Concepts*, 569 F. Supp. 2d at 299); *see also Removatron Int'l Corp.,* 111 F.T.C. at 306-07 n.20; *Thompson Med. Co.,* 104 F.T.C. at 821 (citing *FTC Policy Statement Regarding Advertising Substantiation*, 104 F.T.C. at 839-40 (1984) (appended to *Thompson Med. Co.*).

77. Courts have consistently found that for health and safety claims, advertisers must possess "competent and reliable scientific evidence" substantiating their claims in order to have a "reasonable basis" for such claims. *See FTC v. Nat'l Urological Group, Inc.*, 645 F. Supp. 2d at 1202 (granting the FTC's motion for summary judgment and finding that since all of defendants' "claims regard the safety and efficacy of dietary supplements; [] they must be substantiated with competent and reliable scientific evidence"); *FTC v. Natural Solution, Inc.*, 2007 U.S. Dist. LEXIS 60783, at *11-13 (granting the FTC's motion for summary judgment and applying the "competent and reliable scientific evidence" standard to defendants' claims that their product prevents and treats cancer); *FTC v. QT, Inc.*, 448 F. Supp. 2d at 961 ("Reasonable basis" required defendants to have "competent and reliable scientific evidence" when they made the claim that the Q-Ray bracelet provides immediate, significant, or complete pain relief).

78. Claims that are difficult or impossible for consumers to evaluate for themselves require a high level of substantiation, such as scientific tests. *Removatron Int'l Corp.,* 111 F.T.C.

at 306 n.20; *Thompson Med. Co.,* 104 F.T.C. at 822-23. "The 'placebo' effect of consumer expectations when taking a purported remedy makes it difficult for consumers to verify product effectiveness for themselves." *Daniel Chapter One*, 2009 FTC LEXIS 157, at *230 (initial decision) (citing *FTC v. Pantron I Corp.*, 33 F.3d at 1090 n.1; *Removatron Int'l Corp.,* 111 F.T.C. at 306 n.20; *Thompson Med. Co.,* 104 F.T.C. at 822-23). Consumers cannot effectively determine for themselves the accuracy of the challenged claims.

79. Claims referring to specific facts and figures of a product's capabilities require a high level of substantiation, such as scientific tests. *Removatron Int'l Corp.,* 111 F.T.C. at 306 n.20; *Thompson Med. Co.,* 104 F.T.C. at 822.

80. The inquiry into the "type of product" has consistently called for a "high level of substantiation, such as scientific tests," when a product is related to consumer health. *Daniel Chapter One*, 2009 FTC LEXIS 157, at *230 (initial decision); *Removatron Int'l Corp.*, 111 F.T.C. at 306 n.20; *Thompson Med. Co.,* 104 F.T.C. at 822.

81. The Commission stated in its May 1994 *FTC Enforcement Policy Statement On Food Advertising*: "The Commission's standard for substantiation of health claims in food advertising shares many elements with FDA's approach to such claims in labeling. Like FDA, the Commission imposes a rigorous substantiation standard for claims relating to the health or safety of a product, including health claims for food products. The Commission's standard that such claims be supported by 'competent and reliable scientific evidence' has been more specifically defined in Commission orders addressing health claims for food products to mean: tests, analyses, research, studies or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results." *Enforcement Policy Statement On Food Advertising*, 59 Fed. Reg. 28,388, 28,393 (FTC June 1, 1994)), *also available at* CX0002_0006 (footnotes omitted).

82. "When no specific claim about the level of support is made, the evidence needed depends on the nature of the claim. . . . As a general rule, well-controlled human clinical studies are the most reliable form of evidence." *Dietary Supplements: An Advertising Guide for Industry* at 10 (FTC Apr. 2001), *available at* http://www.ftc.gov/bcp/edu/pubs/business/adv/bus09.pdf, *also available at* CX1014_0019.

83. The sufficiency of the evidence to support efficacy claims for both food and dietary supplements must be evaluated in light of the entire body of scientific evidence. Respondents cannot simply rely upon studies that they quoted in their ads, while discounting research that does not support their claims. *See Dietary Supplements: An Advertising Guide for Industry* at 14 (FTC Apr. 2001), *available at*

http://www.ftc.gov/bcp/edu/pubs/business/adv/bus09.pdf, *also available at* CX1014_0019 ("Studies cannot be evaluated in isolation. The surrounding context of the scientific evidence is just as important as the internal validity of individual studies. Advertisers should consider all relevant research relating to the claimed benefit of their supplement and should not focus only on research that supports the effect, while discounting research that does not. . . . Wide variation in outcomes of studies and inconsistent or conflicting results will raise serious questions about the adequacy of an advertiser's substantiation. . . . If a number of studies of different quality have been conducted on a specific topic, advertisers should look first to the results of the studies with more reliable methodologies.").

84. "[T]he Commission, like FDA, evaluates substantiation for health claims in the context of the surrounding body of evidence, and does not look to isolated studies, especially if those studies are unrepresentative of the larger body of evidence. . . . [T]he Commission believes that qualified claims based on evidence that is inconsistent with the larger body of evidence have the potential to mislead consumers, and, therefore, are likely to violate section 5." *Enforcement Policy Statement On Food Advertising*, 59 Fed. Reg. 28,388, 28,393-94 (FTC June 1, 1994), *also available at* CX0002_0006-07.

85. Despite Respondents' contentions that developing competent and reliable scientific evidence is too costly for foods and that foods should be held to a lower standard, the Commission has consistently required in settlements that health claims for foods be supported by competent and reliable scientific evidence. *See The Dannon Co., Inc.*, 151 F.T.C. 62 (2011) (consent order) (challenging claims that Activia yogurt relieved temporary irregularity and helped with "slow intestinal transit time," and claims that DanActive dairy drink helped prevent colds and flu); *Kellogg Co.*, Docket No. C-4262, 2009 WL 2402679 (F.T.C. July 27, 2009) (consent order) (challenging claims that Frosted Mini-Wheats cereal was clinically shown to improve children's attentiveness by nearly 20%); *Tropicana Prods., Inc.*, 140 F.T.C. 176 (2005) (consent order) (challenging unsubstantiated representations that drinking 2-3 glasses a day of "Healthy Heart" orange juice would produce dramatic effects on blood pressure, cholesterol, and homocysteine levels, thereby reducing the risk of heart disease and stroke); *Unither Pharma, Inc.*, 136 F.T.C. 145 (2003) (consent order) (challenging claims that food bar containing amino acid reduces the risk of heart disease and reverses damage to the heart); *Interstate Bakeries Corp.*, 133 F.T.C. 687 (2002) (consent order) (challenging claims that calcium in Wonder Bread could improve children's brain function and memory); *Conopco, Inc.*, 123 F.T.C. 131 (1997) (consent order) (challenging heart-health claims for Promise margarine); *U.S. v. Eggland's Best, Inc.*, No. 96 CV-1983 (E.D. Pa. Mar. 12, 1996) (stipulated permanent injunction) (challenging claims about product's effect on cholesterol); *Eggland's Best, Inc.*, 118 F.T.C. 340 (1994) (consent order) (challenging claims about product's effect on cholesterol); *The Isaly Klondike Co.*, 116 F.T.C. 74 (1993) (consent order) (challenging claims about effect of Klondike Lite frozen dessert

bars on consumers' serum cholesterol levels); *Bertolli USA, Inc.*, 115 F.T.C. 774 (1992) (consent order) (challenging claims that olive oil had been medically proven to reduce cholesterol, blood pressure, and blood sugar).

86. Moreover, Respondents have demonstrated their ability to fund a scientific research program to ascertain the health benefits of their products. As they told consumers, Respondents spent $34 million in medical research regarding the POM Products. (*See* CCFF ¶ 309). For example, the cost for the two well-conducted, placebo-controlled, randomized, double-blind clinical trials commissioned by Respondents to determine any benefits of POM Juice in treating and preventing cardiovascular disease (the Davidson studies) was approximately $3 million. (*See* CCFF ¶ 878).

87. The POM Products are expensive for consumers to purchase. A one-year supply of POM Juice cost approximately $780 (buying 16-ounce bottles), a one-year supply of POMx Pills cost approximately $315 (buying 90-count bottles), and a one-year supply of POMx Liquid cost approximately $360. (*See* CCFF ¶¶ 127-28, 133, 135, 140, 145-46). Spending money on an expensive and unproven preventative or treatment causes economic injury which also weighs in favor of requiring a higher level of substantiation. *See Daniel Chapter One*, 2009 FTC LEXIS 157, at *234 (initial decision) (citing *Schering Corp.*, 118 F.T.C. at 1115 (initial decision); *Removatron Int'l Corp.,* 111 F.T.C. at 306 n.20). Furthermore, the use of POM Products are not risk-free. (*See* CCFF ¶ 1020-21).

88. "The Court can look to what experts in the relevant area of study would consider to be adequate in determining the amount and type of evidence that is sufficient" to substantiate the advertisers' claims. *FTC v. Braswell*, 2005 U.S. Dist. LEXIS 42976, at *31 (citing *Thompson Med. Co.,* 104 F.T.C. at 821). The credible expert testimony supports a finding that the challenged claims require substantiation in the form of competent and reliable scientific evidence consisting of double-blind, placebo-controlled studies. (*See* CCFF ¶ 1102).

89. The appropriate level of substantiation for those challenged ads that do not make establishment claims is competent and reliable scientific evidence consisting of well-designed, well-conducted, randomized, placebo-controlled, and double-blinded human clinical trials. (*See* CCFF ¶ 1108).

90. Respondents did not possess competent and reliable scientific evidence to substantiate claims that:

    a. Daily use of POM Products treats, prevents, and/or reduces the risk of heart disease. (*See* CCFF Section VII.C, ¶¶ 784-973).

b. Daily use of POM Products treats, prevents, and/or reduces the risk of prostate cancer. (*See* CCFF Section VII.D, ¶¶ 974-1054).

c. Daily use of POM Products treats, prevents, and/or reduces the risk of erectile dysfunction. (*See* CCFF Section VII.E, ¶¶ 1055-1101).

91. Therefore, Respondents violated Sections 5 and 12 of the FTC Act, and Complaint Counsel is entitled to the proposed order against Respondents.

D. Remedy

1. Corporate Liability

92. A corporation is liable for violations of the FTC Act if the corporation "engaged in misrepresentations or omissions of a kind usually relied on by reasonably prudent persons and [] consumer injury resulted." *FTC v. Pantron I Corp.*, 33 F.3d at 1102 (citing *FTC v. Amy Travel Serv.*, 875 F.2d at 573).

93. POM and Roll are each liable, under Sections 5 and 12 of the FTC Act, for their involvement in making the challenged claims. POM is liable for claims made in its advertisements for its products. Roll is liable because of its role in creating POM's advertisements, promoting POM products through its public relations employees, and sponsoring and funding research on POM products. (*See* CCFF ¶¶ 92-107).

94. Additionally, Roll and POM are also jointly liable under the common enterprise theory. (*See* CCFF ¶ 121). The common enterprise theory exists for "situations where corporations are so entwined that a judgment absolving one of them of liability would provide the other defendants with 'a clear mechanism for avoiding the terms of the order.'" *FTC v. Nat'l Urological Group, Inc.,* 645 F. Supp. 2d at 1182.

95. "Where one or more corporate entities operate in a common enterprise, each may be held liable for the deceptive acts and practices of the others." *FTC v. Bay Area Bus. Council, Inc.*, No. 02-C-5762, 2004 U.S. Dist. LEXIS 6192, at *33-34 (N.D. Ill. Apr. 8, 2004) (finding a common enterprise where the corporate defendants were owned by the same person, were operated by the same people, often shared offices, did business under each other's names and accessed the same customer databases, shared and transferred proceeds as needed, and were considered a collaborative effort by the owner); *Telebrands Corp.*, 140 F.T.C. at 451 (initial decision) ("Corporate respondents acting in concert to further a common enterprise are each liable for the acts and practices of the others in furtherance of the enterprise").

96. To determine whether a common enterprise exists, courts will consider a variety of factors including: "common control; the sharing of office space and officers; whether

business is transacted through a maze of interrelated companies; the commingling of corporate funds and failure to maintain separation of companies; unified advertising; and evidence that reveals that no real distinction exists between the corporate defendants." *FTC v. Nat'l Urological Group, Inc.,* 645 F. Supp. 2d at 1182. Courts look for vertical or horizontal commonality. *FTC v. Network Servs. Depot, Inc.*, 617 F.3d 1127, 1142-43 (9th Cir. 2010) (noting evidence showing that the companies pooled resources, staff, and funds; shared common owners and managers; and participated to some extent in a common venture).

97. The common enterprise analysis is not an alter ego analysis. The entities formally may be separate corporations, but operate as a common enterprise. *FTC v. Grant Connect, LLC*, No. 2:09-CV-01349, 2011 U.S. Dist. LEXIS 123792, at *43 (D. Nev. Oct. 25, 2011).

2. Individual Liability

98. Individual Respondents Stewart Resnick, Lynda Resnick, and Matthew Tupper are directly liable for the violations, under Sections 5 and 12 of the FTC Act, given that they participated directly in or had the authority to control the deceptive acts or practices. (*See* CCFF ¶¶ 9-86). It is well established that an individual can be held liable for a corporation's violations of Section 5 if the individual formulates, controls or directs corporate policy. *See Benrus Watch Co. v. FTC*, 352 F.2d 313, 324-25 (8th Cir. 1965); *Griffin Sys., Inc.*, 117 F.T.C. 515, 582 (1994); *see also Standard Educators, Inc. v. FTC*, 475 F.2d 401, 403 (D.C. Cir. 1973). The Commission has also held that where an individual participates in preparation of deceptive representations, he may "be held liable for his own actions in violation of Section 5." *Griffin Sys., Inc.*, 117 F.T.C. at 583.

> When both a corporation and an individual are named in the complaint, to obtain a cease and desist order against the individual, Complaint Counsel must prove violations of the FTC Act by the corporation and that the individual either directly participated in the acts at issue or had authority to control them.

Daniel Chapter One, 2009 FTC LEXIS 157, at *275-76 (initial decision) (citing *FTC v. Standard Educ. Soc'y*, 302 U.S. 112, 119-20 (1937) (finding it proper for Commission to include individuals who were in charge and control of the affairs of respondent corporations in the Commission's cease and desist order).

3. The Order Sets Forth Appropriate Relief

99. The Order sets forth relief appropriate for this case.

> In carrying out this function the Commission is not limited to

> prohibiting the illegal practice in the precise form in which it is found to have existed in the past. If the Commission is to attain the objectives Congress envisioned, it cannot be required to confine its "road block" to the narrow lane the transgressor traveled; it must be allowed effectively to close all roads to the prohibited goal, so that its order may not be "by-passed" with impunity. Moreover, the Commission has wide discretion in its choice of a remedy deemed adequate to cope with the unlawful practices disclosed.

FTC v. Ruberoid Co., 343 U.S. 470, 473, 475 (1952); *Removatron Int'l Corp. v. FTC*, 884 F.2d at 1498 ("Our role in reviewing a Commission order has been defined by the Supreme Court: It has been repeatedly held that the Commission has wide discretion in determining the type of order that is necessary to cope with unfair practices found, and that Congress has placed the primary responsibility for fashioning orders upon the Commission.").

100. The "wide discretion" described in *FTC v. Ruberoid Co.* is subject only to two constraints: the order must bear a "reasonable relation" to the unlawful practices, *Jacob Siegel Co. v. FTC*, 327 U.S. 608, 612-13 (1946), and it must be sufficiently clear and precise that its requirements can be understood, *FTC v. Colgate-Palmolive Co.*, 380 U.S. at 392. *See also Thompson Med. Co. v. FTC*, 791 F.2d 189 (1986) (affirming an order requiring at least two adequate and well-controlled, double-blinded clinical studies for future efficacy claims for a topical analgesic).

101. In determining the appropriate scope of relief, the Commission considers the seriousness and deliberateness of the violations, the ease with which the unlawful conduct can be transferred to other products, and whether the respondents have a history of prior violations. *Telebrands Corp. v. FTC*, 457 F.3d 354, 358 (4th Cir. 2006); *Kraft, Inc. v. FTC*, 970 F.2d at 326; *Sears, Roebuck & Co. v. FTC*, 676 F.2d at 392; *Standard Oil Co. v. FTC*, 577 F.2d 653, 662 (9th Cir. 1978); *Thompson Med. Co.*, 104 F.T.C. at 832-33. All three elements need not be present to warrant fencing-in. *See Stouffer Foods Corp.*, 118 F.T.C. at 811; *Kraft, Inc.*, 114 F.T.C. at 142.

102. The size and duration of the deceptive advertising campaign also is considered in evaluating the seriousness of the violations. *Stouffer Foods Corp.*, 118 F.T.C. at 812-13; *Kraft, Inc.*, 114 F.T.C. at 140. For at least seven years, Respondents engaged in a marketing campaign, in multiple media (including print, Internet, public relations, and point of sale marketing) to promote the POM Products as having been proven to provide, or effectively providing, heart, prostate, and/or erectile function benefits. (*See* CCFF ¶¶ 325-578).

103. The seriousness of the Respondents violations stems from several factors. First, "the overall health ramifications" of the claims makes them serious. *Stouffer Foods Corp.*, 118 F.T.C. at 812-13. Respondents are urging consumers to purchase and use their products to treat, prevent, or reduce the risk of disease without a reasonable basis for doing so. Second, where, as here, a consumer is unable to assess, on their own, the validity of the claim, the seriousness of the violation is enhanced. *Id*.

104. Third, violations also have been found to be "serious" where "claims were consciously made despite flaws in the studies relied upon by [the respondent]." *See Schering Corp.*, 118 F.T.C. at 1121 (initial decision). Respondents claimed that their products were not only effective, but that their benefits were clinically proven. (*See* CCFF ¶¶ 328, 335, 340, 348, 361, 367, 371, 376, 384, 388, 405, 414, 418, 424, 429, 434, 441, 471, 494, 500, 535, 548, 555, 562, 567, 573, 575, 577, CCCL ¶ 40). They did this despite the fact that their data consisted largely either of unblinded, uncontrolled studies on questionable endpoints —such as the prostate and Aviram studies — or well-controlled, double-blind, randomized, placebo-controlled trials with negative results — such as the Ornish CIMT Study, Davidson CIMT Study (2009), Davidson BART/FMD Study, San Diego Study, and Forest Erectile Dysfunction Study (2007). (*See* CCFF ¶¶ 795, 857-58, 882, 914-15, 942, 1002, 1076).

105. The deliberateness of the violations is evidenced by the Respondents' "ready willingness to flout the law." *See Sears, Roebuck & Co. v. FTC*, 676 F.2d at 392. Respondents persisted in making the challenged claims despite expressions of concern about misleading marketing from the New York State Attorney General's office, the Council for Better Business Bureau's National Advertising Division, Dr. Pantuck, several Institutional Review Boards, the FTC, and the Food and Drug Administration's ("FDA"). (*See* CCFF ¶¶ 402, 662-84, 686-88). In addition, Respondents have expressed no remorse for their actions, and in fact are comfortable with continuing to make the challenged claims. (*See* CCFF ¶¶ 618-19, 953, 971-72, 1054, 1098, 1100).

106. A violation is transferrable where other products could be sold using similar techniques. *FTC v. Colgate-Palmolive Co.*, 380 U.S. at 395; *Sears, Roebuck & Co. v. FTC*, 676 F.2d at 392. Respondents sell a variety of foods and supplements, such as POMx bars, POMx iced tea and iced coffee, a POMx sports recovery beverage, Wonderful Pistachios, Wonderful Almonds, Fiji Water, citrus fruit, and wine, that could also be promoted using the kinds of health related representations that were challenged in this matter. (*See* CCFF ¶¶ 12, 123). Indeed, they have a made a variety of additional representations, not challenged in the Commission's complaint, about the potential of their products for other conditions, such as Alzheimer's disease and sports recovery. (*See* CCFF ¶¶ 241, 308, 326, 341, 349, 495, 570, 668). Further, the Respondents have researched potential health benefits of Wonderful Pistachios and Fiji Water. (*See* CCFF ¶ 725).

107. The Commission has entered orders covering many of a company's products on the basis of violations as to a single product. *Litton Indus., Inc.*, 97 F.T.C. 1, 78-80 (1981), *aff'd as modified*, 676 F.2d 364 (9th Cir. 1982); *Sears Roebuck & Co.*, 95 F.T.C. 406, 515-22 (1980), *aff'd*, 676 F.2d 385 (9th Cir. 1982). Here, the Respondents made deceptive representations regarding three products – POM Juice, POMx Pills, and POMx Liquid. (CCCL ¶¶ 40, 74, 90-91).

108. "The more egregious the facts with respect to a particular element, the less important it is that another negative factor be present." *Sears, Roebuck & Co. v. FTC*, 676 F.2d at 392; *see also Thompson Med. Co.*, 104 F.T.C. at 833.

109. Part I of the Order addresses disease claims made for any POM Product (defined as any food, drug or dietary supplement containing pomegranate or its components). It provides that the necessary substantiation for future claims that any POM Product is effective in the diagnosis, cure, mitigation, treatment, or prevention of any disease – including heart disease, prostate cancer, or erectile dysfunction – is approval by the FDA, which may be provided in the form of a tentative final or final over-the-counter drug monograph, a new drug application, or labeling approval under regulations promulgated pursuant to the Nutrition Labeling and Education Act of 1990 ("NLEA").

110. Deference to the FDA's standards and its evaluation of scientific evidence is consistent with prior Commission practice. "It is well settled that in establishing substantiation requirements, the Commission accords substantial weight to FDA regulations and proposed rules." *Removatron Int'l Corp.,* 111 F.T.C. at 305.

111. In *Thompson Med. Co.*, after determining, under a *Pfizer* analysis, that the proper level of substantiation for the company's advertising claims for the topical analgesic Aspercreme was two well-controlled clinical tests, the Commission went on to note,

> [w]e are additionally persuaded to use this level of substantiation because … this is the standard currently being required [by the FDA]. We believe that advertisers of drug products subject to the joint jurisdiction of the FTC and the FDA will benefit from greater regulatory certainty if they can act with reasonable assurance that the two agencies will accept the same evidence to demonstrate the safety and efficacy of a particular ingredient.

Thompson Med. Co., 104 F.T.C. at 821-26.

112. In two settlements, the Commission prohibited respondents from representing that a product promoted hair growth or prevented hair loss unless the product was the subject of a new drug application approved by the FDA for that purpose. *See Synchronal Corp.*, 117 F.T.C. 724, 743 (1994) (consent order); *Nature's Bounty, Inc.*, 120 F.T.C. 206, 237 (1995) (consent order).

113. In the NLEA, Congress directed the FDA to promulgate regulations authorizing claims about diet-disease relationships only if the FDA determined,

> based on the totality of the publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.

21 U.S.C. § 343(r)(3)(B)(i) (2012). The Commission stated in its May 1994 *FTC Enforcement Policy Statement On Food Advertising*: "The Commission regards the 'significant scientific agreement' standard, as set forth in the NLEA and FDA's regulations, to be the principal guide to what experts in the field of diet-disease relationships would consider reasonable substantiation for an unqualified health claim." *Enforcement Policy Statement On Food Advertising*, 59 Fed. Reg. 28,388, 28,393 (FTC June 1, 1994), *also available at* CX0002_0006.

114. The Part I relief proposed is consistent with the relief approved in recent Commission settlements. *See The Dannon Co., Inc.*, 151 F.T.C. 62, 93 (2011) (consent order); *Nestle HealthCare Nutrition, Inc.*, 151 F.T.C. 1, 12-13 (2011) (consent order); *FTC v. Iovate Health Sciences U.S.A., Inc.*, No. 10-CV-587 (W.D.N.Y. July 29, 2010) (stipulated final judgment and order), *available at* http://www.ftc.gov/os/caselist/0723187/100729iovatestip.pdf.

115. Part II of the Order prohibits, in connection with the marketing of any Covered Products (defined as any food, drug, or dietary supplement), misrepresentations about the existence, content, validity, results, conclusions or interpretations of any test, study, or research. This provision is appropriate in light of Respondents' deceptive establishment claims. (*See* CCCL ¶ 74).

116. Courts have granted the Commission similar injunctive relief prohibiting the misrepresentation of any tests studies, or research. *See, e.g.*, *FTC v. QT, Inc.*, No. 1:03-cv-03578 (N.D. Ill. Nov. 13, 2006) (final judgment order), *available at* http://www.ftc.gov/os/caselist/0323011/061113qrayfinaljdgmntorder.pdf (for any drug, device, or other product purporting to provide health-related benefits); *FTC v. Nat'l Urological Group, Inc.*, 1:04-CV-3294-CAP (N.D. Ga. Dec. 16, 2008) (final judgment and permanent injunction), *available at* http://www.ftc.gov/os/caselist/0223165/090115nugjdgmthitech.pdf (for any health-related service or program, weight loss product, erectile dysfunction product, dietary supplement, food, drug, or device); *Direct Mktg. Concepts, Inc.*, No. 1:04-cv-11136-GAO (D. Mass. Aug. 13, 2009) (final order and judgment for permanent injunction),

available at http://www.ftc.gov/os/caselist/0233138/090827directfo.pdf (for any food, drug, dietary supplement, cosmetic, or device). The Commission has also included such a provision in numerous settlements. *See, e.g.*, *Brown*, Docket No. C-4337, 2011 FTC LEXIS 248 (F.T.C. Oct. 13, 2011) (consent order) (for any product or service); *Oreck Corp.*, 151 F.T.C. 289 (2011) (consent order) (for any product); *The Dannon Co., Inc.*, 151 F.T.C. 62 (2011) (consent order) (for any yogurt, dairy drink, or food or drink containing a probiotic); *Nestle HealthCare Nutrition, Inc.*, 151 F.T.C. 1 (2011) (consent order) (for any drink product containing probiotics, or certain nutritionally complete drinks); *Kellogg Co.*, Docket No. C-4262, 2009 FTC LEXIS 154 (F.T.C. July 27, 2009) (consent order) (for any morning food or snack food); *Native Essence Herb Co.*, Docket No. 9328, 2009 FTC LEXIS 101 (F.T.C. May 7, 2009) (consent order) (for any product).

117. Part III of the Order addresses health benefit claims for Covered Products. It provides that representations, other than representations covered by Part I, about the health benefits, performance, or efficacy of any Covered Product must be non-misleading and supported by "competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted in the relevant scientific fields, when considered in light of the entire body of relevant and reliable evidence, to substantiate that the representation is true."

118. "Commission orders requiring respondents to have competent and reliable scientific evidence, as defined in this Order, that is based on the expertise of professionals in the area and that has been conducted and evaluated by persons qualified to do so, are typical and have been consistently upheld." *Daniel Chapter One*, 2009 FTC LEXIS 157, at *278-79 (initial decision) (citing *Telebrands Corp.*, 140 F.T.C. at 347; *aff'd*, 457 F.3d 354; *Kraft, Inc.*, 114 F.T.C. at 149, *aff'd*, 970 F.2d 311; *Thompson Med. Co.*, 104 F.T.C. at 844, *aff'd*, 791 F.2d at 192; *Removatron Int'l Corp.*, 111 F.T.C. at 318, *aff'd*, 884 F.2d at 1498).

119. The seriousness and deliberateness of Respondents' violations, the duration of the deceptive advertising campaign, the difficultly that consumers have in judging the truth or falsity of the challenged claims, and the transferability of the claims justifies the appropriateness of the Order's fencing-in relief.

Respectfully Submitted,

Date: January 11, 2012

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APPENDIX A

Tables Categorizing the Challenged False Establishment and Unsubstantiated Efficacy Claims

Table 1: Ads Making Both False Establishment Claims and Unsubstantiated Efficacy Claims†

Ad	Ad Exhibit Number	Heart Disease	Prostate Cancer	Erectile Dysfunction
POM Juice Print Ads (12) CCFF ¶¶ 325-340, 344-348, 357-388	CX0016 ("Drink and Be Healthy" Ad)	✓[P, R]		
	CX0029 ("10 out of 10 People" Ad)	✓		
	CX0031 ("Floss your arteries. Daily" Ad)	✓		
	CX0034 ("Amaze your cardiologist" Ad)	✓		
	CX0103 ("Decompress" Ad)	✓		
	CX0109 ("Heart Therapy" Ad); CX0192 ("What gets your heart pumping" Ad)	✓[P, R]		
	CX0260/1426 Ex. B ("Drink to Prostate Health" Ad)		✓[T]	
	CX0274/1426 Ex. C ("I'm off to save prostates" Ad)		✓[P, R]	
	CX0314 ("Drink to Prostate Health" Magazine Wrap); CX0372/CX0379/CX0380 ("Lucky I have super health powers" Magazine Wrap)		✓	
	CX0475/1426 Ex. A (Juice Bottle Hang Tag)	✓	✓	✓
*****POMx Pill Print Ads (13) CCFF ¶¶ 397-434	CX0120 ("One Small Pill for Mankind" Ad); CX0122 ("Science, Not Fiction" Ad)		✓	
	CX0169/1426 Ex. L ("The power of POM" Ad); CX0180/1426 Ex. K ("Antioxidant Superpill" Ad); CX0279 ("Science, Not Fiction" Ad)	✓	✓	
	CX0280 ("Live Long Enough" Ad); CX0328 ("Your New Health Care Plan" Ad); CX0331/1426 Ex. J ("Healthy Wealthy" Ad); CX0337 ("The First Bottle You Should Open" Ad)	✓	✓	
	CX0342/CX0353 ("Take Out A Life Ins" Ads); CX0348/CX0350 ("24 Scientific Studies" Ads)	✓	✓	
	CX0351/CX0355 ("Only Antioxidant Supplement Rated X" Ads)	✓	✓	✓
	CX1426 Ex. I ("Antioxidant Superpill" brochure)	✓	✓	
*****News-letters (2) CCFF ¶¶ 435-441	CX1426 Ex. M (POMx Heart Newsletter)	✓		
	CX1426 Ex. N (POMx Prostate Newsletter)		✓	
Web Promo (4) CCFF ¶¶ 443-535	CX0473(POMWonderful.com); CX0473 (POMWonderful.com Community site); CX0473 (Pomegranatetruth.com); *CX0473 (POMPills.com)	✓	✓	✓
PR Promo (7) CCFF ¶¶ 541-567, 572-578	CX0013 (Jan. 2003 POM Juice press release)	✓		
	CX0044 (Sept. 2005 POM Juice press release)	✓		
	*****CX0065_0002 (July 2006 POMx press release)	✓[P, R]	✓[T]	
	CX0128_0002 (June 2007 POM Juice press release)			✓[T]
	CX0473 (June 2008, Tupper on Fox Business show)	✓[T]	✓[T]	
	CX0472 (Feb. 2009, Lynda Resnick on CBS *Early Show*)		✓	
	CX0473 (Mar. 2009, Lynda Resnick interview in Newsweek.com)		✓[P, R]	✓

✓ = The ad makes prevention (P), risk reduction (R), and treatment (T) claims, unless otherwise noted in superscript.

***** = The ad makes establishment claims and efficacy claims for both POMx and POM Juice.

† The ads making false establishment claims (Table 1) by their nature also make unsubstantiated efficacy claims.

APPENDIX A

Tables Categorizing the Challenged False Establishment and Unsubstantiated Efficacy Claims

Table 2: Ads Making Unsubstantiated Efficacy Claims Only

Ad	Ad Exhibit Number	Heart Disease	Prostate Cancer	Erectile Dysfunction
POM Juice Ads (4) CCFF ¶¶ 341-343, 349-356, 536-540	CX0033 ("Life Support" Print Ad)	✓[P, R]		
	CX0036, CX0188 ("Cheat Death" Print Ad)	✓[P, R]		
	CX0463 ("Heart Therapy" Banner Ad)	✓[P, R]		
	CX0466, 1426 Ex. H ("Off to save prostates" Banner Ad)		✓[P, R]	
PR Promo (1) CCFF ¶¶ 570-571	CX0473 (Nov. 2008, Lynda Resnick on *Martha Stewart* Show)		✓	

✓ = The ad makes prevention (P), risk reduction (R), and treatment (T) claims, unless otherwise noted in superscript.

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COMPLAINT COUNSEL'S TRIAL WITNESS INDEX

NAME	TITLE	COMPANY	TRANSCRIPT PAGES†	TRANSCRIPT DATE	VOLUME
Mark Lawrence Dreher	Former Vice President of Scientific and Regulatory Affairs	POM Wonderful, LLC	Tr. 525-588	6/6/2011	Volume 5
James Eastham (Expert)	Chief of Urology, Department of Surgery and Director of Clinical Research, Urology	Memorial Sloan-Kettering Cancer Center	Tr. 1204-1351	6/9/2011	Volume 8
Philip Kantoff	Division Chief, Genitourinary Oncology Program	Dana-Farber Cancer Institute, Harvard Medical School	Tr. 3256-3265	11/4/2011	Volume 19
Elizabeth Leow (Hendry)	Vice President and Executive Creative Director	Roll Global, LLC	Tr. 414-519	5/27/2011	Volume 4
Michael B. Mazis	Professor Emeritus of Marketing	Kogod School of Business, American University	Tr. 2651-2761	9/14/2011	Volume 15
Arnold Melman (Expert)	Professor and Chairman, Department of Urology	Albert Einstein College and Montefiore Medical Center	Tr. 1069-1197	6/8/2011	Volume 7
George Michael Perdigao	President of Advertising and Corporate Communications	Roll Global, LLC	Tr. 589-674	6/6/2011	Volume 5
Fiona Posell	Former Vice President of Corporate Communications and Public Relations Former Vice President of Corporate Communications	Roll Global, LLC POM Wonderful, LLC	Tr. 297-407	5/26/2011	Volume 3
Lynda Rae Resnick	Vice-Chairman (no official title)	Roll Global, LLC POM Wonderful, LLC	Tr. 72-291	05/24/2011-05/25/2011	Volumes 1-2
Stewart A. Resnick	Chairman and President Chairman	Roll Global, LLC POM Wonderful, LLC	Tr. 1628-1791	6/13/2011 & 6/15/2011	Volumes 9-10
Jeffrey Alan Rushton	Former Director of Online Marketing	POM Wonderful, LLC	Tr. 1352-1404	6/9/2011	Volume 8

† None of the trial testimony was *in camera.*

IN THE MATTER OF
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COMPLAINT COUNSEL'S TRIAL WITNESS INDEX

NAME	TITLE	COMPANY	TRANSCRIPT PAGES†	TRANSCRIPT DATE	VOLUME
Frank M. Sacks (Expert)	Professor of Cardiovascular Disease Prevention, Department of Nutrition Professor of Medicine Senior Physician, Channing Laboratory and Cardiology Division	Harvard School of Public Health Harvard Medical School Brigham and Women's Hospital	Tr. 1410-1626	6/13/2011	Volume 9
Meir Jonathan Stampfer (Expert)	Professor of Epidemiology and Nutrition and Faculty Member, Division of Biological Sciences Professor of Medicine Director, Chronic Disease Epidemiology Unit Faculty Member	Harvard School of Public Health Harvard Medical School Brigham and Women's Hospital Dana-Farber Cancer Institute, Harvard Medical School	Tr. 689-884	6/7/2011	Volume 6
David Wayne Stewart (Expert)	Professor of Marketing	A. Gary Anderson Graduate School of Management, University of California, Riverside	Tr. 3158-3242	10/14/2011	Volume 18
Matthew Tupper	Former President	POM Wonderful, LLC	Tr. 885-1069	6/7/2011-6/8/2011	Volumes 6-7

† None of the trial testimony was *in camera.*

IN THE MATTER OF
POM WONDERFUL LLC
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INDEX OF DEPOSITIONS AND OTHER PRIOR TESTIMONY CITED BY COMPLAINT COUNSEL

NAME	TITLE	COMPANY	EXHIBIT NUMBER	DATE
Michael Aviram	Professor and Head of the Lipid Research Laboratory	Technion Faculty of Medicine, Rappaport Institute for Research in Medical Sciences and Rambam Medical Center	CX1358 (FTC Dep.)	3/7/2011
Robert Wesley Bryant	Chief Financial Officer	Roll Global, LLC	CX1354 (FTC Dep.)	2/3/2011
Arthur Louis Burnett, II	Professor of Urology Director of the Basic Science Laboratory in Neurourology Director of the Male Consultation Clinic of the Sexual Medicine Division, Department of Urology	Johns Hopkins University School of Medicine Johns Hopkins University School of Medicine Johns Hopkins Hospital	PX0349 (FTC Dep.)	4/8/2011 (expert)
Ronald Richard Butters	Professor Emeritus of English and Cultural Anthropology	Duke University	PX0350 (FTC Dep.)	4/8/2011 (expert)
Michael Anthony Carducci	Professor of Oncology and Urology	John Hopkins University School of Medicine	CX1340 (FTC Dep.)	12/13/2010
Michael H. Davidson	Medical Director	Radiant Research	CX1336 (FTC Dep.)	12/3/2010
Robert Clifford deGroof	Former Chief Scientific Officer	Accelovance, Inc.	CX1345 (FTC Dep.)	12/21/2010
Jean deKernion	Former Chairman of the Department of Urology and Senior Associate Dean for Clinical Affairs	David Geffen School of Medicine, UCLA	PX0351 (FTC Dep.)	4/6/2011 (expert)
Christopher Forest	Assistant Professor of Clinical Family Medicine	Keck School of Medicine, University of Southern California	CX1337 (FTC Dep.)	12/6/2010
Bradley Kent Gillespie	Vice President of Clinical Development	POM Wonderful, LLC	CX1377 (OS Dep.) CX1349 (FTC Dep.)	11/11/2010 1/20/2011
Staci Glovsky	Former General Manager of POMx	POM Wonderful, LLC	CX1347 (FTC Dep.)	1/12/2011
Irwin Goldstein	Director Clinical Professor of Surgery	San Diego Sexual Medicine, Alvarado Hospital University of California, San Diego	PX0352 (FTC Dep.)	4/11/2011 (expert)
David Heber	Professor of Medicine and Public Health and Director, Center for Human Nutrition	David Geffen School of Medicine, University of California Los Angeles	CX1352 (FTC Dep.) PX0353 (FTC Dep.)	1/28/2011 3/30/2011 (expert)
Sarah Hemmati	Chief Financial Officer	POM Wonderful, LLC	CX1355 (FTC Dep.)	2/3/2011
Malcom Knight	Vice President Product Development & Quality	POM Wonderful, LLC	CX0359 (Trop. Dep.)	8/24/2010
Diane Kuyoomjian	Former Senior Vice President of Marketing	POM Wonderful, LLC	CX1378 (OS Dep.) CX1357 (FTC Dep.)	12/21/2010 2/10/2011
Elizabeth Leow (Hendry)	Vice President and Executive Creative Director	Roll Global, LLC	CX1356 (FTC Dep.)	2/4/2011
Dean Ornish	Founder and President	Preventative Medicine Research Institute	CX1339 (FTC Dep.) PX0355 (FTC Dep.)	12/10/2010 4/26/2011 (expert)
Harin Padma-Nathan	Former Director Former Clinical Professor of Urology	The Male Clinic Keck School of Medicine, University of Southern California	CX1338 (FTC Dep.)	12/7/2010

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INDEX OF DEPOSITIONS AND OTHER PRIOR TESTIMONY CITED BY COMPLAINT COUNSEL

NAME	TITLE	COMPANY	EXHIBIT NUMBER	DATE
George Michael Perdigao	President of Advertising and Corporate Communications	Roll Global, LLC	CX1365 (TCCC Dep.) CX1370 (Welch Dep.) CX1373 (OS Dep.) CX1348 (FTC Dep.)	1/8/2010 5/21/2010 10/1/2010 1/14/2011
David Jay Reibstein	Professor of Marketing	The Wharton School, University of Pennsylvania	PX0356 (FTC Dep.)	4/18/2011 (expert)
Lynda Rae Resnick	Vice-Chairman (no official title)	Roll Global, LLC POM Wonderful, LLC	CX1362 (TCCC Dep.) CX1368 (Welch Dep.) CX1375 (Trop. Dep.) CX1359 (FTC Dep.)	12/9/2009 5/11/2010 10/11/2010 4/13/2011
Stewart A. Resnick	Chairman and President Chairman	Roll Global, LLC POM Wonderful, LLC	CX1363 (TCCC Dep.) CX1367 (Welch Dep.) CX1372 (Trop. Dep.) CX1376 (OS Dep.) CX1360 (FTC Dep.)	12/11/2009 5/5/2010 9/24/2010 10/28/2010 4/12/2011
Jeffrey Alan Rushton	Former Director of Online Marketing	POM Wonderful, LLC	CX1346 (FTC Dep.)	12/21/2010
Michael D. Sumner	Former Senior Research Associate	Preventative Medicine Research Institute	CX1344 (FTC Dep.)	12/17/2010
Matthew Tupper	Former President	POM Wonderful, LLC	CX1364 (TCCC Dep.) CX1369 (Welch Dep.) CX1371 (Trop. Dep.) CX1374 (OS Dep.) CX1406 (Trop. Tr.) CX1353 (FTC Dep.)	12/22/09 5/19/2010 8/4/2010 10/4/2010 11/4/2010 2/2/2011

***In the Matter of POM Wonderful LLC, et al.,* Docket No. 9344**

Complaint Counsel's Exhibit Index

Pursuant to Rule 3.46(b), Complaint Counsel submits its exhibit index. Exhibits listed in the table below were admitted into evidence as part of Complaint Counsel's and Respondents' Joint Exhibit List (JX0002) on May 24, 2011 (Vol. 1, Tr. 7). Exhibits not used at trial, or cited to in Complaint Counsel's proposed findings of fact or post-trial brief have been omitted. Exhibits that have been afforded *in camera* treatment, pursuant to the Court's Order on *In Camera* Treatment dated May 24, 2011, are indicated. It is Complaint Counsel's understanding that Respondents will submit their own exhibit index.

EXHIBIT NUMBER	DOCUMENT TITLE	DATE	RELEVANT TRANSCRIPT PAGES	IN CAMERA
CX0001	Lynda Resnick, "Rubies in the Orchard"	2009	Tr. 12 (opening stmt); Tr. 72, 75-78, 83-86, 122-23, 130-31, 135-40, 146-47, 216-17, 230-231, 257-58, 274-82(LRR); Tr. 2839-41, 2864 (Butters)	
CX0002	FTC Enforcement Policy Statement on Food Advertising	5/1/1994		
CX0003	L. Dornfield outline of meeting with L. Resnick (scope of research, timeline, etc.)	3/19/2001		
CX0004	Memo from L. Resnick re: Details on the Pomegranate Juice Project	3/27/2001	Tr. 147-49 (LRR)	
CX0011	F.Posell email to self re POM PR Plan with attachment	1/1/2003	Tr. 327-31 (Posell)	
CX0012	E-mail from L. Resnick to F. Posell et al re POM Memo	1/5/2003		
CX0013	E-mail from Risa Schulman et al. to Fiona Posell re POM Wonderful Announcement - Jan 9, 2003	1/9/2003	Tr. 358-64 (Posell)	
CX0016	POM Juice Print Ad - Drink and Be Healthy; dissemination spreadsheet	10/12/2003	Tr. 2926-29 (Butters); Tr. 2994-95 (Tupper)	
CX0017	G. Johnson, "An FDA-Authorized Qualifed Health Claim for Pomegranate Juice - A Proposal to POM Wonderful"	11/24/2003		
CX0023	Email from J. Regal to R. Schulman et al re POM Website -- Update & Next Steps (att: Studies out in six months.doc)	5/28/2004		
CX0024	Email from J. Regal to F. Posell, R. Schulman et al re POM website and notes from LRR & Regal meeting	6/1/2004	Tr. 94-104 (LRR)	
CX0025	Email chain (M. Tupper, L. Resnick, B. Elibri, J. Regal et al) re Materials for meeting with David Kessler	7/10/2004		
CX0028	Email from F. Posell to J. Regal re article on "misleading health info"	9/8/2004		
CX0029	POM Juice Print Ad - Studies show that 10 out of 10 people don't want to die; dissemination spreadsheet	11/1/2004		

CX0031	POM Juice Print Ad - Floss your arteries. Daily; dissemination spreadsheet	12/1/2004	Tr. 953-59, 2995-96 (Tupper); Tr. 2911-12 (Butters); Tr. 3189-92 (Stewart); Tr. 487 (Leow)	
CX0033	POM Juice Print Ad - Life Support; dissemination spreadsheet	12/30/2004	Tr. 488 (Leow); Tr. 1065-66 (Tupper)	
CX0034	POM Juice Print Ad - Amaze your cardiologist; dissemination spreadsheet	2/1/2005	Tr. 488 (Leow); Tr. 953-59 (Tupper); Tr. 2910-11, 2921-26 (Butters); Tr. 3192 (Stewart)	
CX0036	POM Juice Print Ad - Cheat death; dissemination spreadsheet	3/10/2005	Tr. 475-77 (Leow); Tr. 2987-94 (Tupper); Tr. 3196-97 (Stewart)	
CX0037	NAD Case Report (#4303)	3/30/2005		
CX0038	Email from S. Henig to F. Posell, et al. re: WSJ article	4/4/2005		
CX0039	Email from P. Holmgren to All POMWonderful et al re: Today's WSJ article about health benefits of pomegranates	4/5/2005		
CX0041	Email from F.Posell to L.Resnick re: Washington Post inquiry	6/14/2005		
CX0043	Email from F. Posell to M. Tupper re: Medical paper in AJC (crediting Resnick Foundation rather than POM)	8/8/2005	Tr. 348-88, 99 (Posell)	
CX0044	Email from F.Posell to L.Resnick et al. re: Dean Ornish	9/16/2005	Tr. 388-93, 405-06 (Posell)	
CX0049	E-mail from Matt Tupper to Fiona Posell, et al re cancer page options	2/6/2006	Tr. 400-02 (Posell)	
CX0050	E-mail from Matt Tupper to Fiona Posell, et al re cancer page options, deciding on option 1	2/6/2006	Tr. 401-05 (Posell)	
CX0054	Email chain from F. Posell to S. Glovsky, et al. email re: Discussion with Lynda	3/29/2006	Tr. 393-98 (Posell)	
CX0055	NAD Case Report (#4468)	4/5/2006		
CX0058	POM Family of Products Meeting Notes	6/16/2006		
CX0060	Email chain from L. Resnick to M. Tupper et al. re: Prostate Cancer Research appears in 7/1/06 edition of The Scotsman (UK)	7/1/2006	Tr. 200-204 (LRR)	
CX0061	Email from D. Ornish to L. Resnick et al. re: publication of PJ myocardial perfusion study	7/2/2006	Tr. 204-207 (LRR)	
CX0062	Email chain from F. Posell to M. Dreher re: FW: Press release announcing health benefits of POMx	7/3/2006	Tr. 372-80 (Posell)	
CX0063	New York Times Article titled "Linking Pomegranates to Prostate Health" by Eric Nagourney	7/4/2006		
CX0064	Email chain from H. Liker to M. Dreher et al. re: FW: Johns Hopkins NDA	7/5/2006		Entire document

CX0065	POM Wonderful Press Release titled "POMx, a Highly Concentrated Form of Healthy Pomegranate Antioxidants, Becomes Available to Consumers for the First Time" w/attached metadata	7/10/2006	Tr. 207-209 (LRR); Tr. 377, 380-83 (Posell)	
CX0069	Chart titled "Potential Claims"	7/18/2006	Tr. 210 (LRR)	
CX0070	Email from J. Regal to L. Resnick et al. re: POMx pills concept statement and medical summary	7/24/2006	Tr. 210-211 (LRR)	
CX0071	Final Copy for Prostate Cancer Ad (8-4-06)	8/4/2006	Tr. 215-16 (LRR)	
CX0072	Email chain from M. Tupper to L. Resnick et al. re: Prostate Cancer Ad	8/6/2006	Tr. 211-14 (LRR); Tr. 1002-03 (Tupper)	
CX0073	Memo from S. Glovsky to L. Leow et al. re: POMx Pills and POMx Liquid Direct Response Agency Kickoff	8/7/2006		
CX0084	October 11, 2006 Email from Staci Glovsky	10/11/2006	Tr. 923-25 (Tupper)	
CX0086	Email from F.Posell to M. Dreher re: Your meeting last Tuesday (outcome of Davidson IMT project)	10/20/2006		
CX0087	Email from M. Dreher to M. Tupper et al. re CSPI - Review on Mangosteen/Noni vs. POM Wonderful Juice with superfruit attachment	10/26/2006	Tr. 1005-1007 (Tupper)	
CX0092	Email chain from M. Dreher to S. Glovsky et al. re: CONFIDENTIAL - Please Review - I'm about to send to legal	1/9/2007		
CX0094	Email chain from S. Glovsky to R. Pfeffer forwarding Email from C. Rainey to S. Glovsky et al. re: Structure Function Claims	1/15/2007	Tr. 541-42 (Dreher)	
CX0095	Email chain from R. Jones to L. Leow et al. re: PLEASE CALL Liz asap!	1/17/2007	Tr. 511-13 (Leow)	
CX0098	Email chain from M. Tupper to M. Dreher et al. re Juice Claims List	2/1/2007		
CX0100	Post POM Research Summit Strategic Planning Overview w/ attached metadata	2/26/2007		
CX0101	POM Juice Print Ad - Self-preservation; dissemination spreadsheet	2/26/2007		
CX0103	POM Juice Print Ad - Decompress; dissemination spreadsheet	3/1/2007	Tr. 2930-34 (Butters); Tr. 3220-22 (Stewart)	
CX0105	Email from F. Posell to L. Resnick et al. re: POM history including medical historical info	3/8/2007	Tr. 332-40 (Posell)	
CX0108	Email from M. Dreher to P. Holmgren re: 2007 juice study publications	3/20/2007		

CX0109	POM Juice Print Ad - Heart therapy; dissemination spreadsheet	4/1/2007	Tr. 585 (Dreher)	
CX0115	POM Wonderfual Press Release titled "POM Wonderful Introduces POMx Pills, Powerful Antioxidant Supplement Made from California Wonderful Pomegranates"	5/9/2007		
CX0120	POMx Print Ad - One small pill for mankind; dissemination spreadsheet	5/28/2007	Tr. 1003-05 (Tupper)	
CX0122	POMx Print Ad - Science, not fiction ($20M); dissemination spreadsheet	6/1/2007		
CX0126	Email chain from J. Stein to L. Resnick et al. re: The ad for POM pills and two pages of ad copy w/handwritten notes	6/23/2007	Tr. 497-501 (Leow)	
CX0127	Email from F. Posell to M. Tupper and M. Dreher re: Updated ED release	6/25/2007	Tr. 1718-19 (SAR)	
CX0128	Email from P. Holmgren to All PomWonderful re: POM ED Press Release	6/27/2007	Tr. 261-263 (LRR)	
CX0129	Creative Brief re: POMx Revised Print Ad	6/28/2007		
CX0130	Creative brief for POMx print ad, with handwritten markup	6/28/2007		
CX0131	Creative Brief re: POMx Revised Print Ad	6/28/2007		
CX0132	Q1 2007 POM Research Summary (Chart) w/attached metadata	7/18/2007		
CX0133	M. Tupper to M. Dreher email re: UCLA dedication of human nutrition lab to the Resnicks	8/14/2007	Tr. 2027-28 (Heber)	
CX0136	Online Juice Survey Aug. 2007 Power Point presentation	8/29/2007		
CX0147	New/Change in Artwork - Concept Development and Approval	10/18/2007		
CX0163	Email from M. Dreher to C. Nelson et al. re: Juice Superpower study to be published	12/14/2007		
CX0169	POMx Print Ad - The power of POM, in one little pill; dissemination spreadsheet	1/6/2008	Tr. 960-63 (Tupper)	
CX0170	G. Beggs to C. Nelson email re: hits on PomegranateTruth.com	1/15/2008		
CX0173	Email chain from J. Rushton to R. Pfeffer email re: I only found two (prostate cancer metatags)	1/24/2008	Tr. 1385-87 (Rushton)	
CX0177	POM Pills Website Printout	1/28/2008	Tr. 172-47 (LRR)	
CX0180	POMx Print Ad - The antioxidant superpill ($23M); dissemination spreadsheet	2/3/2008		
CX0182	Proposed responses to Emily Sohn for Superfruits article in LA Times	2/11/2008		
CX0185	Email from C. Nelson to A. Murtaza et al. re 2.21 POM Lynda Meeting Recap with attachment	2/26/2008	Tr. 626-29 (Perdigao)	
CX0188	POM Juice Print Ad - Cheat death.	4/1/2008	Tr. 191-95 (LRR)	

CX0192	POM Juice Print Ad - What gets your heart pumping?; dissemination spreadsheet	5/1/2008	Tr. 1065-66 (Tupper)	
CX0193	Email from M. Cregar to M. Tupper et al. re: revised POM Wonderful spot on NBC Universal	5/6/2008	Tr. 1056-59 (Tupper)	
CX0194	Email from M. Perdigao to S. McFillin re: inadequate testing for POM Wonderful spot on NBC Universal	5/6/2008	Tr. 661-65 (Perdigao)	
CX0200	Email from J. Rushton to M. Shreeves re: Creative Brief and Initial Content	6/2/2008	Tr. 1392-95 (Rushton)	
CX0203	Email from J. Rushton to S. Bowerman et al. re: Heart Health	6/4/2008		
CX0209	Email from M. Cregar to M. Tupper re: blogger package	6/24/2008	Tr. 1398-1402 (Rushton)	
CX0211	Email from L. Resnick to M. Perdigao, et al. re: health messaging, marketing, and 2008 launch efforts	6/25/2008		
CX0214	E-mail from M. Perdigao to L. Leow re POM Juice creative development	7/18/2008	Tr. 510-11 (Leow); Tr. 631-32 (Perdigao)	
CX0215	Email from M. Perdigao to E. Gettman, et al. attaching 11 approved outdoor headlines (POM juice campaign)	7/24/2008	Tr. 632-37 (Perdigao)	
CX0217	Email from D. Kuyoomjian to B. Fischer et al. re: POM 7/21 LRR Meeting Recap with attachment	8/4/2008		
CX0219	Email from L. Rubin to D. Kuyoomjian Medical Facts Sheet Summary w/attachments	8/6/2008		
CX0221	Marketing: Beverages power-point presentation	8/6/2008		
CX0236	TIME Magazine "Drink to Prostate Health" Ad, and other antioxidant and prostate health website and Ad Copy	9/9/2008	Tr. 496-97 (Leow)	
CX0238	Email from V. DeCarbo to D. Kuyoomjian et al., re POM Key Messaging	9/16/2008		
CX0242	B. Fisher to J. Sugarman email re: Comcast pushback on support for health claims	10/3/2008		
CX0243	E-mail from D. Kuyoomjian to L. Leow et al. re: POM comic book headline directions	10/8/2008	Tr. 507-10 (Leow)	
CX0246	Email from C. Nelson to K. Genkinger, et al., re: Copy Points for Banner Ads	10/10/2008		
CX0247	Email from D. Kuyoomjian to A. Murtaza et al. re: POM LRR Meeting Notes with attachment 10/16/08	10/20/2008	Tr. 1369-1372 (Rushton)	
CX0248	M. Perdigao to D. Kuyoomjian, et al. email re: L. Resnick-approved ad taglines	10/20/2008	Tr. 506-07 (Leow)	
CX0251	POM Juice Print Ad - Imitation may be sincere, but is it pure?; dissemination spreadsheet	11/1/2008	Tr. 1040-42 (Tupper)	

CX0252	Email from H. Mizrahi to D. Kuyoomjian, et al. re: updated briefs for online ads, homepage refresh	11/12/2008	Tr. 1395-1398 (Rushton)	
CX0255	Email from A. Pantuck to C. Belmonte re: FDA - IRB Information for POM (attaching FTC Dietary Supplements Advertising Guide & 5/8/2008 letter from M. Dreher to A. Pantuck)	11/21/2008		
CX0259	Report: December 2008 AccentHealth Panel Ad Effectiveness	12/1/2008	Tr. 42 (opening stmt)	
CX0260	POM Juice Print Ad - Drink to prostate health; dissemination spreadsheet	12/1/2008	Tr. 585 (Dreher); 2943-44 (Butters)	
CX0261	D. Kuyoomjian to M. Flynn, et al. email re: Pom juice banners & homepages follow-up	12/9/2008	Tr. 1372-74 (Rushton)	
CX0262	Email from M. Tupper to D. Kuyoomijian et al. re: Medical Research (Results Summary)	12/16/2008	Tr. 938-41 (Tupper)	
CX0264	Email chain from R. Pfeffer to M. Perdigao et al re: Pills Ad Brief - Your Input Please w/attachments	1/12/2009		
CX0265	Email thread from R. Pfeffer to M. Perdigao et al. re: Pills Ad brief	1/12/2009	Tr. 665-68 (Perdigao)	
CX0266	Email from D. Kuyoomjian to M. Perdigao et al. re New POMx Pills Ad with attachments	1/12/2009	Tr. 1007-1010 (Tupper)	
CX0269	Email from D. Kuyoomjian to M. Perdigao, et al. re POM health claims meeting preparation	1/22/2009	Tr. 652-56 (Perdigao)	
CX0271	M. Tupper email to D. Kuyoomjian et al re The Delicious Juice that actually clears your arteries	1/26/2009	Tr. 1042-45(Tupper)	
CX0274	POM Juice Print Ad - I'm off to save prostates; dissemination spreadsheet	2/1/2009	Tr. 1039-40 (Tupper); Tr. 1725-26 (SAR)	
CX0276	POM LRR Meeting Notes - Feb. 10, 2009	2/10/2009	Tr. 469-75 (Leow)	
CX0279	POMx Print Ad - Science, not fiction ($25M); dissemination spreadsheet	3/1/2009		
CX0280	POMx Print Ad - Live long enough to watch your 401k recover ($25M); dissemination spreadsheet	3/1/2009		
CX0282	Email from N. Gutterman to J. Simms, et al. re: past POM Marketing Research	3/2/2009		
CX0283	Email from M. Tupper to J. Kalan attaching consumer comments from POM survey (July 2004)	3/2/2009		
CX0285	L. Resnick notes for her presentation to the Milken Forum, "Rubies in the Orchard"	3/9/2009		
CX0286	Email from C. Nelson to G. Bovitz, et al. re: POM advertising research project (attaching ad copy)	3/18/2009		

CX0292	POM Wonderful market research - Juice Market research library 2003-March 2009	4/7/2009		
CX0293	Email from J. Kalan to D. Kuyoomjian attaching updated slides on consumer research	4/9/2009		
CX0295	US Juice Discussion How do we double the business?	4/13/2009	Tr. 1395-98 (Rushton)	
CX0308	Email from P. Kimery to D. Kuyoomjian re Knowledge Base 2009 Health Benefits with attachment	5/4/2009	Tr. 3020-23 (Tupper)	
CX0313	C. Nelson to D. Kuyoomjian email attaching Final Report - POM Wonderful Campaign Copy test	5/27/2009		
CX0314	Email from A. Hernandez to C. Nelson re: US Comic Risk and Time Magazine Wrap - Drink to prostate health with attachments	6/2/2009		
CX0319	Email from M. Shreeves to J. Rushton et al. re: POM Sales Sheet used at Medical Conferences w/attached POM Draft Sales Sheet 6-2-09 Letter.docx	6/11/2009		
CX0320	Email from M. Perdigao to L. Leow, et al. re: recent list of claims made in past POM communication	6/11/2009	Tr. 516-18 (Leow); Tr. 670-73 (Perdigao)	
CX0328	POMX Print Ad - Your new health care plan; dissemination spreadsheet	8/21/2009	Tr. 969-73 (Tupper)	
CX0330	POMx Print Ad - Healthy, wealthy, and wise	9/1/2009		
CX0331	POMx Print Ad - Healthy, wealthy, and wise ($32M); dissemination spreadsheet	9/27/2009		
CX0336	POM Wonderful website pages	12/10/2009	Tr. 917-19 (Tupper)	
CX0337	POMx Print Ad - The first bottle you should open in 2010; dissemination spreadsheet	1/3/2010	Tr. 1707-12 (SAR)	
CX0340	Email from J. Rushton to M. Dreher, L. Jones re RE: Expert Articles for 2010	1/29/2010	Tt. 1402-03 (Rushton)	
CX0342	POMx Print Ad - Take out a life insurance supplement ($32M); dissemination spreadsheet	2/22/2010		
CX0344	Warning Letter from Roberta C. Wagner, FDA, to POM Wonderful	2/23/2010		
CX0348	POMx Print Ad - 24 scientific studies ($32M); dissemination spreadsheet	4/1/2010	Tr. 250-53 (LRR); 2934-43 (Butters), Tr. 3176-77, 3181-82 (Stewart)	
CX0350	POMx Print Ad - 24 scientific studies ($34M); dissemination spreadsheet	4/26/2010		
CX0351	POMx Print Ad - The only antioxidant supplement rated X ($32M); dissemination spreadsheet	6/1/2010	Tr. 2943 (Butters)	
CX0353	POMx Print Ad - Take out a life insurance supplement ($34M); dissemination spreadsheet	6/14/2010		

CX0355	POMx Print Ad - The only antioxidant supplement rated X ($34M); dissemination spreadsheet	7/1/2010		
CX0357	Handwritten organizational structure diagram	7/15/2010		Entire document
CX0359	Deposition of Malcolm Knight (person most knowledgeable of POM Wonderful LLC) -- POM Wonderful LLC v. Tropicana, No. CV-09-00566 DSF (CTx)	8/24/2010		
CX0369	Reibstein Expert Report - Bovitz Ad Evaluation Questionnaire	3/11/2011		
CX0370	Reibstein Expert Report - POM A&U Study.pdf	3/11/2011		
CX0371	Declaration of Naomi Eskin, on behalf of Complaint Counsel, Federal Trade Commission	3/24/2011		
CX0372	Magazine Wrap - Lucky I have super health powers	12/2009		
CX0379	TIME Magazine Wrap - Lucky I have super health powers	10/2009		
CX0380	Magazine Wrap - Lucky I have super health powers	11/0/2009		
CX0404	POMx Print Ads - Science, not fiction ($25M)	7/8/2008 1/5/2009	Tr. 3192-93 (Stewart)	
CX0409	Compilation of marketing creative briefs for POM Juice and POMx	dates range from 01/10/2004 to 09/17/2009	Tr. 15 (opening stmt); Tr. 481-87, 502-06, 513-16 (Leow); Tr. 3192-94 (Stewart)	
CX0410	Compilation of summaries of meetings with L. Resnick re: POM products	dates range from 03/19/2001 to 06/04/2009	Tr. 107-22 (LRR)	
CX0411	Compilation of notes and agendas for meetings with L. Resnick re: POM products	dates range from 04/07/2005 to 08/15/2008		
CX0419	Spreadsheet of meta-descriptions and meta-keywords listed by page		Tr. 1379-85 (Rushton)	
CX0427	Website keyword performance tracking spreadsheet		Tr. 1387-91 (Rushton)	
CX0430	2003 Press Coverage of Fresh Pomegranates and Pomegranate Juice - Excerpts		Tr. 340-43, 351-57 (Posell)	
CX0431	2004 Press Coverage of Fresh Pomegranates and Pomegranate Juice - Excerpts			
CX0432	2005 Press Coverage of Fresh Pomegranates and Pomegranate Juice - Excerpts			
CX0433	2006 Press Coverage Fresh Pomegranates & Pomegranate Juice - Excerpts		Tr. 346-50, 369-71, 383-84 (Posell)	
CX0435	Mar 2008; 2008 Juice U.S. Print Positioning Report; 2009 Juice U.S. Print Positioning		Tr. 643-52 (Perdigao)	
CX0453	Chart: Lost Consumers care less about health and more about value			

CX0454	Excerpts from POM Consumer Complaint Log		Tr. 1046-49(Tupper)	
CX0455	Consumer Comment Log - Excerpts		Tr. 253-56 (LRR); Tr. 1049-51(Tupper)	
CX0456	Consumer Comment Log - Excerpts		Tr. 31 (opening stmt); Tr. 195-97 (LRR); Tr. 1051-56(Tupper)	
CX0459	POM Juice Print Ad - Decompress		Tr. 489, 495-96 (Leow); Tr. 3003-06, 3027-29, 3037-38 (Tupper)	
CX0463	Banner ad - Heart therapy - Backed by $25 million in medical research			
CX0466	Banner ad - Hurry, prostates everywhere are in danger. I'm off to save prostates. The antioxidant superpower			
CX0468	Banner ad - Amaze your urologist. The antioxidant superpower			
CX0470	POMx Print Ads - The only antioxidant supplement rated X		Tr. 496, 509 (Leow)	
CX0471	POM Juice and POMx Ads (B/W & Color Versions)		Tr. 152-60, 186-90, 266-69 (LRR); Tr. 501-02 (Leow); Tr. 1062-64, 2996-97 (Tupper)	
CX0472	CD containing Roll Intl. website capture, appearances by L. Resnick			
CX0473	CD containing website captures (Ex. 2 from J. Rushton deposition)		Tr. 13 (opening stmt); Tr. 1361-63 (Rushton), Tr. 1714-15 (SAR)	
CX0474	Declaration of Stephen Kolozsvary on behalf of VMS Integrated Media Intelligence Solutions			
CX0475	Pom Super Health Powers Hang Tag (FTC Complaint, Ex. A)			
CX0481	Screenshot captured from J. Rushton deposition exhibit 2, "PomWonderful Health Benefits.wmv" video		Tr. 269-70 (LRR)	
CX0485	POM Consumer Complaint log			
CX0486	FTC deposition of Fiona Posell	1/19/2011	Tr. 303-4, 364-66 (Posell)	
CX0537	Scientific and Clinical Monograph for POM Wonderful Pomegranate Juice	2008		
CX0538	Cardiovascular Research Review 2009 Participant Roster, Reference List, and copy of M. Davidson CIMT study	2009		
CX0542	Journal Article - Pomegranate juice consumption inhibits serum angiotensin converting enzyme activity and reduces systolic blood pressure	12/20/2000	Tr. 741-43 (Stampfer); Tr. 1452-54, 1460 (Sacks); Tr. 2089-90, 2093-95 (Heber)	

CX0543	Journal Article - Pomegranate j-Juice Supplementation to Atherosclerotic Mice Reduces Macrophage Lipid Peroxidation, Cellular Cholesterol Accumulation, and Development of Atherosclerosis	5/8/2001		
CX0544	Letter from A. Pantuck to Dr. Dornfield and H. Liker re: protocol concepts for 2 clinical studies	11/8/2001		
CX0548	Letter from H. Liker to S. Resnick re: agreement on monthly, annual payments	1/8/2002		
CX0552	The Beverage Study Protocol	6/12/2002		
CX0555	Email from CJRAISIN to H. Liker & D. Ornish re: Study Planning	9/18/2002	Tr. 2416-18 (Ornish)	
CX0560	Email from Megan C. to Caren (cjraisinm) Pilot Study Cross-Over	11/15/2002	Tr. 2420 (Ornish)	Personal information is *in camera*
CX0561	PMRI Beverage Study- Pilot Treadmill Stress Thallium at Baseline List	11/22/2002	Tr. 2411-13 (Ornish)	Personal information is *in camera*
CX0568	Clinical Trial Agreement involving the Resnick Trust, UCLA, and A. Pantuck re: Phase II study evaluating pomegranate juice in patients with recurrent adenocarcinoma of the prostate	1/30/2003	Tr. 1721 (SAR)	
CX0570	Letter from J. deKernion, K. Barrett, and L. Rome re: Phase II Study Evaluating Pomegranate Juice in Patients Without Recurrent Adenocarcinoma of the Prostate	2/5/2003		
CX0573	Email chain (M. Tupper, S. Resnick, G. Tupper et al) re Study Protocol	2/13/2003	Tr. 916-17 (Tupper)	
CX0576	Ornish Study Issues	2/27/2003		
CX0578	R. Schulman PowerPoint re New Research Directions	3/3/2003		
CX0579	Letter from H. Liker to P. Jones re agreeing to serve as a consultant for POM Wonderful	3/6/2003		
CX0580	Email from Linkpmri to CJRAISIN, D.Ornish, et al. re: Randomization Settles/Smith	3/7/2003		Personal information is *in camera*
CX0583	Beverage Study Protocol I	3/17/2003	Tr. 2448-51 (Ornish)	
CX0584	The Beverage Study Protocol II	3/17/2003		
CX0585	Memo from R. Schulman to L. Resnick, S. Resnick, et al. re: Confidentiality issue with J. Joseph due to his relationship with Welch's, USDA	3/26/2003		
CX0588	Letter from Radiant to Roll International Attn: H. Liker re Letter of Intent for POM Protocol	5/1/2003		
CX0589	Letter from D. Ornish to S. Resnick et al re PMRI study	5/12/2003		

CX0591	Email from D. Ornish to S. Resnick et al re weekend update (Beverage Study)	5/16/2003	Tr. 2427-29 (Ornish)	
CX0597	The Beverage Study Protocol II	6/21/2003	Tr. 1483-84 (Sacks)	
CX0599	The Beverage Study I Protocol	6/25/2003	Tr. 1472-733, 1475-77 (Sacks)	
CX0603	Agenda 8/4/2003 - PMRI Research Team Meeting	8/4/2003	Tr. 2430 (Ornish)	
CX0604	Clinical Trial Research Agreement signed by C. Cooper on behalf S. Resnick	8/21/2003	Tr. 906-910 (Tupper)	
CX0605	Talking points for E. Herbert (discussing pomegranates and PJ with D. Heber or H. Liker)	9/3/2003		
CX0606	Letter Agreement between Resnick Trust and Preventive Medicine Research Institute -- Attn D. Ornish re: two clinical trials	9/19/2003	Tr. 904-906 (Tupper)	
CX0609	PMRI Beverage I Study - Nuclear Stress RPP Comparisons Baseline 3 & 12 Months Summary	10/2/2003		Personal information is *in camera*
CX0610	C. Cooper et al interoffice memo to S. Resnick et al re Preventive Medicine Research Institute Pomegranate Juice Studies	10/3/2003	Tr. 1677-82 (SAR)	
CX0611	Journal Article - Pomegranate juice consumption for 3 years by patients with carotid artery stenosis reduces common carotid intima-media thickness, blood pressure and LDL oxidation	10/7/2003	Tr. 743-48 (Stampfer); Tr. 973-75 (Tupper); Tr. 1454-60 (Sacks); Tr. 1660-1664, 1667 (SAR); Tr. 2090 (Heber)	
CX0613	B. Velasco (Roll) to D. Ornish, Letter Agreement for Pomegranate Juice Studies	10/28/2003	Tr. 2431-36, 2451-53 (Ornish)	
CX0616	Radiant Development Meeting Minutes re: Roll International Corporation Protocol #202528	11/25/2003		
CX0622	Email from H. Padma-Nathan to H. Liker re: POM Wonderful collaboration	1/1/2004		
CX0626	Email from C. Forest to H. Padma-Nathan re POM Protocol Draft	1/30/2004	Tr. 1715-18 (SAR)	
CX0628	K. Azadzoi Roll Beverage Study Final Report	2/4/2004		
CX0632	Email from M. Sumner to D.Ornish et al re: Continuing Bev 1 results w/attached Summed Scores.ppt;Bev 1 stress summary report 2-6-04.doc; Case Summaries.doc; Summed scores.ppt	2/7/2004	Tr. 2438-39 (Ornish)	
CX0633	PMRI Research Team Meeting Agenda	2/9/2004	Tr. 1473-75 (Sacks); Tr. 2439-40 (Ornish)	
CX0637	Email from H. Padma-Nathan to H. Liker re: Rabbit Study	3/1/2004		
CX0642	Email From G. Weidner to H. Liker et al. re: transmittal of the Bev Study II SPSS data files	3/12/2004		

CX0644	Emails between H. Padma-Nathan and C. Forest re: feedback from H. Liker on POM ED Study	3/24/2004		
CX0655	Email from G. Tupper to M. Tupper and H. Liker re ED Protocol	5/14/2004		
CX0659	Draft Budget: Development of a Sports Drink based on Pomegranate Juice Extract	6/11/2004	Tr. 2049-50 (Heber)	
CX0660	G. Weidner PowerPoint presentation re: Can Pomegranate Juice Consumption Affect Coronary Heart Disease?	6/16/2004	Tr. 1528-29 (Sacks)	
CX0664	Email from M. Sumner to G. Weidner et al re: Bev 1 perfusion - summed scores analysis w/attachments	7/8/2004	Tr. 1477-79, 1624-25 (Sacks)	
CX0665	Clinical Study Agreement between Essential Group, Inc. and S. Resnick and L. Resnick as Trustees of the Stewart and Lynda Resnick Revocable Trust	7/19/2004		
CX0666	Protocol for Phase II Study Evaluating Pomegranate Juice in Patients with Recurrent Adenocarcinoma of the Prostate	7/21/2004		
CX0667	Email chain between R. Schulman and H. Liker et al. re POM Medical research timing and advertising	7/26/2004		
CX0672	Emails between H. Liker and D. Ornish re AHA Abstract	8/14/2004		
CX0680	Emails between D. Ornish, M. Sumner, R. Gibbons et al re Abstract No. 14913	9/2/2004	Tr. 2442-2444 (Ornish)	
CX0684	Brief Summary of Results re: Protocol #202528;BART-The Effects of Pomegrate Juice of Flow-Mediated Vasodilation	9/13/2004	Tr. 764-66 (Stampfer); Tr. 1508-09, 1512-13 (Sacks); Tr. 2105-06, 2139-40 (Heber)	
CX0686	Full copy, no signature -- C. Forest ED Study (Protocol # 2004-001) Amendment 1	9/14/2004		
CX0695	Study Meeting Minutes re: POM Wonderful #202528	10/6/2004		
CX0697	Email from M. Eller to PMRI re IT IS OFFICIAL	10/21/2004		
CX0699	Emails between D. Ornish and P. Fontanarosa re JAMA04-0304 Decision Letter	11/19/2004	Tr. 2444-2445 (Ornish)	
CX0701	Email from M. Eller to D. Ornish et al re Bev 1 paper	12/2/2004	Tr. 1477 (Sacks); Tr. 2397-2401 (Ornish)	
CX0704	Email from C. Forest to H. Liker re: POM study deviations due to holidays, possible procedure	1/11/2005		
CX0706	Letter from H. Liker to S. Resnick re: increasing H. Liker's salary from $175K to $250K	1/24/2005	Tr. 1634-37 (SAR)	

CX0710	Letter from W. Foltz to H. H. Liker re: request that PCF participate "to some extent" in clinical trials to determine whether pomegranate juice can affect PSA	2/3/2005		
CX0714	Letter from W. Roberts (AJC) to D. Ornish re: Effects of Pomegranate Juice on Myocardial Perfusion in Patients with Coronary Disease w/Attachments	2/28/2005		
CX0715	Email chain from D. Ornish to M. Sumner re: Bev I - Poster and AJC revisions	3/10/2005	Tr. 2446-2448 (Ornish)	
CX0716	Roll International Protocol #202528 with Amendment #3 Summary of Changes	3/16/2005	Tr. 1497-1501, 1509-12, 1619-22 (Sacks)	
CX0717	Email from M. Sumner to G. Weidner re: Bev 1 and Bev 2! w/attachments	3/24/2005	Tr. 2458-61 (Ornish)	
CX0718	Email from M. Sumner to G. Weidner et al. re: Stewart Resnick	3/24/2005		
CX0719	Email from J. Daubenmier to Michael Sumner re: bev 2	3/25/2005		
CX0720	Email chain from M. Sumner to G. Weidner re: FW: Bev 2 Pomegranate IMT data	3/29/2005		
CX0724	Email from G. Weidner to Dean Ornish et al re: Bev II - important	4/5/2005		
CX0726	Email from D. Ornish to G. Weidner et al re: Bev II update - Please read, Dean	4/20/2005		
CX0739	A Radomized, Double-Blind, Placebo-Controlled Study of Pomegranate Juice for Men with Rising Prostate-Specific Antigen Levels Following Surgery or Radiation for Prostate Cancer -- Final Protocol; Sponsor Roll Int'l, Principal Investigators A. Pantuck and	5/3/2005		
CX0740	Protocol for A Randomized, Double-Blind, Placebo-Controlled Study of Pomegranate Juice for Men with Rising Prostate-Specific Antigen Levels Following Surgery or Radiation for Prostate Cancer, Protocol # GUP-0205-1	5/3/2005		
CX0747	Federal Trade Commission press release on Tropicana settlement; FTC complaint against Tropicana; Decision & Order in Tropicana Docket No. C-4145	6/2/2005		
CX0752	Email from M. Sumner to D. Ornish et al. re: Bev 2 Summary w/attached Bev 2 Summary 06-16-5.doc	6/16/2005		

CX0754	Email from D. Ornish to S.Resnick et al. re: Beverage Study II Results Summary	8/4/2005	Tr. 754-55 (Stampfer); Tr. 1482-1489 (Sacks); Tr. 1682-85 (SAR); Tr. 2103 (Heber); Tr. 2453-58 (Ornish)	
CX0756	Email from H. Liker to L. Resnick re: 300-subject Davidson study	8/5/2005	Tr. 162-66 (LRR)	
CX0757	Email from D. Ornish to M. Sumner, G. Weidner re FW: Conference Call - Monday, 8/15	8/6/2005	Tr. 2457-58 (Ornish)	
CX0762	Letter from A. Pantuck to R. Figlin re: IRB #05-07-059-01 - A Randomized, Double-Blind, Placebo-Controlled Study of Pomegranate Juice for Men with Rising Prostate-Specific Antigen Levels Following Surgery or Radiation for Prostate Cancer	10/5/2005		
CX0764	Email from M. Dreher to H. Liker re: Draft of Research Overview	10/10/2005	Tr. 544-48 (Dreher)	
CX0765	M. Rosenblat, T. Hayek, M. Aviram - Anti-oxidative effects of pomegranate juice (PJ) consumption by diabetic patients on serum and on macrophages	10/13/2005	Tr. 1522-23 (Sacks)	
CX0770	Email from M. Dreher to M. Tupper and H. Liker with cc to others re: research updates	11/7/2005		
CX0774	Memo from R. Figlin to A. Pantuck re: Request for Additional Information Prior to Issuing an Approval Notice for IRB #05-07-059-01	11/18/2005		
CX0779	Email from M. Dreher to C. Crawford et al. re: R&D 2005 Budget Update	12/27/2005		
CX0780	Email chain from aachrekar to M. Dreher re : POM proposal	1/7/2006		
CX0784	Radiant Protocol #202528 Carotid IMT Data	2/10/2006		
CX0785	Clinical Trial Agreement between Resnick Trust, UC Regents, and Radiant Research	2/14/2006		Entire document
CX0786	Letter from A. Pantuck to J. Abbruzzese re: responses to reviewers for Clinical Cancer Research	2/16/2006		
CX0787	M. Aviram email to M. Tupper, et al., attaching Agri Food Chem mice study	3/7/2006		
CX0788	IMT Posterior Wall Measurements Ranked by Percent Change (Protocol #202528)	3/9/2006		
CX0790	Letter from A. Pantuck to J. Abbruzzese re: responses to reviewers for Clinical Cancer Research	3/28/2006		
CX0799	Email from M. Tupper to H. Liker et al. re: IMT data	4/21/2006	Tr. 555 (Dreher)	
CX0800	Email chain from H. Liker to M.Tupper et al. re: IMT data	4/22/2006	Tr. 1685-86 (SAR)	
CX0802	Letter from M. Dreher to L. Pellicore re NDI	5/1/2006		Entire document

CX0805	Email from M. Dreher to J. Hill, et al. re: proposal draft	5/12/2006		
CX0806	POM Confidentiality Agreement with JHU	5/18/2006		
CX0811	Letter from H. Liker to D. Umporowicz re determining that the Pomegranate Juice or Extract on Rising Prostate Specific Antigen Levels, etc. Study meets all of the requirements for exemption from an IND	6/15/2006		
CX0812	Email chain from M. Dreher to D. Heber re: PDF of PJ and Prostate Cancer Paper and Quote You Wanted	6/30/2006	Tr. 534-38 (Dreher)	
CX0813	E-mail chain from M. Dreher to M. Aviram re: POMx more potent antioxidant compared with pomegranate juice	7/1/2006	Tr. 381 (Posell)Tr. 538-41 (Dreher)	
CX0815	Journal Article - Phase II Study of Pomegranate Juice for Men with Rising Prostate-Specific Antigen Following Surgery or Radiation for Prostate Cancer	7/1/2006	Tr. 198-200, 258-60 (LRR); Tr. 780-86 (Stampfer); Tr. 1289-1303 (Eastham); Tr. 1723-24 (SAR); Tr. 3080-96 (Dekernion)	
CX0816	American Association for Cancer Research Press Release - Pomegranate Juice Slows PSA Acceleration Rate After Prostate Cancer Surgery, Radiation	7/1/2006		
CX0819	Email from R. deGroof to G. Thames re UCLA & Accelovance Study	7/26/2006		
CX0825	A Placebo Controlled, Randomized, Double Blind Study to Compare Antioxidant Levels in Normal Subjects with Elevated Waist Circumference When Administered 1 or 2 Pomegranate Dietary Supplement Capsules for 4 Weeks (POM Wonderful Protocol No. A001, Version	8/24/2006	Tr. 1514-16 (Sacks)	
CX0828	Letter from M. Dreher to L. Pellicore re NDI	8/30/2006		Entire document
CX0834	Email from H. Liker to J. Heinemann and C. Forest re: POM ED Article	9/12/2006		
CX0837	Email from H. Liker to M. Dreher re Ornish data	9/25/2006		
CX0839	Protocol 06-0704, The Effect of POMx, a Nutritional Supplement Derived from Pomegranates, on Human Biomarkers Associated with Cardiovascular Health in Healthy, Overweight Adults	10/4/2006	Tr. 1513-14 (Sacks)	
CX0856	Email from C. Forest to H. Liker and H. Padma-Nathan re: revisions to the ED article based on IJIR reviewers' comments	12/26/2006		
CX0858	Email chain from S. Glovksy to K. Martin re: Question about Heber research data	1/9/2007		

CX0859	Clinical Study Report - A Placebo Controlled, Randomized, Double Blind Study to Compare Antioxidant Levels in Normal Subjects with Elevated Waist Circumference When Administered 1 or 2 Pomegranate Dietary Supplement Capsules for 4 weeks	1/11/2007	Tr. 1516-18 (Sacks); Tr. 2045-46, 2142 (Heber)	
CX0860	Email from D. Heber to M. Dreher re: research results and marketing substantiation	1/16/2007		
CX0865	M. Aviram to M. Dreher, et al. email re: POMx promotes cardiovascular health (health claim discussion)	1/22/2007		
CX0867	Email chain from M. Davidson to M. Dreher et al re: POM Wonderful Summit w/attachments	1/24/2007		
CX0873	Email from M. Dreher to M. Tupper, et al. re: D. Heber 2007 Research Plan and Outline for S. Resnick Meeting 2/28	2/9/2007	Tr. 2017, 2027, 2123 (Heber)	
CX0874	Email: M. Dreher to D. Heber re POM Research, add'l studies on fast track	2/12/2007	Tr. 542-44 (Dreher)	
CX0877	Preliminary Data Analysis: The Effect of POMx, a Nutritional Supplement Derived from Pomegranates, on Human Biomarkers Associated with Cardiovascular Health in Healthy, Overweight Adults (Protocol 06-0704)	2/15/2007	Tr. 1514 (Sacks); Tr. 2138 (Heber)	
CX0879	Email chain from M. Dreher to D. Heber re: POM pilot Study Report	2/16/2007		
CX0881	Emails between C. Forest and H. Liker re POM manuscript question and publication timing	2/21/2007		
CX0897	Letter from M.Dreher to D.Heber re $100K donation	4/19/2007	Tr. 2020-21 (Heebr)	
CX0901	Email from M. Dreher to P. Salsman forwarding email from H. Liker to S. Resnick and cc to others re: AMA abstract on our IMT study	5/29/2007		
CX0902	Email from H.Liker to S.Resnick et al. re: American Heart Association abstract on our IMT study	5/29/2007	Tr. 1687 (SAR)	
CX0905	Email from D. Heber to M. Dreher re focus on pomegranate and prostate cancer	6/4/2007	Tr. 570-72 (Dreher); Tr. 2031-2033 (Heber)	
CX0906	Email chain from M. Dreher to M. Tupper et al. re: POMx Research Portfolio Overview	6/11/2007		
CX0908	Journal Article - Efficacy and safety of pomegranate juice on improvement of erectile dysfunction in male patients with mild to moderate erectile dysfunction: a randomized, placebo-controlled, double-blind, crossover study	6/14/2007	Tr. 2292-98 (Burnett)	

CX0918	Email chain between A. Pantuck and H. Liker re: updated POM data	8/14/2007		
CX0919	Email from H. Liker to M. Dreher et al. re: Question	8/29/2007	Tr. 574-77 (Dreher)	
CX0920	Email from H. Liker to M. Dreher, et al. re: keeping unpublished data out of public domain	8/29/2007		
CX0930	Email from A. Pantuck to M. Carducci, D. Heber, N. Seeram re POM Neoadjuvant Study	10/4/2007		
CX0934	Journal Article - Safety and Antioxidant Activity of a Pomegranate Ellagitannin-Enriched Polyphenol Dietary Supplement in Overweight Individuals with Increased Waist Size	10/30/2007	Tr. 766 (Stampfer); Tr. 1519-21 (Sacks); Tr. 2114-17, 2122-23 (Heber)	
CX0936	Email chain from J. Walczak to H. Liker et al re: IRB Questions	12/9/2007		
CX0939	Letter from M. Dreher to M. Carducci re NDI	12/10/2007	Tr. 581-85 (Dreher)	
CX0940	Email chain from M. Carducci to J. Walczak et al re: IRB Questions	12/10/2007	Tr. 577-81 (Dreher)	
CX0942	Email from J. Walczak to M. Carducci et al re POM w/attached letter to R. Moore (IRB) & consent	12/12/2007		
CX0944	M. Aviram to M. Dreher, et al. email re: convincing S. Resnick to publish Davidson research results	1/1/2008		
CX0948	Email from M. Dreher to M. Aviram et al. re: The strength and importance of this paper Is the big number in patients	1/6/2008		
CX0949	Email from D. Heber to D. Elashoff re Study collaboration	1/16/2008	Tr. 2047-48 (Heber)	
CX0952	Email from D. Heber to M. Dreher re using Revocable Trust for gift donation	1/28/2008	Tr. 2022 (Heber)	
CX0953	POM Human Studies: Claims Assessment (March 2008)	3/1/2008	Tr. 551-55 (Dreher)	
CX0955	ASCO Abstract - Long term follow up of pomegranate juice for men with prostate cancer and rising PSA shows durable improvement in PSA doubling time	3/6/2008		
CX0959	Email chain (M. Tupper, S. Resnick, D. Heber, M. Dreher, D. Kessler, H. Liker) re POM Human Research Summary (attachment: POM Human Study Claims Assessment ppt)	3/25/2008	Tr. 2071-72, 2155 (Heber)	
CX0962	E-mail from M. Davidson to H. Liker re: funding for Private Health Management, list of recommended lipidologists/cardiologists	4/8/2008		
CX0964	Email from H. Liker to M. Dreher re Re: Follow-up	4/12/2008		

CX0965	Email from H. Liker to M. Tupper et al re Davidson research question	4/14/2008		
CX0966	Email from S. Belknap to A. Pantuck, et al. re: tradeoff between number of interim analysis and the statistical power of a study	4/17/2008		
CX0967	Letter from S. Steinborn to M. Rusk and E. Glennon re: POM's Second Submission In Response to FTC Inquiry Issued January 17, 2008; excerpts	4/18/2008		Entire document
CX0969	Email from M. Aviram to P. Josephson et al. re: Conference Call to discuss IMT study	4/18/2008		
CX0975	Email from A. Pantuck to M. Dreher, re: labeling and advertising, IRB, and marketing health claims	5/7/2008		
CX0976	Email from A. Pantuck to M. Dreher attaching POMx IRB IND issues	5/12/2008		
CX0977	Email from M. Dreher to M. Davidson et al re CIMT paper for possible consideration for Thursday's call w/attachment	5/14/2008		
CX0982	POM Wonderful 2008 Research Summit Compendium of Documents	6/16/2008		
CX0994	Email from M. Dreher to M. Tupper re: Ornish Research	7/21/2008	Tr. 548-49 (Dreher)	
CX0998	Email from M. Dreher to M. Tupper re BART Research Question	7/30/2008	Tr. 549-51 (Dreher)	
CX1006	Email from D. Heber to M. Dreher attaching detail 2009 POM research budget doc	9/9/2008	Tr. 566-70 (Dreher); Tr. 2017-20 (Heber)	
CX1012	Letter from H. Liker to C. Belmonte (Radiant) re: IND exemption	10/15/2008		
CX1014	Email from Pantuck to Radiant re: FTC's Dietary Supplements: An Advertising Guide for Industry and FDA-IRB information for POM w/ attachements including letter from Dreher	11/21/2008		
CX1015	Email from M. Tupper to M. Dreher re: Friday's medical research meeting w/attachments	11/30/2008	Tr. 560-61 (Dreher)	
CX1020	Email from H. Liker to A. Pantuck re: University of Miami IRB and FDA IND inquiry	12/9/2008		
CX1027	Email from M. Dreher to D. Heber re: Check	1/12/2009		

CX1029	POM Wonderful: Medical Research Portfolio Review	1/13/2009	Tr. 61 (opening stmt); Tr. 190-91 (LRR); Tr. 555-66 (Dreher); Tr. 941-43, 950-54, 959-967, 969, 973, 975-97, 1010-1014, 3008-14, 3033-34 (Tupper); Tr. 1658-59, 1664-66, 1712-13, 1752-75(SAR); Tr. 1925-26 (Liker)	
CX1031	Protocol for An Open-Label 48-Month Extension Study of the Effects of Pomegranate Extract on Rising Prostate-Specific Antigen Levels in Men Following Primary Therapy for Prostate Cancer, Protocol # GUP-0205-1X	1/20/2009		Entire document
CX1032	Protocol for A Randomized, Double-Blind, Placebo-Controlled Study of the Effect of Pomegranate Extract on Rising Prostate-Specific Antigen Levels in Men Following Primary Therapy for Prostate Cancer, Protocol # GUP-0205-1	1/20/2009		Entire document
CX1033	Protocol for A 48-Month Extension to the Randomized, Double-Blind, Placebo-Controlled Study of the Effects of Pomegranate Extract on Rising Prostate-Specific Antigen Levels in Men Following Primary Therapy for Prostate Cancer, Protocol # GUP-0205-1XX	1/20/2009		Entire document
CX1039	Meeting with Dr. Rosen on POM Erectile Dysfunction (2/9/09): Summary	2/9/2009		
CX1056	Email from D. Ford to M.Carducci re Protocol NA_00013035	5/6/2009		
CX1057	Am. J. Cardiology Manuscript Draft - The Effects of the consumption of pomegrantate juice on CIMT in men and women at moderate risk of CHD	5/8/2009		
CX1060	Email from M. Tupper to M. Aviram, et al. re: continuing research, lack of good surrogate marker for CVD	5/12/2009		
CX1063	POM Cardiovascular Advisory Board Meeting: Key questions to be addressed	5/12/2009		
CX1065	M. Davidson, Effects of Consumption of PJ on CIMT (published copy)	5/13/2009	Tr. 755-64 (Stampfer); Tr. 1489-97, 1501-08 (Sacks); 2125-26 (Heber)	
CX1066	Email Chain (M. Carducci, M. Tupper, S.Chen, A. Murgo) re Dear Dr. Chen	5/14/2009	Tr. 3029-33, 3036-37 (Tupper)	
CX1074	Letter from B. Gillespie to FDA re: IND for clinical studies of POMx	5/29/2009		Entire document
CX1080	Email from H. Liker to M. Tupper, B. Gillespie re: Pantuck's analysis of his data, and attached article on	7/7/2009	Tr. 997-1002 (Tupper)	

CX1081	Letter from B. Gillespie to H. Liker re: 2009 POM Medical Research Review	7/21/2009		
CX1082	Colorado Multiple Institutional Review Board, Continuing Review Form	7/21/2009		
CX1084	POM Medical Research Review Meeting Summary & Next Steps	7/27/2009		Entire document
CX1088	Email Chain (H. Liker, M. Carducci et al) re POM interim analysis	9/4/2009		Entire document
CX1090	Curriculum Vitae for A. Pantuck	10/20/2009		
CX1091	Pre-IND #106932 Submissions	10/20/2009		Entire document
CX1094	Email from B. Gillespie to C. Belmonte et al. re: DSMB interim analysis, SAP modification	11/17/2009		
CX1097	E-mail from H. Liker to B. Gillespie re: DSMB on Radiant POMx study, not on capsule study	12/8/2009		
CX1102	Email Chain (B. Gillespie, M. Carducci) re After our meeting on 1/8	1/7/2010		Entire document
CX1104	Prostate Cancer Endpoint: Expert Panel	1/8/2010		
CX1109	Letter from UCLA to D. Heber re Study Continuation Review Application Request re Antioxidant Effect of Pomegranate Juice extract vs. Placebo in Type 2 Mellitus Patients following a Glucose Load	3/2/2010		
CX1110	Protocol (V.3): Safety and Efficacy of POMx in Men with Prostate Cancer: An 18-Month, Randomized, Double-Blind, Dose-Finding Study of the Effects of Two (2) Doses of Pomegranate Juice Extract Capsules (1or 3 capsules/day) on Rising Prostate Specific Antig	3/10/2010		
CX1116	M. Aviram's Resume	4/1/2010		Personal information is *in camera*
CX1118	Protocol: A Randomized, placebo-controlled, pre-surgical study of the effects of pomegranate pills in men with prostate cancer prior to radical prostatectomy	4/13/2010		Entire document
CX1120	M. Carducci CV	5/6/2010		
CX1127	Letter from J. Hill to M. Johnson & J. Evans re: responses to interrogatories	6/8/2010		
CX1128	Memo from A. Pantuck to the FTC re: CID interrogatory responses for IRB #02-10-049	6/17/2010		
CX1132	Letter from D. Heber to FTC attorneys- Interrogatory Responses	6/17/2010	Tr. 2024-27 (Heber)	
CX1134	Letter from M. Davidson to J. Evans re: Civil Investigative Demands	6/24/2010		

CX1136	Letter from M. Ehrlich to M. Johnson re M. Sumner's response to CID	7/2/2010		
CX1138	Letter to M. Johnson from T. Turner w/attached Carducci supplemental interrogatory responses to CID	7/15/2010		
CX1145	POM Protocol: 2007-001 Clinical/Statistical Report (Selected Tables)	8/4/2010		Entire document
CX1146	POM Wonderful Company Protocol: 2007-001 Clinical/Statistical Report	8/4/2010		Entire document
CX1147	Forest Curriculum Vitae	8/5/2010		
CX1149	E-mail from D. Ornish to E. Nach re: Response to FTC; 4/28/03 Urology Times article	8/13/2010	Tr. 2425-26 (Ornish)	
CX1150	Letter to D. Heber re $75K donation to support research	8/13/2010		
CX1152	Botanic IND submission for POMx as treatment for ED (Application #108326) Volume 1.1	9/30/2010		Entire document
CX1161	Email from C. Belmonte to A. Pantuck, B. Gillespie et al. re: DSMB Safety and Efficacy Review meeting	10/7/2010		Entire document
CX1165	Email from D. Richardson to B. Gillespie et al. Roll PSA Sponsor Meeting Minutes with attachment	11/10/2010		Entire document
CX1174	Abstract Submitted to: ASCO Genitourinary Cancer Symposium: A Phase II Study of PJ for Men with Rising Prostate-Specific Antigen following Primary Therapy	2/17/2011	Tr. 736, 786-90 (Stampfer); Tr. 3098-3100 (Dekernion)	
CX1175	"Pomegranate Extract Produces Mixed Results in Prostate Cancer"	2/28/2011	Tr. 1310-17 (Eastham); Tr. 1730-40 (SAR); Tr. 3100-01 (DeKernion)	
CX1176	Prostate Cancer Foundation Board of Directors website printout	3/11/2011	Tr. 233-36 (LRR)	
CX1180	"Pomegranate Juice May Not Affect the Carotid Artery with Caveats"	01/00/2010	Tr. 1706-07 (SAR)	
CX1188	Seeram, et al. In vitro antiproliferative, apoptotic and antioxidant activities of Punicalagin, ellagic acid and a total pomegranate tannin extract are enhanced in combination with outer polyphenol as found in pomegranate juice (J. Nutr. Biochem article)	12/10/2004		
CX1193	Article by C. Forest, H. Liker, & H. Padma-Nathan, Efficacy & Safety of Pomegranate Juice on Improvement of ED in Male Patients with Mild to Moderate ED: a randomized, placebo-controlled, double-blind, crossover study	2007		

CX1198	Journal Article - Effects of Pomegranate Juice Consumption on Myocardial Perfusion in Patients With Coronary Heart Disease	5/11/2005	Tr. 748-54 (Stampfer); Tr. 1460-73, 1591-93, 1622-24 (Sacks); 2100 (Heber)	
CX1213	C. Forest ED Study Table 3 Secondary Efficacy IIEF Scores			
CX1222	Presentation re Risk Evaluation; Cardio CRP with TC: HDL Ratio			
CX1237	1/9/03 E-mail from CJRAISNRN to G.Weidner et al. re: Update Resnicks on pilot study; signed CID Certificate of Compliance by D. Ornish; 8/4/10 E-mail chain between D. Ornish and E. Nach re: FTC Response		Tr. 2441 (Ornish)	
CX1240	Correspondence between FDA and POM re: Pre-IND application file for POMx and meeting minutes			Entire document
CX1241	Chart of Institutions Conducting POM Wonderful Research		Tr. 1643-47 (SAR)	
CX1254	POMx in Heart Health: Antioxidant Effects Presentation by D. Heber		Tr. 766-70 (Stampfer); Tr. 1518-19 (Sacks); Tr. 2118-21 (Heber)	
CX1253	Pomegranate Juice Concentrate vs. POMx Liquid Extract: Process and Specifications (Draft)			Entire document
CX1258	PowerPoint presentation: What Makes Pomegranate Unique? Research on Pomegranate Chemistry (J. Reed, et al.)			
CX1263	POM Wonderful Medical research Expenses Charts: Summary; Schedule C for 1988 Trust; and POM detail			
CX1265	Categorized research summaries			Entire document
CX1276	POM Wonderful Medical Research Expenses Excel spreadsheet		Tr. 1018-35 (Tupper); Tr. 1641-43, 1666-68 (SAR)	
CX1279	Powerpoint: The "POM Wonderful" Scientific Business model		Tr. 1666 (SAR)	
CX1284	POM Wonderful NIDDM Study Synopsis (2nd Study)			
CX1286	Prostate Cancer Foundation handbook "Nutrition, Exercise and Prostate Cancer" selection		Tr. 237-43, 290 (LRR); Tr. 2176 (Heber)	
CX1287	Expert Report of James A. Eastham, M.D.	3/3/2011	Tr. 1235, 1265-66, 1276-77 (Eastham)	
CX1288	Exhibits A & B to Expert Report of James A. Eastham, M.D.		Tr. 1214-1215, 1287-88, 1304-07 (Eastham)	
CX1289	Expert Report of Arnold Melman, M.D.	3/4/2011	Tr. 1070, 1127-8, 1130, 1135-36 (Melman)	
CX1290	Exhibits A-D to Expert Report of Arnold Melman, M.D.		Tr. 1070, 1115-1133 (Melman), Tr. 1719-21 (SAR); Tr. 2636-37 (Goldstein)	
CX1291	Expert Report of Frank Sacks, M.D.	3/3/2011	Tr. 1414-1418 (Sacks)	

CX1292	Appendices 1-4 to Expert Report of Frank Sacks, M.D.		Tr. 1410-11, 1447-48 (Sacks)	
CX1293	Expert Report of Meir Stampfer, M.D., M.P.H., Dr.P.H.	3/4/2011	Tr. 689-723, 746-48, 752-54, 766, 770-72, 789-94, 856-58 (Stampfer)	
CX1294	Exhibits A & B to Expert Report of Meir Stampfer, M.D., M.P.H., Dr.P.H.		Tr. 734-35 (Stampfer)	
CX1295	Expert Report of David W. Stewart, Ph.D.	4/4/2011	Tr. 3169-75, 3185-96, 3231(Stewart)	
CX1297	Expert Report of Michael B. Mazis	3/29/2011	Tr. 2697-700, 2759-60 (Mazis)	
CX1298	Exhibits A & B to Rebuttal Report of Michael B. Mazis		Tr. 2651 (Mazis)	
CX1306	Declaration of G. Weidner (with Exhibit A)	2/1/2011		
CX1336	FTC Deposition of Michael Davidson	12/3/2010	Tr. 1688-94 (SAR)	
CX1337	FTC Deposition of Christopher Forest	12/6/2010		
CX1338	FTC Deposition of Harin Padma-Nathan	12/7/2010		Pages 14:10-12, 14:17-18
CX1339	FTC Deposition of Dean Ornish	12/10/2010	Tr. 2402-2410, 2414-15, 2418-21 (Ornish)	Pages 150:4-19, 151:22, 161:1-15
CX1340	FTC Deposition of Michael Carducci	12/13/2010	Tr. 1728-30 (SAR)	
CX1341	FTC Deposition of Allan Pantuck	12/15/2010		
CX1342	FTC Deposition of James Hill	12/15/2010		
CX1344	FTC Deposition of Michael Sumner	12/17/2010		
CX1345	Deposition of Robert deGroof	12/21/2010		
CX1346	FTC Deposition of Jeffrey Rushton	12/21/2010		
CX1347	FTC Deposition of Staci Glovsky	1/12/2011		Pages 9:6-8, 116:4-18
CX1348	FTC Deposition of Michael Perdigao	1/14/2011	Tr. 656-57 (Perdigao)	Pages 11:5-6, 11:13-14
CX1349	FTC Deposition of Brad Gillespie	1/20/2011		Pages 7:25-8:1, 48:17-21, 51:11-20, 57:19-23, 58:8-14, 59:11-15, 61:5-9, 61:24-62:20, 67:12-68:2, 69:1-16, 69:25-70:2, 74:10- 13, 76:2-82:18, 85:4-17, 86:19-88:20, 94:5-95:2, 102:6-103:4, 127:18-23, 153:6-10, 165:9-174:12, 176:25-178:24, 192:6-193:6, 202:25-205:4, 205:21-206:3, 232:2-233:2, 250:14-252:13

CX1350	FTC Deposition of Harley Liker	1/21/2011	Tr. 1920-22)Liker	
CX1351	FTC Deposition of Monique McLaws	1/21/2011		
CX1352	FTC Deposition of David Heber	1/28/2011	Tr. 1638-1641 (SAR); Tr. 2022-24, 2159-61 (Heber)	Pages 278:16-284:21, 286:7-287:14, 289:30-292:17, 294:5-295:25
CX1353	FTC Deposition of Matt Tupper	2/2/2011		
CX1354	FTC Deposition of Robert Bryant	2/3/2011		Pages 11:20-12:3, 15:1-46:20, 48:23-93:18
CX1355	FTC Deposition of Sarah Hemmati	2/3/2011		Pages 12:8-13, 13:4-11, 13:16-23, 20:16-22, 22:10-12
CX1356	FTC Deposition of Liz Leow	2/4/2011		Page 9:1-2, 9:15-17
CX1357	FTC Deposition of Diana Kuyoomjian	2/10/2011		Page 11:17-19
CX1358	FTC Deposition of Michael Aviram	3/7/2011		Page 13:27
CX1359	FTC Deposition of Lynda Resnick		Tr. 2841-44, 2865-66 (Butters)	
CX1360	FTC Deposition of Stewart Resnick			Page 136:12
CX1362	Deposition of Lynda Resnick in POM Wonderful, LLC v. The Coca Cola Company (2:08-cv-06237)	12/9/2009	Tr. 285 (LRR)	
CX1363	Deposition of Stewart Resnick in POM Wonderful, LLC v. The Coca Cola Company (2:08-cv-06237)	12/11/2009	Tr. 1701-04 (SAR)	
CX1364	Deposition of Matt Tupper in POM Wonderful, LLC v. The Coca Cola Company (2:08-cv-06237)	12/22/2009	Tr. 1016 (Tupper)	
CX1365	Deposition Transcript of M. Perdigao in POM Wonderful v. The Coca Cola Company	1/8/2010		
CX1367	Deposition of Stewart Resnick in POM Wonderful, LLC v. Welch Foods, Inc. (2:09-cv-00567)	5/5/2010		
CX1368	Deposition of Lynda Resnick in POM Wonderful, LLC v. Welch Foods, Inc. (2:09-cv-00567)	5/11/2010	Tr. 131-33 (LRR)	
CX1369	Deposition of Matt Tupper in POM Wonderful, LLC v. Welch Foods, Inc. (2:09-cv-00567)	5/19/2010		
CX1370	Deposition of Michael Perdigao in POM Wonderful, LLC v. Welch Foods, Inc. (2:09-cv-00567)	5/21/2010		
CX1371	Deposition of Matt Tupper in in POM Wonderful, LLC v. Tropicana Products, Inc. (2:09-cv-00566)	8/4/2010	Tr. 1061 (Tupper)	
CX1372	Deposition of Stewart Resnick in POM Wonderful, LLC v. Tropicana Products, Inc. (2:09-cv-00566)	9/24/2010		
CX1373	M. Perdigao Deposition Transcript in POM Wonderful, LLC v. Ocean Spray Cranberries, Inc. (2:09-cv-00565)	10/1/2010		
CX1374	Deposition of Matt Tupper in POM Wonderful, LLC v. Ocean Spray Cranberries, Inc. and accompanying exhibits (2:09-cv-00565)	10/4/2010		
CX1375	Deposition of Lynda Resnick in POM Wonderful, LLC v. Tropicana Products, Inc. (2:09-cv-00566)	10/11/2010	Tr. 79-80, 104-06, 155-56, 161-62, 167-70, 270 (LRR)	

CX1376	Deposition of Stewart Resnick in POM Wonderful, LLC v. Ocean Spray Cranberries, Inc. and accompanying exhibits (2:09-cv-00565)	10/28/2010	Tr. 1725-26 (SAR)	
CX1377	Deposition Transcript of B. Gillespie in in POM Wonderful, LLC v. Ocean Spray Cranberries, Inc. and accompanying exhibits (2:09-cv-00565)	11/11/2010		
CX1378	D. Kuyoomjian deposition transcript (POM Wonderful LLC v. Ocean Spray Cranberries, Inc.)	12/21/2010		
CX1379	POM Wonderful LLC's Response to Request for Admissions	3/16/2011		Entire document
CX1380	POM Wonderful LLC's Response to Second Request for Admissions	3/28/2011		
CX1381	POM Wonderful LLC's Supplemental Responses to First Set of Interrogatories	1/13/2011		
CX1382	Lynda Rae Resnick's Supplemental Responses to First Set of Interrogatories	1/14/2011		CX1382_0010
CX1383	Roll Global LLC's Supplemental Responses to First Set of Interrogatories	1/14/2011		
CX1384	Stewart A. Resnick's Supplemental Responses to First Set of Interrogatories	1/14/2011		
CX1395	POM Complaint - POM Wonderful, LLC v. The Coca Cola Company (2:08-cv-06237)	9/22/2008		
CX1396	POM Complaint - POM Wonderful, LLC v. Welch Foods, Inc. (2:09-cv-00567)	1/3/2009		
CX1397	POM Complaint - POM Wonderful, LLC v. Ocean Spray Cranberries, Inc. (2:09-cv-00565)	1/23/2009		
CX1398	POM Complaint - POM Wonderful, LLC v. Tropicana Products, Inc. (2:09-cv-00566)	1/23/2009		
CX1399	POM 1st Amended Complaint - POM Wonderful, LLC v. The Coca Cola Company (2:08-cv-06237)	7/27/2009		
CX1404	Plaintiff POM Wonderful LLC's Responses to Defendant Tropicana Products, Inc.'s Interrogatories (Set One), Civ. No. 09-00566 (C.D. Cal.)	12/7/2009		Entire document
CX1406	Trial Testimony of Matt Tupper in POM Wonderful, LLC v. Tropicana Products, Inc. (2:09-cv-00566)	11/4/2010		
CX1407	Trial Testimony of David Heber in POM Wonderful, LLC v. Tropicana Products, Inc. (2:09-cv-00566)	11/12/2010		
CX1418	Certification of formation, as amended, for POM Wonderful LLC	5/15/2001		
CX1419	NYAG Letter to POM re: false or misleading advertising	3/1/2005		
CX1421	Trustee certification for the Stewart and Lynda Resnick Revocable Trust	2/1/2008		

CX1426	FTC Administrative Complaint, Docket No. 9344	9/24/2010	Tr. 170-72, Tr. 175-80, 217-19, 243-49, 264-66 (LRR); Tr. 490-95 (Leow); Tr. 537-41 (Dreher); Tr. 605-09, 668-70 (Perdigao), Tr. 2867, 2870-71, 2895, 2899, 2961-62 (Butters)	
CX1436	Copy of F. Posell's LinkedIn profile		Tr. 304, 313-14 (Posell)	
PX0004	Aviram M, Dornfeld L, Rosenblat M, Volkova N, Kaplan M, Coleman R, Hayek T, Presser D, and Fuhrman B, Pomegranate juice consumption reduces oxidative stress, atherogenic modifications to LDL, and platelet aggregation: studies in humans and in atherosclero	2000		
PX0025	Expert Report and attached Exhibits or Appendices of Dean Ornish, M.D., re In the Matter of Pom Wonderful LLC and Roll International Corp and Stewart A. Resnick, Lynda Rae Resnick, and Matthew Tupper, Docket No. 9344	2011		
PX0045	Expert Report On Scientific Studies in Support of Health Benefits of Pomegranate Juice by David Heber, MD, PhD, FACP, FACN, CNS In re: Pom Wonderful LLC v. Tropicana Products, Inc. Case No. CV-09-00566 DSM dated July 12, 2010	2010		
PX0046	Expert Report On Scientific Studies in Support of Health Benefits of Pomegranate Juice by David Heber, MD, PhD, FACP, FACN, CNS In re: Pom Wonderful LLC v. Welch Foods, Inc. Case No. CV-09-00567 AHM (AGRx) dated July 12, 2010	7/12/2010		
PX0047	Expert Report On Scientific Studies in Support of Health Benefits of Pomegranate Juice by David Heber, MD, PhD, FACP, FACN, CNS In re: Pom Wonderful LLC v. Ocean Spray Cranberries, Inc. Case No. CV09-00565DDP (RZx) dated September 10, 2010	9/10/2010		
PX0051	Azadzoi kM, Schulman RN, Aviram M, and Stroky MB, Oxidative Stress in Arteriogenic Erectile Dysfunction: Prophylactic Role of Antioxidants, J. Urology 174: 386-393 (2005)	2005		

PX0056	De Nigris F, Williams-Ignarro S, Sica V, Lerman LO, D'Armiento FP, Byrns RE, Casamassimi A, Carpentiero D, Schiano C, Sumi D, Fiorito C, Ignarro LJ, and Napoli C, Effects of Pomegranate Fruit Extract rich in punicalagin on oxidation-sensitive genes and eN	2007		
PX0057	De Nigris F, Balestrieri ML, Williams-Ignarro S, D'Armiento P, Fiorito C, Ignarro LJ, Napoli C, The influence of pomegranate fruit extract in comparison to regular pomegranate juice and seed oil on nitric oxide and arterial function in obese Zucker rats,	2007		
PX0058	Ignarro LJ, Byrns RE, Sumi D, de Nigris F, and Napoli C, Pomegranate juice protects nitric oxide against oxidative destruction and enhances the biological actions of nitric oxide, Nitric Oxide 15 (2006) 93-102.	2006		
PX0059	De Nigris F, Williams-Ignarro S, Lerman LO, Crimi E, Botti C, Mansueto G, D'Armiento FP, De Rosa G, Sica V, Ignarro LJ, Napoli C, Beneficial effects of pomegranate juice on oxidation-sensitive genes and endothelial nitric oxide synthase activity at sites	2005		
PX0061	Pantuck AJ, Zomorodian N, Rettig M, Aronson WJ, Heber D, Belldegrun AS, Long Term Follow Up of Phase 2 Study of Pomegranate Juice for Men with Prostate Cancer Shows Durable Prolongation of PSA Doubling Time, J. of Urology Vol. 181 No. 4, Supplement (2009)	2009		
PX0127	Rock W, Rosenblat M, Miller-Lotan R, Levy AP, Elias M, and Aviram M, Consumption of Wonderful Variety Pomegranate Juice and Extract by Diabetic Patients Increases Paraoxonase 1 Association with High-Density Lipoprotein and Stimulates Its Catalytic Activit	2008		
PX0149	Expert Report and Attached Exhibits or Appendices of Arthur Burnett, M.D. re In the Matter of Pom Wonderful LLC and Roll International Corp and Stewart A. Resnick, Lynda Rae Resnick, and Matthew Tupper, Docket No. 9344	2011		
PX0149a01				

PX0158	Expert Report and Attached Exhibits or Appendices of Ronald R. Butters, PH.D., re In the Matter of Pom Wonderful LLC and Roll International Corp and Stewart A. Resnick, Lynda Rae Resnick, and Matthew Tupper, Docket No. 9344	2011		
PX0161	Expert Report and Attached Exhibits or Appendices of Jean deKernion, M.D., re In the Matter of Pom Wonderful LLC and Roll International Corp and Stewart A. Resnick, Lynda Rae Resnick, and Matthew Tupper, Docket No. 9344	2011		
PX0163	Pound, et al., Natural History of Progression After PSA Elevation Following Radical Prostatectomy (Abstract), JAMA 1999; 281(17): 1591-1597	1999		
PX0172	Smith MR, et al., Rosiglitazone versus Placebo for Men with Prostate Cancer and a Rising Serum Prostate Specific Antigen after Radical Rrostatectomy and/or Radiation Therapy, Cancer, 2004 October 1; 101(7): 1569-74	2004		
PX0175	Carducci, et al., A Phase II Study of Pomegranate Extract for Men with Rising Prostate-Specific Antigen Following Primary Therapy, J. Clin. Oncol. 29: 2011 (suppl 7; abstr 11)	2011		
PX0189	Expert Report and Attached Exhibits or Appendices of Irwin Goldstein, M.D., re In the Matter of Pom Wonderful LLC and Roll International Corp and Stewart A. Resnick, Lynda Rae Resnick, and Matthew Tupper, Docket No. 9344	2011		
PX0192	Expert Report and Attached Exhibits or Appendices of David Heber, MD, PhD, FACP, FACN, CNS, re In the Matter of Pom Wonderful LLC and Roll International Corp and Stewart A. Resnick, Lynda Rae Resnick, and Matthew Tupper, Docket No. 9344	2011		
PX0206	Expert Report and Attached Exhibits or Appendices of Denis R. Miller, MD, re In the Matter of Pom Wonderful LLC and Roll International Corp and Stewart A. Resnick, Lynda Rae Resnick, and Matthew Tupper, Docket No. 9344	2011		
PX0209	Beals JH, Muris TJ, Pitofsky R, In Defense of the Pfizer Factors, August 2010	2010		

PX0223	Expert Report and Attached Exhibits or Appendices of David J. Reibstein, Survey of POM wonderful 100% Pomegranate Users, Survey Analysis, re In the Matter of Pom Wonderful LLC and Roll International Corp and Stewart A. Resnick, Lynda Rae Resnick, and Matt	3/18/2011		
PX0227	POM A&U Study Questionnaire			
PX0237	Reibstein Survey Questionnaire			
PX0276	Initial Disclosures of Respondents and Documents Referenced Therein and Not Objected to by Respondents	10/25/2010		
PX0277	Respondent's First Supplemental Disclosures and Documents Referenced Therein and Not Objected to by Respondents	11/2/2010		
PX0295a01				
PX0295a07				
PX0295a15				
PX0296a01				
PX0349	Deposition transcript of Arthur Burnett In the Matter of Pom Wonderful and accompanying exhibits not objected to by Respondents			
PX0350	Deposition transcript of Ronald Butters In the Matter of Pom Wonderful and accompanying exhibits not objected to by Respondents			
PX0351	Deposition transcript of Jean deKernion In the Matter of Pom Wonderful and accompanying exhibits not objected to by Respondents			
PX0351a4				
PX0351a5				
PX0352	Deposition transcript of Irwin Goldstein In the Matter of Pom Wonderful and accompanying exhibits not objected to by Respondents			
PX0352a02				
PX0353	Deposition transcript of David Heber In the Matter of Pom Wonderful and accompanying exhibits not objected to by Respondents			
PX0355	Deposition transcript of Dean Ornish In the Matter of Pom Wonderful and accompanying exhibits not objected to by Respondents			
PX0364	Answer and Defenses of Respondents and Attached Exhibits re In the Matter of Pom Wonderful LLC and Roll International Corp and Stewart A. Resnick, Lynda Rae Resnick, and Matthew Tupper, Docket No. 9344	10/18/2010		

PX0370	“Rubies in the Orchard” by Lynda Resnick	2009		
PX0516	Creative Brief: POMx FSI	10/1/2007		
PX0517	Email from C. Nelson to B. Fisher re: Creative Brief – pomtruth web advertising	1/8/2008		
PX0519	Email string from C. Nelson to C. Nelson re: Pomegranatetruth.com	1/18/2008		
PX0520	Email from M. Cregar to M. Perdigao re: Creative Briefs_2008 POM Juice	5/20/2008		
PX0521	Creative Brief: 2008 POM Juice – Real Age Dedicated Email Blast	9/24/2008		
PX0522	Email from C. Nelson to M. Perdigao re: TV Creative brief	3/30/2009		
PX0523	Email string from M. Shreeves to D. Kuyoomjian re: Creative Brief Event Booth	4/6/2009		