

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)
)
)
STEWART A. RESNICK,)
LYNDA RAE RESNICK, and)
MATTHEW TUPPER, individually and)
as officers of the companies.)
_____)

Docket No. 9344

PUBLIC

COMPLAINT COUNSEL'S PRE-TRIAL BRIEF [CORRECTED]

TABLE OF CONTENTS

| | | |
|------|--|----|
| I. | STATEMENT OF FACTS | 1 |
| A. | The Respondents | 1 |
| 1. | The Corporate Respondents: POM Wonderful and Roll Global | 2 |
| 2. | The Individual Respondents: Stewart Resnick, Lynda Resnick, and Matthew Tupper | 4 |
| B. | The Challenged Products: POM Juice and POMx | 7 |
| C. | Marketing and Sale of the Challenged Products | 9 |
| 1. | Founding POM Wonderful and Creating the Brand | 9 |
| 2. | Overview of POM Wonderful Ads and Claims | 13 |
| 3. | “Backed by Medical Research”: Overview of Science Funded by and Marketed by Respondents | 17 |
| i. | The Early Research | 17 |
| ii. | Building Relationships with Researchers | 19 |
| iii. | Cardiovascular Disease Research | 20 |
| iv. | Prostate Cancer Research | 22 |
| v. | Erectile Dysfunction Research | 26 |
| 4. | Respondents’ Knowledge of Substantiation Requirements | 27 |
| II. | RESPONDENTS’ DECEPTIVE ADVERTISING CLAIMS | 30 |
| A. | The Legal Framework for Determining What Claims Respondents’ Advertisements Convey | 30 |
| B. | Respondents Represent That the Challenged Products Effectively Prevent, Reduce The Risk of, and/or Treat Heart Disease, Prostate Cancer, and Erectile Dysfunction, and That Their Research Proves the Efficacy of Those Products | 32 |
| C. | Respondents’ Heart Disease Prevention, Reduction of Risk, and Treatment Claims | 39 |
| 1. | Website Claims | 39 |
| 2. | Print Advertisement Claims | 41 |
| 3. | Other Marketing Material Claims | 43 |
| D. | Respondents’ Prostate Cancer Prevention, Reduction of Risk, and Treatment Claims | 44 |
| 1. | Website Claims | 44 |
| 2. | Print Advertisement Claims | 45 |
| 3. | Other Marketing Materials | 46 |
| E. | Respondents’ Erectile Dysfunction Prevention, Reduction of Risk, and Treatment Claims | 48 |
| 1. | Website Claims | 48 |
| 2. | Print Advertisement Claims | 49 |
| F. | Respondents’ Advertising Claims Are Material | 51 |

| | | |
|------|---|-----|
| III. | RESPONDENTS’ ADVERTISING CLAIMS ARE FALSE AND UNSUBSTANTIATED AND VIOLATE SECTIONS 5 AND 12 OF THE FTC ACT | 54 |
| A. | The Current State of Science on the Antioxidant Theory Does Not Provide Adequate Support for Respondents’ Disease Claims | 56 |
| B. | Heart Disease Claims Are False and Unsubstantiated | 59 |
| 1. | Overview of the type of medical research required to support claims for the prevention, reduction of risk, or treatment of heart disease. | 59 |
| 2. | Respondents’ evidence is inadequate to substantiate their claims that the Challenged Products prevent, reduce the risk of, or treat heart disease. | 65 |
| 3. | Respondents’ studies do not prove claims that the Challenged Products prevent, reduce the risk of, or treat heart disease. | 74 |
| C. | Prostate Cancer Claims Are False and Unsubstantiated | 75 |
| 1. | Respondents did not possess or rely upon competent and reliable scientific evidence to substantiate their claims that the Challenged Products prevent or reduce the risk of prostate cancer. | 75 |
| 2. | Respondents did not possess or rely upon competent and reliable scientific evidence to substantiate their claim the Challenged Products treat prostate cancer. | 77 |
| 3. | Clinical studies, research, and/or trials do not prove that the Challenged Products prevent, reduce the risk of, or treat prostate cancer. | 80 |
| D. | Erectile Dysfunction Claims Are False and Unsubstantiated | 81 |
| 1. | Respondents did not possess or rely upon competent and reliable scientific evidence to substantiate their claims that the Challenged Products prevent, reduce the risk of, or treat erectile dysfunction. | 81 |
| 2. | Clinical studies, research, and/or trials do not prove that the Challenged Products prevent, reduce the risk of, or treat erectile dysfunction. | 85 |
| E. | Disease claims for foods must be supported by competent and reliable scientific evidence. | 85 |
| IV. | CORPORATE RESPONDENTS POM AND ROLL ARE LIABLE FOR THE DECEPTIVE AND FALSE ADVERTISING | 87 |
| V. | RESPONDENTS STEWART A. RESNICK, LYNDIA RAE RESNICK, AND MATTHEW TUPPER ARE INDIVIDUALLY LIABLE | 92 |
| VI. | THE NOTICE ORDER SETS FORTH RELIEF APPROPRIATE FOR THIS CASE | 93 |
| VII. | CONCLUSION | 101 |

TABLE OF AUTHORITIES

| | |
|--|------------------------|
| <i>Am. Home Prods. v. F.T.C.</i> , 695 F.2d 681 (3d Cir. 1982)..... | 30, 31 |
| <i>Chicago Bridge & Iron Co N.V. v. F.T.C.</i> , 534 F.3d 410 (5th Cir. 2008)..... | 94 |
| <i>Continental Wax Corp. v. F.T.C.</i> , 330 F.2d 475 (2d Cir. 1964)..... | 94 |
| F.T.C., <i>Dietary Supplements: An Advertising Guide For Industry</i> , available at http://business.ftc.gov/documents/bus09-dietary-supplements-advertising-guide-industry (requiring competent and reliable scientific evidence)..... | 98 |
| F.T.C., <i>Enforcement Policy Statement on Food Advertising</i> , (May 1994)..... | 85, 98 |
| <i>F.T.C. Policy Statement on Deception</i> , appended to <i>Cliffdale Assoc., Inc.</i> , 103 F.T.C. 110, 174 (1984)..... | 32 |
| <i>F.T.C. v. Bay Area Bus. Council, Inc.</i> , No. 02 C 5762, 2004 U.S. Dist. LEXIS 6192 (N.D. Ill. Apr. 9, 2004)..... | 88 |
| <i>F.T.C. v. Bronson Partners, LLC</i> , 564 F. Supp. 2d 119 (D. Conn. 2008)..... | 32 |
| <i>F.T.C. v. California Pacific Research, Inc.</i> , No. CV-N-88-602, 1991 U.S. Dist. LEXIS 12967 (D. Nev. Aug. 27, 1991)..... | 87 |
| <i>F.T.C. v. Colgate-Palmolive Co.</i> , 380 U.S. 374 (1965)..... | 31, 52, 94, 95 |
| <i>F.T.C. v. Direct Mktg. Concepts, Inc.</i> , 569 F. Supp. 2d 285 (D. Mass. 2008), <i>aff'd</i> , 624 F.3d 1 (1st Cir. 2010)..... | 55, 86 |
| <i>F.T.C. v. Direct Mktg. Concepts, Inc.</i> , 624 F.3d 1 (1st Cir. 2010)..... | 50, 55, 86 |
| <i>F.T.C. v. Iovate Health Sciences USA Inc.</i> , No. 10-CV-587 (W.D.N.Y. July 29, 2010)..... | 99 |
| <i>F.T.C. v. Kennedy</i> , 574 F. Supp. 2d 714 (S.D. Tex. 2008)..... | 89 |
| <i>F.T.C. v. National Lead Co.</i> , 352 U.S. 419 (1957)..... | 94, 97 |
| <i>F.T.C. v. Nat'l Urological Group.</i> , 645 F. Supp. 2d 1167 (N.D. Ga. 2008), <i>aff'd</i> , 356 F. App'x 358 (11th Cir. 2009)..... | 31, 52, 55, 86, 88, 89 |
| <i>F.T.C. v. Network Servs. Depot, Inc.</i> , 617 F.3d 1127 (9th Cir. 2010)..... | 88 |
| <i>F.T.C. v. Pantron I Corp.</i> , 33 F.3d 1088 (9th Cir. 1994)..... | 54, 87 |

| | |
|---|--|
| <i>F.T.C. v. QT, Inc.</i> , 448 F. Supp. 2d 908 (N.D. Ill. 2006); <i>aff'd</i> , 512 F.3d 858 (7th Cir. 2008)..... | 55, 83, 87 |
| <i>F.T.C. v. Ruberoid Co.</i> , 343 U.S. 470 (1952)..... | 94 |
| <i>F.T.C. v. Sterling Drug, Inc.</i> , 317 F.2d 669 (2d Cir. 1963) | 30 |
| <i>In re Brake Guard Prods., Inc.</i> , 125 F.T.C. 138 (1998), <i>pet. review denied</i> , <i>Jones v. F.T.C.</i> , 1999 U.S. LEXIS 22885 (9th Cir. Sept. 13, 1999)(unpublished)..... | 56, 96 |
| <i>In re Bristol-Myers Co.</i> , 102 F.T.C. 21(1983), <i>pet. review denied</i> , 738 F.2d 554 (2d Cir. 1984)..... | 56 |
| <i>In re Daniel Chapter One</i> , No. 9329, Initial Decision (F.T.C. Aug. 5, 2009), <i>pet. review denied</i> , 2010 U.S. App. LEXIS 25496 (D.C. Cir. Dec. 10, 2010)..... | 30, 50, 51, 52, 54, 55, 56, 86, 92, 98 |
| <i>In re Kraft, Inc.</i> , 114 F.T.C. 40 (1991), <i>pet. review denied</i> , 970 F.2d 311 (7th Cir. 1992)..... | 30, 31, 32, 51, 52, 53 |
| <i>In re Novartis Corp.</i> , 127 F.T.C. 580 (1999), <i>pet. review denied</i> , 223 F.3d 783 (D.C. Cir. 2000)... | 30, 32, 51, 52 |
| <i>In re Removatron Int'l Corp.</i> , 111 F.T.C. 206 (1988), <i>pet. review denied</i> , 884 F.2d 1489 (1st Cir. 1989)..... | 31, 38, 56, 87 |
| <i>In re Schering Corp.</i> , 118 F.T.C. 1030 (1994)..... | 87, 96 |
| <i>In re Telebrands Corp.</i> , 140 F.T.C. 278 (Sept. 15, 2004), <i>aff'd</i> 140 F.T.C. 278 (2005), <i>pet. review denied</i> , 457 F.3d 354 (4th Cir. 2006)..... | 30, 32, 88, 92 |
| <i>In re Thompson Med. Co., Inc.</i> , 104 F.T.C. 648 (1984), <i>pet. review denied</i> , 791 F.2d 189 (D.C. Cir. 1986)..... | 30, 31, 32, 50, 54, 55, 56, 94, 95, 96, 99 |
| <i>Jacob Siegel Co. v. F.T.C.</i> , 327 U.S. 608 (1946)..... | 94 |
| <i>Nestlé Healthcare Nutrition, Inc.</i> , F.T.C. Dkt. No. 4312 (Jan. 12, 2011)..... | 99 |
| <i>North Texas Specialty Physicians v. F.T.C.</i> , 528 F.3d 346 (5th 2008)..... | 94 |
| Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, 104 Stat. 2353 (codified in 21 U.S.C. § 343 (i), (q), and (r))..... | 98 |

Oxford English Dictionary, online version (2d ed. Mar. 2011) available at
<http://www.oed.com/view/Entry/2983?redirectedFrom=advertoial#eid>.....33

Porter & Dietsch, Inc. v. F.T.C., 605 F.2d 294 (7th Cir. 1979).....94, 95

Sears, Roebuck & Co. v. F.T.C., 676 F.2d 385 (9th Cir. 1982).....94, 95

Zauderer v. Office of Disciplinary Council, 471 U.S. 626, 652 (1985).....31

I. STATEMENT OF FACTS

Although the pomegranate has been around for centuries, only in the last decade have Stewart and Lynda Resnick, and their companies POM Wonderful LLC and Roll Global LLC, elevated its status in the eyes of the American consumer through brand recognition (the “POM Wonderful” brand), product line expansion (*e.g.*, seasonal fresh pomegranate, 100% pomegranate juice, and pomegranate extract), and a marketing campaign focused “on the health benefits associated with pomegranates and pomegranate juice.” *POM Wonderful LLC v. Tropicana Products, Inc.* Complaint at CX1398_0004. As best told by Lynda Resnick, POM Wonderful created an “overnight sensation” by generating demand for an 8,000-year-old “fruit that the overwhelming majority of Americans didn’t know existed.” Lynda Resnick, *Rubies in the Orchard: The POM Queen’s Secrets to Marketing Just About Anything* (“*Rubies in the Orchard*”), CX0001 at 1, 2.

The Resnicks and the other Respondents in this matter have spent “millions of dollars to research and promote” health benefits of POM Wonderful 100% Pomegranate Juice and POMx pomegranate extract (*POM v. Tropicana* Complaint at CX1398_0004), a point often cited in their product advertising. In turn, through their advertising, the Respondents have communicated to consumers, quite effectively, specific health benefits in the areas of heart, prostate, and erectile function.

A. The Respondents

Together, Stewart and Lynda Resnick oversee a collective of privately-owned companies that offer a variety of consumer goods and services. These businesses include Teleflora, described as “the largest flower delivery service in the world”; Fiji Water, “the No. 1 imported

bottled water brand in the United States”; Paramount Citrus, “the largest integrated grower, shipper and packer of fresh citrus in the U.S.”; Paramount Farms, “the world’s largest vertically integrated grower and processor of pistachios and almonds”; and POM Wonderful, “the world’s largest producer of ‘Wonderful’ variety pomegranates” and maker of a line of pomegranate-based products. *See* Roll Global Website, at www.roll.com (last visited Apr. 30, 2011). Other Roll companies include Neptune Pacific Line, a cargo and bulk shipping company, and Suterra, a maker of environmentally-conscious pest control products. *Id.* The Resnicks have managed these companies over many years through a company called Roll International Corporation (recently renamed Roll Global LLC), and have built a formidable infrastructure for the collective businesses, including a full-service in-house advertising agency and a robust public relations department. The Resnicks also founded a non-profit organization, The Resnick Family Foundation. Among other activities, the Foundation funds pomegranate-related scientific research, as do POM Wonderful, Roll, and the Stewart and Lynda Resnick Revocable Trust. The Resnick Family Foundation, Inc.’s Supp. Amend. Resp. at CX1412_0009-11; The Stewart and Lynda Resnick Revocable Trust’s Supp. Amend. Resp. at CX1413_0007-11.

1. The Corporate Respondents: POM Wonderful and Roll Global

Respondent POM Wonderful LLC (“POM Wonderful”), the self-described largest grower and distributor of pomegranates and pomegranate juice in the United States, is a Delaware-incorporated company headquartered at 11444 West Olympic Boulevard, Los Angeles, California. Answer and Defenses of Respondents ¶ 1. POM Wonderful grows, processes, distributes, and markets the “Wonderful” variety of fresh pomegranates, and products derived from Wonderful pomegranates, including POM Wonderful 100% Pomegranate Juice

(“POM Juice”), various POM Juice blends, a POM Juice concentrate, and recently a “Lite” POM Juice. *See* POM Wonderful website Products page, www.pomwonderful.com (last visited May 6, 2011). From the remains of the juicing process, POM Wonderful produces POMx, an extract that the company incorporates into POMx Pills, POMx Liquid, POMx Tea, POMx Recovery, POMx Bars, and POMx Shots. *Id.*

Respondent Roll Global LLC (“Roll”), the recent successor-in-interest to Roll International Corporation, is a \$2 billion company incorporated in Delaware and headquartered at the same Los Angeles address as POM Wonderful. *See* Roll Global Website, “About Us” page (last visited May 5, 2011); Answer and Defenses of Respondents ¶ 2. Roll provides “shared services” such as advertising, public relations, consulting, accounting, and human resources to POM Wonderful and the other Roll companies.¹ Answer and Defenses of Respondents ¶ 2.

Roll’s in-house advertising agency, Fire Station, provides advertising services to POM Wonderful and the other Roll companies. Prior to Fire Station’s creation about four years ago, Roll offered advertising services to its affiliated companies through marketing personnel employed elsewhere within Roll (*e.g.*, Telefora). Tr. of L. Resnick Dep. at CX1359_0027. Over the years, the POM Wonderful marketing team and advertising personnel at Roll and FireStation have collaborated to create content for, and determine placement of, the print, outdoor, direct mail, online advertisements, and public relations communications for the POM Wonderful

¹The Roll Law Group, P.C., housed in the same building as the Corporate Respondents, provides legal services to the Roll family of companies and for various “trusts, charitable organizations, non-profit associations and agricultural cooperative associations that have business relationships with Roll and its affiliates.” *See* <http://www.rolllawgroup.com/aboutus.php> (last visited May 5, 2011).

products. The agency takes marketing concepts provided by POM Wonderful – typically in the form of a “creative brief” – and develops specific ad content that is then reviewed with POM Wonderful’s marketing team. *Id.* at CX1359_0055-57. Fire Station also works with employees of POM Wonderful to monitor and report on the effectiveness of POM Wonderful’s advertisements. Answer and Defenses of Respondents ¶ 2. According to Roll, “POM’s advertising materials, whether in draft or final form, are often reviewed or seen by POM’s Vice President of Marketing, other members of POM’s marketing department, Fire Station employees, Matt Tupper, frequently by Lynda Resnick and previously by affiliated advertising and PR employees.” POM Wonderful LLC’s Supp. Resp. to First Set of Interrog. at CX1381_0011.

Respondents POM Wonderful and Roll are owned 100% by Stewart and Lynda Resnick, as the sole trustees of the Stewart and Lynda Resnick Revocable Trust dated December 27, 1988 (“the Resnick Trust”). Trustee Certification for S. and L. Resnick Revocable Trust at CX1421_0002-3.

2. The Individual Respondents: Stewart Resnick, Lynda Resnick, and Matthew Tupper

In addition to being a trustee of the Resnick Trust, Respondent Stewart Resnick is the Chairman of POM Wonderful. Answer and Defenses of Respondents ¶ 3. He is also the Chairman and President of Roll, and a Director of Roll. *Id.* From the companies’ inceptions, he has actively participated in their business operations, including the hiring of POM Wonderful’s outside medical director, Dr. Harley Liker, and other key employees, such as POM Wonderful’s Chief Financial Officer and the current and past personnel responsible for handling POM Wonderful’s sponsorship of medical research. Tr. of S. Resnick Dep. at CX1360_0024-25. Mr.

Resnick holds frequent business meetings with Respondent Matthew Tupper, the president of POM Wonderful, and makes final decisions about the investments and expansion of the company. Tr. of S. Resnick Dep. at CX1360_0021-22. Mr. Resnick also has been committed to the development of POM Wonderful's scientific research program, for example by engaging scientific consultants, participating in scientific advisory board meetings, and convening company-sponsored research summits. Tr. of S. Resnick Dep. at CX1360_0086, 111-112.

Respondent Lynda Resnick is co-trustee of the Resnick Trust and co-Director of Roll with Stewart Resnick. Answer and Defenses of Respondents ¶ 4. Her self-described title at POM Wonderful is "POM Queen." Tr. of L. Resnick Dep. at CX1359_0038; *Rubies in the Orchard*, CX0001. The "POM Wonderful Juice Project" was Mrs. Resnick's brainchild in 2001. CX0004. From POM Wonderful's inception, she has directed the creative development of the company and the vision of the POM Juice and POMx advertising campaigns. *Rubies in the Orchard*, CX0001 at Chapter 1. Over the years, Mrs. Resnick has been intimately involved in the marketing operations, for example through routine meetings with POM Wonderful and Roll/Fire Station marketing personnel, reviewing and providing input on various marketing materials in all forms of media (L. Resnick Supp. Resp. to First Set of Interrog. at CX1382_0008), developing in-house market research (Tr. of L. Resnick Dep. at CX1359_0078), and participating in decisions regarding which studies to reference in product advertising (Tr. of M. Tupper Dep. at CX1353_0198).² She also has participated in the hiring and firing of POM

²At various times, Mrs. Resnick has tried to wean herself from the day-to-day business of POM Wonderful, especially when the other businesses demand her attention. Tr. of L. Resnick Dep. at CX1359_0023. Nevertheless, as recently as 2009, she has made a point to meet routinely with the POM Wonderful and Fire Station marketing teams about the ad campaigns, and to provide input on the content of the POM Wonderful website. Tr. of L. Resnick Dep. at

Wonderful marketing executives. Tr. of L. Resnick Dep. at CX1359_0042, 46; Tr. of M. Tupper at CX1353_0024-25. Recognizing the value of public relations – what she calls the “unsung hero of marketing” – Mrs. Resnick has embraced opportunities to share with the public her business and marketing insights and what she considers to be the unique attributes of her companies’ products. *Rubies in the Orchard*, CX0001 at 172. In her book *Rubies in the Orchard* – as well as in media interviews and speeches – she addresses the intrinsic value of the POM Wonderful products, including among other things that the juice “reduces arterial plaque and factors leading to atherosclerosis. . . [and has a] powerful effect against prostate cancer.” Tr. of L. Resnick Dep. at CX1359_0019; *Rubies in the Orchard*, CX0001 at 4.

Respondent Matthew Tupper is the President and Chief Operating Officer of POM Wonderful, and in those capacities has set the policies and practices of the company. Answer and Defenses of Respondents ¶ 5. Hired by Roll in 2001, Mr. Tupper quickly gained experience in POM Wonderful’s juice business and, in 2003, assumed management of the day-to-day operations of POM Wonderful. Tr. of M. Tupper Dep. at CX1353_0043-44. Mr. Tupper has been intimately involved in the spectrum of POM Wonderful operations, including overseeing management of POM Juice processing and bottling, and the marketing and sales of the POM Wonderful line of products. *Id.* at CX1353_0009-10. Throughout his tenure, he has participated in company decisions on advertising claims and has been responsible for the hiring and firing of key marketing executives. *Id.* at CX1353_0024-25. Mr. Tupper has worked closely with Stewart Resnick and POM Wonderful’s research advisors to determine the areas of scientific research the company will sponsor. *Id.* POM Wonderful’s vice-president of clinical

CX1359_0071; Tr. of J. Rushton Dep. at CX1346_0042.

development reports to Mr. Tupper, as did that officer's predecessor, the vice-president of scientific and regulatory affairs. *Id.* As president, Mr. Tupper has been a public face of the company, explaining to the media and to consumers POM Wonderful's view of the health benefits of the company's products, including their claimed benefits for atherosclerosis, blood flow to the heart, and prostate cancer. *See, e.g.,* Complaint Ex. E-7.

B. The Challenged Products: POM Juice and POMx

POM Juice is produced by crushing and squeezing Wonderful variety pomegranates, resulting in a liquid concentrate. To make it ready for sale, the concentrate is reconstituted to make 100 percent pomegranate juice, pasteurized, and bottled for retail. Tr. of M. Tupper Dep. at CX1353_0089-90. [REDACTED]

[REDACTED] CX0967_0014. [REDACTED]

[REDACTED] *Id.* [REDACTED]

[REDACTED]

[REDACTED] *Id.*; Tr. of M. Tupper Dep. at CX1353_0109.

[REDACTED]

[REDACTED] CX0967_0014. Unlike fresh pomegranates that are available only seasonally (October through December), POM Juice is sold year-round. POM Wonderful sells POMx directly to consumers via the company website

³ Material in **{bracketed bold font}** is the subject of motions for *in camera* treatment currently before the Court. Although Complaint Counsel objects to *in camera* treatment of some of this information, Complaint Counsel is redacting references to this material while the Court's ruling is pending.

and telephone sales. POMx Pills also are available through a few U.S. retail outlets that sell dietary supplement products. Tr. of M. Tupper Dep. at CX1353_0105.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] (POM Wonderful U.S. Sales for POM Juice and POMx at CX0393_0001). [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] *Id.* at CX0393_0002-3.

According to Respondents, POM Juice and POMx treat and reduce the risk of heart disease, prostate cancer, and erectile dysfunction due to the products' antioxidant – specifically polyphenol antioxidant – content. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Feb. 20, 2008 Resp. of POM Wonderful LLC to FTC's Inquiry Issued Jan. 17, 2008 at CX0184_0001. According to POM Wonderful, POM Juice and POMx do not contain

⁴ [REDACTED]

the fiber and vitamin C found in fresh pomegranates. Tr. of L. Resnick Dep. at CX1359_255; POM Juice Nutrition Facts Panel; POMx Pills Nutrition Facts Panel.

C. Marketing and Sale of the Challenged Products

“Pure 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.” – Lynda Resnick (Rubies in the Orchard, CX0001 at 10).

1. Founding POM Wonderful and Creating the Brand

POM Wonderful began bottling, selling, and marketing POM Juice on a regional basis in the Fall of 2002, and in national markets in 2003. Tr. of M. Tupper Dep. at CX1353_0041-42. The Resnicks’ investment in the pomegranate business, however, began 15 years prior when they acquired California farmland containing over 100 acres of mature pomegranate trees. *Rubies in the Orchard*, CX0001 at 1-2. 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_002. By the late 1990s, the Resnicks had developed a pomegranate juice concentrate and had begun sponsoring scientific research to explore the product’s antioxidant properties and health benefits.

In 2000, the Resnicks formed Paramount Juice Company and, shortly thereafter changed the name to POM Wonderful LLC. CX1418_0001-3. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] CX0004_0001. However, almost half of people surveyed by the company at that time had never heard of a pomegranate. CX0105_0002. [REDACTED]

[REDACTED]

[REDACTED] Lynda Resnick viewed these challenges as opportunities. As she states in *Rubies in the Orchard*, she could easily “sell ice to Eskimos” but over time discovered “it was even better to sell the Eskimos ice *sculptures* – and charge a premium for the value added. . . . [or perhaps] sell them heaters.” *Rubies in the Orchard*, CX0001 at 22-23, 33.

[REDACTED]

[REDACTED]

CX0967_0009. [REDACTED]

[REDACTED]

[REDACTED]

CX0004_0012. [REDACTED]

[REDACTED] *Id.* [REDACTED]

[REDACTED] *Id.* [REDACTED]

[REDACTED] CX0004_0004. [REDACTED]

[REDACTED] *Id.* [REDACTED]

[REDACTED] *Id.*

Having arrived at the “Unique Selling Proposition” for POM Juice, the next steps were to

determine the target audience for the product, and the style and tone of the advertising campaign. The overarching goal of each campaign was to break through the clutter of competing advertising messages, the myriad of which consumers naturally shield themselves from so as not to become overwhelmed. Tr. of L. Resnick Dep. at CX1359_0242-243; *e.g.*, CX0409_0005. So notes Lynda 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.” Tr. of L. Resnick Dep. at CX1359_0243-244.

[REDACTED]

CX0004_0004. As it turned out, however, young adults were early responders to the brand. Tr. of L. Resnick Dep. at CX1359_0096-110. Over the years, POM Wonderful’s target audience for POM Juice has consisted of affluent, professional, health-conscious individuals (even “hypochondriacs”) ages 25-49, including men who feared getting prostate cancer and women concerned about heart disease. Compilation of marketing creative briefs at CX0409. The target audience for POMx, individuals age 25-64, encompassed older, frequent dietary supplement users and persons “seeking a natural cure for current ailments or to maintain health and prevent future ailments” including prostate cancer and heart disease. Compilation of marketing creative briefs at CX0409 (*e.g.*, CX0409_0015-16, 18, 20, 61); CX0074.

Lynda Resnick met frequently, even daily, with the POM Wonderful marketing department – particularly in the company’s nascent years – to discuss the marketing concepts for

the advertising campaigns. Tr. of L. Resnick Dep. at CX1359_0108-110. The POM Wonderful marketing team then solidified the vision for the advertising in the form of “creative briefs,” which were concise statements of the marketing assignments. According to Lynda Resnick, while the brief writing process was organic, the end product was “only as good as the brief that goes into it. 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.” *Rubies in the Orchard*, CX0001 at 74.

The POM Wonderful marketing department generated creative briefs for a variety of contexts – to summarize creative requirements for an entire multimedia campaign or for a specific advertisement (*e.g.*, magazine ad) or promotional piece (*e.g.*, juice bottle hang tag). Tr. of L. Resnick Dep. at CX1359_0056-57, 59-60, 108. Among the topics of each brief were the project objective, target audience, and tonality. The briefs also offered “reasons to believe” and “mandatories” that were key messages to communicate to consumers; for example, drinking POM Juice daily would “help reduce plaque in your arteries up to 30%”; “you will have clean arteries”; or POM Juice was the only juice backed by “published clinical reports proving excellent health benefits.” CX0409_0001, 6, 10, 13.

The POM Wonderful marketing team envisioned the tone of the POMx ads as “clinical, serious, straightforward” as this would be the company’s foray into the dietary supplement industry. CX0409_0097. The ads would emphasize that POMx offers the same powerful health benefits as POM Juice, but in a convenient pill or extract form without the sugar or calories of the juice. The ads and direct mail pieces would also display more detailed content about published research on POM Juice and feature quotes from leading scientists conducting POM-sponsored research in the areas of markers of prostate cancer and cardiovascular disease.

CX0409_0023-25. The company intended to sell POMx via direct mail, which afforded opportunities to highlight the medical research and reinforce the core advertising messages via monthly newsletters and other direct mail pieces. CX0409_0079, 0105.

2. Overview of POM Wonderful Ads and Claims

With Lynda Resnick's vision and POM Wonderful's creative briefs as guides, the marketing team at Fire Station developed specific promotional pieces and advertising campaigns for POM Juice and POMx. Tr. of L. Resnick Dep. at CX1359_0103-108. Lynda Resnick typically reviewed new promotional pieces to ensure the look, feel, and headlines were in keeping with the brand image and core advertising messages. *Id.* at CX1359_0117, 135-137. After the POM Wonderful marketing department approved final ad copy, over time the company tended to mix and match approved headlines and body copy depending on their marketing needs. As Mr. Tupper notes, the marketing department often drew "from the same artistic themes and headlines . . . use[d] for other forms of ads and format[ted] them correctly." Tr. of M. Tupper Dep. at CX1353_0114-115.

Over the past eight years, the core message employed by the Respondents' marketing teams is that POM Juice and POMx are "antioxidant superpowers," proven by scientific research to provide heart, prostate, and erectile function benefits. Many of the POM Juice advertisements and the entire POMx campaign conveyed this message in a serious, objective tone; for example, in some cases they used an advertorial format that offered substantial content about scientific findings. Since 2004, POM Juice ads have also embraced a lighthearted approach to convey the core health benefit message. Two hallmark juice campaigns that ran after 2004 were the Dressed Bottle campaign and the Super Hero campaign. The Dressed Bottle campaign

communicated core health benefit messages (*e.g.*, heart disease prevention), by cloaking the POM Juice bottle in various attire (*e.g.*, in a bikini top, wrapped in a blood pressure cuff, hooked up to an EKG, or modeled as a hospital intravenous drip bag). The Super Hero campaign portrayed the POM Juice bottle in a series of comic book style vignettes, a goal of which was to communicate that POM Juice is the only juice that can save the day, and more importantly men's prostates, by offering real, clinically researched benefits. *See, e.g.*, Complaint Ex. B, C.

When POMx launched in 2007, the advertisements focused on the products' claimed prostate and heart benefits. The print ads routinely appeared in widely-circulated newspapers, such as the Washington Post *Parade* magazine, and employed an advertorial format with quotations about the scientific research taken from press clips and Respondents' published research. *See, e.g.*, Complaint Ex. H. Because POMx purported to have the same health benefits as POM Juice, the quoted research typically pertained to POM Juice studies.

In the last two years, Respondents also have claimed that POM Juice and POMx are effective for erectile dysfunction. These claims have appeared on POM Juice hang tags, on the POM Wonderful website, and in print advertisements for POMx. Complaint Ex. A, F; CX0347_0001.

As early as 2007, Respondents incorporated into their advertisements the message that the POM products are backed by millions of dollars in medical research, under headlines such as "Science, Not Fiction." 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). *E.g.*, CX0101; CX0330. As articulated in one POMx creative brief, the purpose for referencing the amount of money invested in medical research was to emphasize that POM

Wonderful does not “just say our product is great, we have clinical studies that prove its efficacy.” See CX0409_0057.

The advertisements and promotional campaigns incorporated a spectrum of media outlets, including packaging and labeling (POM Juice and POMx), direct mail pieces (POMx), magazine and newspaper advertising (POM Juice and POMx), billboard and other outdoor advertising (POM Juice), and a multitude of Internet techniques (POM Juice and POMx). POM Wonderful disseminated promotional material via company-owned websites (*e.g.*, pomwonderful.com, pompills.com, pomegranatetruth.com) and on third-party sites (*e.g.*, banner advertising). For both products, the company invested in search engine marketing (*e.g.*, paid search terms) via providers such as Google and Yahoo. *Rubies in the Orchard*, CX0001 at 190; Tr. of J. Rushton Dep. at CX1346_0065-66.

POM Wonderful also engaged in consumer and medical outreach about POM Juice and POMx. The company reached out to bloggers to provide them information and product samples. Tr. of L. Resnick Dep. at CX1359_0162-165; Tr. of J. Rushton Dep. at CX1346_0150-151. A marketing department employee served as a consumer advocate and regularly fielded consumer inquiries about the products. Tr. of L. Resnick Dep. at CX1359_0182-183; Tr. of M. Tupper Dep. at CX1353_0072-77, 210-214, 217-219. POM Wonderful personnel responsible for medical outreach distributed product information at medical conferences and in the offices of physicians and alternative medicine practitioners, and developed relationships with medical professionals in hope that they would serve as POM “ambassadors.” At one time, the POM Wonderful marketing team used an advertising vehicle in urologists’ offices called a “magazine wrap,” which was a POM Juice advertising overlay that wrapped around issues of *Time*

magazine displayed in office waiting rooms. Tr. of M. Tupper Dep. at CX1353_0203.

Public relations pieces that would generate third-party endorsements were seminal contributions to the marketing of POM Juice and POMx. According to Lynda Resnick, “[t]here is nothing as effective in the entire world as getting someone else to say something good about your product or service.” *Rubies in the Orchard*, CX0001 at 127. As she states, “the press loved us because the fruit was so new yet so old, and the health story was a revelation. . . .” *Id.*; see also Tr. of L. Resnick Dep. at CX1359_0064-65. Fiona Possell, Respondents’ public relations representative from 2002 to 2008, was responsible among other things for “send[ing] out press releases touting various positive aspects of pomegranates from their uniqueness to their health benefits.” CX0430. She also had occasion to provide background information to Respondents’ science consultants prior to their interviews with journalists, for example expressing her confidence to Respondent’s Medical Director, Dr. Harley Liker, that “after speaking to you, [the journalist] will be on ‘message’ with POM Wonderful” and hoping that Respondents’ consultant Dr. David Heber, would “be prepared to talk to our message points.” CX0607.

Respondents’ consumer research confirmed that the POM Juice marketing approach was working. According to a 2009 on-line survey commissioned by Respondents, consumers cited health reasons more often than the other choices provided (*e.g.*, taste) as the reason for drinking pomegranate juice. CX0402. More specifically, disease prevention – such as “helps protect against prostate cancer” – was a reason why POM Juice users chose to purchase the product. *Id.*; CX1297_0012-13.

3. “Backed by Medical Research”: Overview of Science Funded by and Marketed by Respondents

“We have new medical breakthroughs on a regular basis, so there is always something new and exciting to learn about POM.” – Lynda Resnick (Rubies in the Orchard, CX0001 at 127).

Respondents have invested a substantial amount of time, funding, and effort into studying whether POM Juice and POMx may provide health benefits.⁵ As Lynda Resnick writes 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.)

Rubies in the Orchard, CX0001 at 152-153.

i. The Early Research

In the late 1990s, the Respondents began funding exploratory pomegranate research under the direction of POM Wonderful’s medical director, Dr. Leslie Dornfeld, a professor at University of California, Los Angeles (UCLA), and Dr. Michael Aviram, of the Rambam Medical Center’s Lipid Research Laboratory in Israel. *Rubies in the Orchard, CX0001 at 77-78.*

[REDACTED]

[REDACTED]

CX0967_0011-0013. [REDACTED]

[REDACTED]

⁵ In addition to the Corporate Respondents, the Resnicks’ Revocable Trust and the Resnick Family Foundation funded Respondents’ pomegranate research.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] *Id.* The first study, published in 2001, examined consumption of pomegranate juice by ten elderly, hypertensive patients over a two-week period.⁶ In 7 of the 10 patients, the study reportedly showed a 36% decrease in enzyme activity that is associated with atherosclerosis. However, the study did not employ a control group and was not blinded. The second study, published in 2004, explored consumption of pomegranate juice over one year by ten elderly patients with severe carotid artery stenosis.⁷ The pomegranate juice patients experienced a 26% decrease in carotid intima media thickness (“CIMT”), an indirect measure of arterial plaque, whereas patients who did not drink pomegranate juice reportedly showed a 9% increase in CIMT. In addition, systolic (but not diastolic) blood pressure was significantly reduced by 12% after 12 months in the pomegranate juice group, and remained unchanged in an untreated comparison group. As with Dr. Aviram’s prior study, the CIMT study was unblinded and lacked a control group.

Respondents used the results of the comparative analysis of polyphenol-rich beverages and Dr. Aviram’s two small-scale human studies to launch the POM Juice advertising campaign.

See, e.g., CX0016; CX0029. Thereafter, [REDACTED]

⁶M. Aviram & L. Dornfeld, *Pomegranate Juice Consumption Inhibits Serum Angiotensin Converting Enzyme Activity and Reduces Systolic Blood Pressure*, 158 *Atherosclerosis* 195 (2001). CX0542_0001-4.

⁷M. Aviram et al., *Pomegranate Juice Consumption for 3 Years by Patients with Carotid Artery Stenosis Reduces Common Carotid Intima-Media Thickness, Blood Pressure and LDL Oxidation*, 23 *Clin. Nutr.* 423 (2004). CX0611_0001-33.

[REDACTED] CX0545_0001-2; CX0620_0001-3. Since that time, Dr. Aviram has received over [REDACTED] from Respondents. CX1276_0001.

ii. Building Relationships with Researchers

On or about 2001, after the death of Dr. Dornfeld, the Resnicks hired Dr. Harley Liker, a physician at the University of California Los Angeles (UCLA), as Corporate Respondents' outside medical director to assist the companies with their pomegranate research program.⁸ CX1350_0029. In that capacity, Dr. Liker served as the liaison between the Respondents and the research institutions. On behalf of the Corporate Respondents, Dr. Liker solicited research contracts, participated in the development of research protocols, and interfaced with the study investigators to obtain status reports. As a result of these endeavors, Dr. Liker is a named author on several research publications funded by Respondents. CX1193_0001-4; CX0611_0001-33; CX0815_0001-18. Since 2002, Dr. Liker has received [REDACTED] for his consulting work. POM Wonderful LLC's Resp. to Request for Admissions at CX1379_0037.

In 2002, POM Wonderful's VP of Marketing approached Dr. David Heber, Director of UCLA's Center for Human Nutrition, about being a spokesperson for POM Wonderful, and also discussed with Dr. Liker giving Dr. Heber some research "as a direct way to get his support." CX0008_0001-2. Over the years, Respondents have funded numerous pomegranate-related research projects at UCLA, including many by Dr. Heber examining topics such as

⁸Over the years, Dr. Liker has developed a close working relationship with the Resnicks and their companies. In addition to his role as the Corporate Respondents' outside medical director, he has served as a wellness physician to their employees. CX1360_0035-36. On occasion, Dr. Liker also has reviewed advertising copy and assisted with Respondents' public relations efforts. CX0554_0001-13; CX0607_0001-3.

pharmacokinetics and bioavailability of pomegranate polyphenols. Jan. 28, 2011 Tr. of D. Heber Dep. at CX1352_0023. In addition, Dr. Heber has served as a paid consultant to Respondents, and has received [REDACTED] in grants to UCLA for his consulting work. Jan. 28, 2011 Tr. of D. Heber Dep. at CX1352_0425.

All told, sixty-five percent of the studies sponsored by Respondents as of late summer 2010 were conducted by Dr. Aviram and researchers at UCLA. CX1282_0001.

iii. Cardiovascular Disease Research

In 2002, Respondents contracted with Dr. Dean Ornish, head of the Preventive Medicine Research Institute (PMRI), to conduct human cardiovascular research on POM Juice to further Dr. Aviram's preliminary research in Israel. PMRI developed two pomegranate juice studies.

Dr. Ornish's first trial (Bev 1 Study) was a randomized, double-blinded, placebo-controlled study of the effects of pomegranate juice on myocardial perfusion in human subjects with stable coronary heart disease. The study, published in 2005, reported "an average improvement of 17% in myocardial perfusion in the experimental group and an average worsening of 18% in the control group" after three months.⁹ Significantly, the study protocol had called for a twelve-month study, but Dr. Ornish and Respondents agreed to halt the study at three months without disclosing that the study was cut short. CX0744_0001-10; Tr. of D. Ornish Dep. at CX1339_0088-89, 123-124. On or about 2008, Respondents began referencing the results of the Ornish myocardial perfusion study in their print advertising. *See, e.g.*, CX0169.

⁹M.D. Sumner et al., *Effects of Pomegranate Juice Consumption on Myocardial Perfusion in Patients with Coronary Heart Disease*, 96 Am. J. Cardiology 810, 813 (2005). CX0744_0001-10.

Dr. Ornish's second study (Bev 2 Study) was a randomized, double-blinded, placebo-controlled study of fifty-five patients designed to replicate Dr. Aviram's CIMT results. In 2005, Dr. Ornish relayed to Respondents the study results, which showed "no significant changes in the experimental group relative to the placebo." Tr. of S. Resnick Dep. at CX1360_0169-170; CX0754_0001. Thereafter, Respondents made no attempt to have Dr. Ornish's study and its results published, but continued to make cardiovascular benefit claims based on Dr. Aviram's 2004 unblinded, uncontrolled CIMT study. CX0754_0002; *see, e.g.*, CX0034; CX0169; CX0471_0046.

While Dr. Ornish's studies were underway, Respondents approached Dr. Michael Davidson, a cardiologist and Executive Medical Director of Radiant Research, to conduct research on the effects of pomegranate juice on certain markers of cardiovascular disease. Tr. of M. Davidson Dep. at CX1336_0098-99. In 2005, Dr. Davidson provided Respondents with results of his randomized, double-blinded, placebo-controlled study of 45 patients to determine whether pomegranate juice improved blood vessel function as measured by brachial artery reactivity testing ("BART"). The Davidson BART trial showed no statistically significant differences between the active and placebo groups after 13 weeks, and no significant changes in blood pressure. Respondents did not attempt to have this study published.

In a second effort to replicate Dr. Aviram's 2004 CIMT study, but in a somewhat healthier patient population, Respondents funded an 18-month study by Dr. Davidson of the effect of pomegranate juice on CIMT in 289 persons with moderate coronary heart disease (CHD). At the twelfth month of this randomized, double-blinded, placebo-controlled study, the pomegranate juice group experienced significant improvements in one CIMT measure compared to the placebo

group. At the end of the 18-month trial, however, there was no difference between the active and placebo groups in any CIMT measures. In addition, as in the Davidson BART trial, the Ornish CIMT trial, and the Ornish myocardial perfusion study, there were no significant changes in blood pressure.¹⁰ Respondents learned of the results of the Davidson study in 2006, but for over two and a half years delayed authorization for Davidson to publish the results. Tr. of M. Davidson Dep. at CX1336_0144. Nevertheless, from 2006 through 2009, Respondents continued to make cardiovascular benefit claims for POM Juice and POMx based on Dr. Aviram's 2004 unblinded, uncontrolled CIMT study. *See, e.g.*, CX0034; CX0169; CX0471_0046. Finally, after analyzing subgroups, which yielded positive results, Respondents permitted the study to be published in 2009.¹¹ Tr. of M. Davidson Dep. at CX1336_0168-169, 180-181.

iv. Prostate Cancer Research

[REDACTED]

[REDACTED]

[REDACTED] CX0967_0001-58. These preliminary studies were never published. Based upon some of the initial results, Respondents contracted with

¹⁰An exploratory subgroup analysis indicated that pomegranate juice provided a benefit to persons with markers of more significant CHD risk; however, the authors noted that because the observations were “based on analyses that were not preplanned and had no correction for multiple comparisons . . . these findings will need to be confirmed in future investigations.” CX1199_0013.

¹¹M. Davidson et al., *Effects of Consumption of Pomegranate Juice on Carotid Intima-Media Thickness in Men and Women at Moderate Risk for Coronary Heart Disease*, 104 Am. J. Cardiology 936 (2009). CX1199_0001-14.

UCLA to conduct a clinical trial on prostate cancer, the results of which were published in 2006.¹² This Phase II¹³ study led by Dr. Allan Pantuck, evaluated the effect of POM Juice on 46 men previously treated for prostate cancer by radiation therapy or surgery. The researchers measured the participants' prostate specific antigen (PSA) levels every three months, and used the measurements to calculate the participants' PSA doubling time ("PSADT").¹⁴ The investigators found that the mean PSADT significantly increased from a mean of 15 months at baseline to 54 months after treatment. However, they concluded that further research was needed to address the limitations of the study, namely the lack of a blinded control group.

After publication of the Pantuck Phase II study, Respondents began promoting POM Juice and POMx to consumers as beneficial for prostate cancer. *See, e.g.*, CX0120; CX0122; CX0260. Despite Dr. Pantuck's concern that "the lay interpretation" of POM Wonderful's ads will be that "[POM Juice] shows promise for the treatment of prostate cancer" (CX0071_0001), Respondents

¹²A.J. Pantuck et al., *Phase II Study of Pomegranate Juice for Men with Rising Prostate-Specific Antigen Following Surgery or Radiation for Prostate Cancer*, 12 *Clinical Cancer Res.* 4018 (2006). CX0815_0001-18.

¹³Generally, preventative or therapeutic agents become standard of care after undergoing several phases of clinical testing. Pre-clinical studies would include animal and *in vitro* studies in which a potential treatment is studied for safety. Phase I trials test a treatment in a small number of patients to find a safe dose, to decide how a new treatment should be administered (orally or by injection), and to see how the treatment affects the human body. Phase II trials test a treatment in a larger number of people to determine if the treatment has an effect. Phase III trials test a treatment in an even larger number of people to compare the new treatment with a standard treatment. Phase IV trials test a treatment in several hundred to thousands of people to further assess the long-term safety and effectiveness of a treatment.

¹⁴Usually measured in months, PSADT is the time it takes for PSA levels to double. As noted by the authors of the Pantuck study, "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.

moved ahead with their advertising and funded another clinical study on prostate cancer led by Dr. Pantuck.¹⁵

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] During the course of recruiting patients for this study, some research institutions either sought an Investigational New Drug (“IND”) application¹⁷ or requested that Respondents seek guidance from the FDA on the need for an IND because the protocols were designed to determine a “treatment” effect. CX0759_0001-4; CX1020_0001-16; CX0811_0001. Thereafter, Respondents provided assurance to the institutions that they did not intend to make any treatment or disease claims.¹⁸ *See e.g.*, CX0811_0001.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

¹⁵ [REDACTED] CX1032_0001-64.

¹⁶ [REDACTED]

¹⁷In general terms, an IND is an application to the FDA to allow a study sponsor to initiate a clinical trial to test a therapeutic agent in humans.

¹⁸ [REDACTED] CX1020_0001-16.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Johns Hopkins University questioned whether Respondents needed to submit an

IND to the FDA because the study protocols were designed to determine a treatment effect. The

study proceeded after Respondents submitted a letter to Johns Hopkins stating that it did not

intend to market POMx as a treatment for prostate cancer. CX0942_0001-19. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] CX1056_0001; CX1066_0001-3. [REDACTED]

19 [REDACTED]

[REDACTED]

20 [REDACTED]

[REDACTED]

21 [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] CX1074_0001-6; CX1107_0001-83. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Tr. of M. Carducci Dep.

at CX1340_0039.

v. Erectile Dysfunction Research

In 2003, Respondents began sponsoring research on the potential effect of POM Juice on erectile dysfunction. Respondents approached Dr. Kazem Azadzoi, who evaluated the effect of POM Juice in rabbits with ED and concluded that pomegranate juice increased intracavernous blood flow and smooth muscle cell relaxation, possibly by increasing bioavailability of nitric oxide. The study was published in 2005.²⁴

Thereafter, Respondents sponsored a double-blinded, placebo-controlled study of the effect of POM Juice on 53 human subjects with mild to moderate erectile dysfunction, which was published in 2007.²⁵ This study, led by Dr. Harin Padma-Nathan and Christopher Forest of the

²² [REDACTED] X1107_0001-83.

²³ [REDACTED]

²⁴Azadzoi et al., *Oxidative Stress in Arteriogenic Erectile Dysfunction: Prophylactic Role of Antioxidants*, 174 J. of Urology 386 (2005). CX1185_0001-8.

²⁵C.P. Forest et al., *Efficacy and Safety of Pomegranate Juice on Improvement of Erectile Dysfunction in Male Patients with Mild to Moderate Erectile Dysfunction: a Randomized,*

Male Clinic, showed no statistically significant difference between POM Juice and placebo. Despite the research showing no statistically significant difference between POM Juice and placebo, Respondents began promoting POM Juice as beneficial for erectile dysfunction. *See, e.g.,* Complaint Ex. B; Ex. F; CX0347. [REDACTED]

[REDACTED] CX1152-1160.

4. Respondents' Knowledge of Substantiation Requirements

As Respondents promoted their products as a cure all for a variety of diseases, they repeatedly ignored warning signals indicating that their marketing did not match their science. As early as 2003, Respondents sought input from an outside consultant on a regulatory strategy for obtaining a qualified health claim from the FDA. The strategy involved submitting a health claim petition to FDA that described the claim and evaluated the science to support the claim. Respondents decided not to pursue a health claim petition at that time. Nevertheless, Respondents chose to make cardiovascular claims in the POM Juice advertising.

Through their annual research summits with outside researchers, the Respondents are aware of the inadequacies of their scientific research and the level of substantiation necessary to legally make disease claims. At these summits, POM Wonderful focused on reviewing the latest POM research results, discussing current research status, gaps and future directions, providing updates on POM products and other relevant activities, and enhancing interactions among investigators, leaders in the medical community, and POM. CX0984_0002; S. Resnick Dep. at 100-01. In addition to these summits, the Respondents conduct medical research portfolio

Placebo-controlled, Double-blind, Crossover Study, Int'l J. Impotence Res. 1-4 (2007). CX0908_0001-4.

reviews that identified how POM Wonderful’s research fell short of the level of science needed for health claims and drug approval. For example, one summary noted that for prostate cancer PSA was not an accepted endpoint and that there was “no data on prostate cancer prevention, prior to radiation or prostatectomy” while the heart disease research had “holes” and the erectile dysfunction study failed to show statistical significance. CX1058. Furthermore, in marketing a new product in POMx, Lynda Resnick was aware that the Dietary Supplements Health and Education Act did not allow dietary supplements to make disease claims to consumers, including through advertisements, websites, or product labels. CX0054_0001. Nonetheless, the Respondents still proceeded to make such health claims.

The Respondents’ awareness of the necessary level of evidence and their continued disregard for those standards is evident. The Respondents’ health claims for POM Juice have been the subject of two decisions by the Council for Better Business Bureaus’ National Advertising Division (NAD).²⁶ In 2005, the NAD issued a decision recommending that POM Wonderful modify some of its claims to avoid misleading consumers into believing that drinking eight ounces of POM Juice would prevent arterial plaque build-up in healthy individuals. In 2006, Welch Foods, Inc. filed a claim with the NAD, challenging POM Wonderful’s various disease prevention and treatment claims. The NAD rejected POM Wonderful’s assertions that some claims were puffery, found that their studies did not support their claims, and again recommended that POM Wonderful modify their claims.

However, the Respondents’ pattern of ignoring warning signals about their lack of

²⁶POM Wonderful, LLC, Case #4303 (Mar. 30, 2005); POM Wonderful LLC, Case #4468 (Apr. 5, 2006).

substantiation continued. In May 2008, POM Wonderful sought clearance from NBC for a television commercial, which included copy stating that POM Juice’s antioxidants promoted prostate health. NBC’s advertisement reviewer found that POM Wonderful’s substantiation failed to meet the network’s clinical testing guidelines. NBC considered human studies only, and the prostate cancer study relied upon by POM Wonderful was neither randomized nor controlled, and clearly stated the need for further research to prove validity. CX0193. Also, in May 2008, UCLA’s Institutional Review Board (“IRB”) expressed concern about the Respondents’ advertising. In response, Mark Dreher sent a letter along with a copy of the FTC’s *Dietary Supplements: An Advertising Guide for Industry* to Dr. Pantuck explaining that FDA governs “non-disease structure and function claims[,]” that “the FTC oversees advertising claims[,]” and that “[a]s a policy, POM does not make drug related disease claims associated with treatment, cure, prevention, or diagnosis.” CX0195_0001; CX0976_0006. Despite this representation to UCLA’s IRB, Respondents made no attempt to curb their claims.

Moreover, regulatory agencies like the FDA and the FTC have expressed concerns with POM Wonderful’s advertisements. [REDACTED]

[REDACTED] Respondents made no attempt to change their advertising. Complaint Ex. B; Ex. F. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] CX0344_0001-5.

In sum, Respondents had knowledge of the necessary level of substantiation for the claims they were making, received numerous signals over the years concerning their claims for POM

Juice and POMx, and persisted in discounting these signals.

II. RESPONDENTS' DECEPTIVE ADVERTISING CLAIMS

An “advertisement is deceptive under the [FTC] Act if it is likely to mislead consumers, acting reasonably under the circumstances, in a material respect.” *In re Daniel Chapter One*, No. 9329, Initial Decision, at *81 (F.T.C. Aug. 5, 2009), *pet. review denied*, 2010 U.S. App. LEXIS 25496 (D.C. Cir. Dec. 10, 2010) (quoting *Kraft, Inc. v. FTC*, 970 F.2d 311, 314 (7th Cir. 1992)). To evaluate whether an advertisement is deceptive, the Commission applies a three-part inquiry as to: “(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 first and third prong are discussed below.

A. The Legal Framework for Determining What Claims Respondents' Advertisements Convey

“The primary evidence of the claims an advertisement conveys to reasonable consumers is the advertisement itself.” *Daniel Chapter One*, Initial Decision, at *83 (citing *Telebrands Corp.*, 140 F.T.C. 278, 290 (Sept. 19, 2005), *aff'd*, 457 F.3d 354 (4th Cir. 2006); *Novartis Corp.*, 127 F.T.C. 580, 680 (May 13, 1999); *Kraft*, 1991 FTC LEXIS 38, at *12). 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, at *82 (citing *American Home Prods. Corp. v. FTC*, 695 F.2d 681, 687 (3d Cir. 1982); *Kraft*, 1991 FTC LEXIS 38, at *14; *Thompson Med.*, 104 F.T.C. at 323 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)).

The claims conveyed by an advertisement may be express or implied. “Express claims directly represent the fact at issue while implied claims do so in an oblique or indirect way.” *Kraft*, 970 F.2d at 318 (citing *Thompson Medical*, 104 F.T.C. at 788). “Even literally true statements can have misleading implications.” *Id.*, at 322 (citing *Zauderer v. Office of Disciplinary Council*, 471 U.S. 626, 652 (1985); *Thompson Med.*, 791 F.2d at 197; *Removatron Int’l Corp.*, 111 F.T.C. 206, 292-95 (1988), *aff’d*, 884 F.2d 1389 (1st Cir. 1989); *American Home Prods.*, 695 F.2d at 687); *see also Nat’l Urological Group*, 645 F. Supp. 2d 1167, 1189 (N.D. Ga. 2008).

Courts have consistently held that “the Commission may rely on its own reasoned analysis to determine what claims, including implied ones, are conveyed in a challenged advertisement, so long as those claims are reasonably clear from the face of the advertisement.” *Kraft*, 970 F.2d at 319. 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.” *Nat’l Urological Group*, 645 F. Supp. 2d at 1189; *see also Kraft*, 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.”); *FTC v. Colgate-Palmolive Co.*, 380 U.S. 374, 391-92 (1965) (stating that the FTC is not required to conduct consumer surveys before determining that a commercial has a tendency to mislead).

An advertisement may have more than one reasonable interpretation. *In re Telebrands Corp.*, 140 F.T.C. at 290 (citing *Kraft*, 114 F.T.C. at 120-21 n.8; *Thompson Medical*, 104 F.T.C. at 787 n.7). “Statements susceptible of both a misleading and a truthful interpretation will be construed against the advertiser.” *FTC v. Bronson Partners*, 564 F. Supp. 2d at 127 n.6 (quoting *Country Tweeds, Inc. v. FTC*, 326 F.2d 144, 148 (2d Cir. 1964)). “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 290 (citing *Kraft*, 114 F.T.C. at 122 and *Deception Statement*, 103 F.T.C. at 177, n.20.). Furthermore, “if an ad is targeted at a particular audience, the Commission analyzes ads from the perspective of that audience.” *Telebrands Corp.*, 140 F.T.C. at 290 (citing *Deception Statement*, 103 F.T.C. at 178-79).

Although proof of intent to make a particular claim is not required to find a party liable 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*, 140 F.T.C. 278, 304 (citing *Novartis*, 127 F.T.C. at 683 and *Thompson Med.*, 104 F.T.C. at 791).

B. Respondents Represent That the Challenged Products Effectively Prevent, Reduce The Risk of, and/or Treat Heart Disease, Prostate Cancer, and Erectile Dysfunction, and That Their Research Proves the Efficacy of Those Products

As discussed in detail below, a facial analysis of Respondents’ advertising and promotional materials results in the conclusion that each advertisement created the net impression that the Challenged Products are effective in treating and/or preventing or reducing the risk of heart disease, prostate cancer, and/or erectile dysfunction, and often that their scientific research proves it, as alleged in the Complaint. Further supporting this facial analysis is the compelling

evidence that Respondents intended to make these claims as described in Section I.C. Moreover, the claims are particularly strong when viewed from the perspective of Respondents' target audiences such as health-conscious individuals (even "hypochondriacs") ages 25-49, men who feared getting prostate cancer, and women concerned about heart disease, and for POMx, persons "seeking a natural cure for current ailments or to maintain health and prevent future ailments." (Compilation of marketing creative briefs at CX0409; e.g., CX0409_0015-16, 18, 20, 61, POM_Q9-0003186-89,)

The central theme of the vast majority of Respondents' advertising and marketing is disease prevention or treatment. Premised on the theory that antioxidants fight disease-causing free radicals, the promotion of the Challenged Products as superior sources of antioxidants provides the platform for Respondents to make a variety of disease claims, including the heart disease, prostate cancer, and erectile dysfunction claims alleged in the Complaint. POM Juice as the "Antioxidant Superpower" appears repeatedly in the text of advertisements. (*See, e.g.,* Complaint Exs. A and E-2 at 3:34).

In addition, the ads set up the premise that without a superior antioxidant product like the challenged products, the risk of contracting either heart disease or prostate cancer is more likely than not. For example, a 2004 advertorial²⁷ titled "Studies Show That 10 Out of 10 People Don't Want to Die," (CX0029_0001) states:

Fighting Free Radicals

Let's start with the problem: free radicals . . . unstable little molecules that can accelerate aging, lead to heart disease and

²⁷The Oxford English Dictionary defines "advertorial" as "[a]n advertisement written in the form of an editorial, which purportedly provides objective information about a commercial or industrial subject." *Oxford English Dictionary* (2d ed. 2011).

stroke, and have even been implicated in cancer. Where do they come from? Everywhere. Free radicals are formed by exposure to air pollution, alcohol, pesticides, sunlight, tobacco smoke, drugs, even fried foods. Of course, when you're very young, your body's self-repair mechanism can neutralize the activity of many free radicals. But by the time you're in your twenties, those mechanisms just don't work as well. That's where antioxidants come in. They neutralize free radicals, helping to prevent the cell and tissue damage that leads to disease. Which brings us back to POM Wonderful Pomegranate Juice.

Then, the advertorial ominously warns:

The Heart Stopping Truth

Remember: heart disease is America's number one killer. For women as well as men. 98% of heart attacks are due to atherosclerosis, or too much plaque in the arteries. That same plaque increases your chance of stroke. One final scary statistic: half of patients who have a severe heart attack have normal cholesterol levels. In other words, we're all at risk.
(CX0029_0002)

By emphasizing the asserted free-radical- disease fighting properties of antioxidants and touting POM Juice as “the Antioxidant Superpower,” Respondents’ advertising cloaks the Challenged Products in the guise of a veritable cure-all for its target audience. Indeed, in promotional interviews, Respondent Lynda Resnick aggressively sought to present POM Juice as the panacea for our time. In a November 2008 interview available on YouTube, Ms. Resnick described POM Juice as “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 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.” (Complaint Exh. E-6). Similarly, Respondents’ “Cheat death” series of advertisements, which depicts the POM Juice bottle with a

noose around its neck, perpetuates the image of POM Juice as a “magic elixir.” (CX0036_0001). The copy below the image boasts, “[i]t 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.”²⁸

Building on “the Antioxidant Superpower” concept, Respondents drive home their disease-fighting message by emphasizing that their purported health benefits are “Backed by Science” and supported by “Real Studies. Real Results.” (Complaint Exs. E-1 at 0:06 and E-2 at 9:01). Advertisements for the Challenged Products routinely reference the millions of dollars Respondents have purportedly spent on “medical research,” a number that has ranged from \$20 million to \$34 million over the years.²⁹ The 2009 hang tag displayed on all of its 100% POM Juice bottles expressly stated:

It’s 100% pure! It’s heroically healthy! It’s The Antioxidant Superpower, POM

²⁸ Moreover, Respondents expressly tell consumers that the intent of the Cheat Death ad was to convey its benefit in preventing heart disease. The typical POM response to any consumer who contacted POM to complain about the tonality of the “Cheat Death” advertisement stated “Our advertising campaign is created with the intent of using imagery that irreverently and boldly conveys to consumers that drinking our juice may help prevent disease. POM Wonderful Pomegranate Juice has many distinct health benefits that set it apart from other products, and recent medical research supports an acknowledgment that drinking pomegranate juice may lessen factors that contribute to heart disease. Since heart disease is, sadly, the number one cause of death in the United States for men and women, we feel that it is important to communicate to our consumers the powerful benefits of drinking 100% pomegranate juice.” (CX0456_0002-5.)

²⁹ [REDACTED] POM Medical Research Expenses Spreadsheet at CX1276.) Moreover, there is no correlation to actual results or published studies which ostensibly “back” up Respondents’ claims. The \$32 million touted in the ad is merely a running cumulative tally of all the respondents’ research expenses and includes everything from in vitro, animal, and human studies whether or not published or yielding positive or negative results, to animal feed studies, to expenses such as legal costs, research conference costs, and medical show exhibition fees. (M. Tupper Dep. at 48-49.)

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!

(Complaint Ex. A.) A February 2009 print advertisement in *Fitness Magazine*, which was part of the Super Hero, carried the bold headline: “HOLY HEALTH! \$25 million in medical research,” and copy that read: “In a time of major health problems, one 16-ounce hero will unleash its incredible healing powers: POM Wonderful 100% pure pomegranate juice. Backed by an unheard of \$25 million in medical research . . .” (Complaint Ex. D.) In January 2010, the POM Wonderful website boasted, “[o]nly POM Wonderful products are backed by \$32 million in medical research. Actually we are the only pomegranate juice backed by any medical research at all.” (Complaint Ex. E-5 at 02:00; *see also* Complaint Ex. E-3 at 00:14 (“Health Benefits” webpage, April 30, 2009)); (Complaint Ex. E-1 at 01:17 (“Backed by Science” web page, Apr. 28, 2009)).

Without fail, the advertisements further advance the “backed by science” representation by discussing the results and statistical findings of its medical research in the areas of heart disease, prostate cancer, and erectile dysfunction, citing publications in scientific journals, and highlighting POM Wonderful’s affiliations with prominent research institutions, doctors, and scientists.

Respondents’ advertisements for POM Juice commonly point out that they’ve worked with top scientists, including a Nobel Laureate and leading universities, list the number of published, peer-reviewed papers on their products to date, and cite statistics like “our scientific research shows that pomegranate juice is 8 times better than green tea at preventing formation of oxidized (sticky) LDL” and “a clinical pilot study shows that an 8 oz. Glass of [POM Juice],

consumed daily, reduces plaque in the arteries up to 30%.” (*See, e.g.*, CX0029_0002, CX0016).

Typical is the section of the pomwonderful.com website, titled “The Science of POM Wonderful,” depicting a microscope and the POM Juice bottle alongside the text,

For centuries, the pomegranate has been valued as a symbol of health. Could the legends have some basis in fact? In 1998, research began in an effort to get some answers. 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.

(Complaint Exhibit E-2 at 8:52). A list of selected study references followed, organized under the subheadings “Cardiovascular,” “Cancer Studies,” and “Erectile Function.” This portion of pomwonderful.com also included an array of links to scientific articles and graphs illustrating POM Juice’s purported health benefits. *Id.* at 8:52-10:30.

In spite of the fact that POMx Pills and Liquid are different products, Respondents have transferred wholesale to POMx advertising and marketing, the POM juice studies to supposedly prove to consumers that POMx has the same purported disease treatment and prevention benefits as POM Juice.³⁰ In April 2010, for instance, Respondents disseminated a print advertisement for POMx Pills with a headline in large, capital letters, “24 SCIENTIFIC STUDIES. NOW IN ONE EASY-TO-SWALLOW PILL.” (CX0016.) The advertisement stated “\$32 million in medical

³⁰The advertisements invariably show the image of a capsule and a bottle of POM Juice linked by an equal sign, with the caption “The antioxidant power of our 8oz juice.” *See, e.g.*, Complaint Exs. I-L. Many of the POMx Pills print advertisements contain some variation of the slogan, “The power of POM. Now in one little pill.” Complaint Ex. I (POMx package insert). *See also* Complaint Ex. L (stating in a large-type headline “The power of POM, in one little pill.”); Complaint Ex. E-9 (“Take it daily. Feel it forever.”).

research. Science. Not fiction” and under the subheading “Complicated studies. Simplified,” cited “[a]n initial UCLA study . . . reporting ‘statistically significant prolongation of PSA doubling times,’ according to Dr. Allen [sic] J. Pantuck in *Clinical Cancer Research*, 2006,” and a “preliminary study . . . [showing that] ‘[s]tress-induced ischemia (restricted blood flow to the heart) decreased in the pomegranate group,’ Dr. Dean Ornish reported in the *American Journal of Cardiology*, 2005.” Like the pomwonderful.com website, the pompills.com web pages are replete with similar research content. (Complaint Ex. E-9 at 00:36).

As the Commission concluded in *Removatron International Corporation*, a case involving a purported hair removal device,

[R]eferences to clinical testing, research and case studies are express claims that the respondents’ representations are supported by scientific evidence. In addition, the claims of tissue destruction, papilla dehydration and coagulation, together with the visual depiction of the hair’s elements, provide a scientific aura and can reasonably interpreted as implying a scientific level of support. Accordingly, we find that the net impression of these advertisements and promotional materials is that respondents’ claims were based on competent scientific proof.³¹

111 F.T.C. at 298 (internal citations omitted). Thus, Respondents’ repeated references to the scientific testing conducted on its products clearly convey the challenged establishment claims that clinical studies, research, and/or trials prove that consumption of the Challenged Products

³¹Respondents may argue that their advertisements do not convey the claims alleged in the Complaint because of the use of qualifiers such as “initial,” “pilot,” or “preliminary” to describe Respondents’ medical research. However, when juxtaposed with the bold claims about research spending and other indicia of scientific credibility, these qualifiers do little to break through the “scientific aura” generated by Respondents’ advertisements. In fact, as Complaint Counsel’s rebuttal witness, Dr. David Stewart, asserts in his report, empirical evidence has shown that “the presence of qualifiers increases the credibility of claims relative to the absence of a similar claim without a qualifier.” (Stewart Report at 15).

prevents, reduces the risk of, and/or treats the enumerated diseases.

The advertising and marketing that conveys Respondents' express and virtually express claims for heart disease, prostate cancer, and erectile dysfunction are set forth in detail below by disease.

C. Respondents' Heart Disease Prevention, Reduction of Risk, and Treatment Claims

The Complaint alleges that Respondents have represented, expressly or by implication, that drinking eight ounces of POM Juice, or taking one POMx Pill or one teaspoon of POMx Liquid, daily:

- “[P]revents 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.” (Complaint ¶ 19A); and
- “[T]reats heart disease, including by (1) decreasing arterial plaque, (2) lowering blood pressure, and/or (3) improving blood flow to the heart.” (Complaint ¶ 19B).

The Complaint also alleges that the Respondents have represented, expressly or by implication, that *clinical studies, research, and/or trials prove* the above claims. (Complaint ¶ 12A and B.)

These representations are found, either expressly or by implication, throughout POM Wonderful's websites, in print advertisements, and in other marketing materials.

1. Website Claims

Respondents websites are replete with links to scientific articles, statistical findings from studies, and explanatory text about heart disease and the respondents' research demonstrating that the challenged products effectively prevent and treat it.

The April 2009 “Health Benefits” section of POM's website, pomwonderful.com, depicts

the image of a POM Juice bottle suspended on an intravenous drip. Under the subheading “Cardiovascular,” the page summarized two of its sponsored studies. The first was “a 2005 study published in the American Journal of Cardiology show[ing] [that] . . . [p]atients drinking [POM Juice] experienced a 17% improvement in blood flow, compared to . . . patients drinking a placebo.” The second was a “pilot study on 19 patients with atherosclerosis . . . at the Technion Institute in Israel [that] demonstrated a reduction in arterial plaque growth. After one year, arterial plaque decreased by 30% for those patients who consumed 8oz. of [POM Juice] daily, compared to . . . patients who drank a placebo.”

In January 2010, a pomfills.com webpage titled “The Heart of the Matter,” stated “Amaze your cardiologist. Take POMx,” continuing on to explain that “POMx is made from the only pomegranates supported by \$32 million of initial scientific research from leading universities.” (Complaint Ex. E-9 at 1:18, January 2010; *see also* Complaint Ex. E-8, April 2009). The webpage also highlighted the results of a study led by Dean Ornish at the University of California, reporting that “patients who consumed 8oz of [POM Juice] daily for 3 months experienced 17% improved blood flow,” as well as Michael Aviram’s atherosclerosis study in which a 30% decrease in arterial plaque was reported. (Complaint Ex. E-9, at 0:41). Michael Aviram was described as “one of the world’s preeminent cardiovascular researchers,” and is quoted as stating, “POMx is as potent an antioxidant as pomegranate juice and just like pomegranate juice, POMx may promote cardiovascular health.” Finally, the webpage depicted the caduceus symbol (two serpents entwining a staff), reinforcing the medical theme.

Respondents also used the “POM Glossary” page on its website as an opportunity to promote POM Juice. (Complaint Ex. E-2 at 0:19.) For example, the definition of “ACE” (*i.e.*,

angiotensin-converting enzyme) includes 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%.” (Complaint Ex. E-2 at 01:26.) The definition of “Atherosclerosis” concludes 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%.” (Complaint Ex. E-2 at 4:44).

Although Respondents have added qualifiers such as “promising,” “emerging” and “pilot” at various points on the website, the effect is merely nominal, and, arguably even lends the website an air of scientific credibility when juxtaposed with introductory text warnings about the dangers of heart disease such as “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.” (Complaint Ex. E-2, at 0:44) and the repeated admonition that drinking an 8 oz. glass of POM Juice daily is healthy and treated heart disease in its sponsored studies.

2. Print Advertisement Claims

As early as 2003, a POM Juice advertisement began with a headline that promised consumers, “Drink and be healthy,” and continued “**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.” (CX0442.) This communicates that drinking POM Juice prevents, reduces the risk of, and/or treats heart disease.

Respondents’ “Dressed Bottle” campaign included a series of print advertisements touting, expressly and by implication, the benefits of drinking POM Juice to prevent, reduce the

risk of, and/or treat heart disease. One advertisement, with the headline “Floss your arteries. Daily,” depicts a POM Juice bottle on the shelf of a medicine cabinet. (CX0031_0001). The copy beneath this image elaborates on the “Floss your arteries” headline in no uncertain terms:

Clogged arteries lead to heart trouble. It’s that simple. That’s where we come in. Delicious POM Wonderful Pomegranate Juice has more naturally occurring antioxidants than any other drink. 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 POM Wonderful.

Respondents effectively give viewers a prescription for unclogging their arteries, thereby warding off “heart trouble,” by touting that “Just eight ounces a day can reduce plaque by up to 30%!” An asterisk directs the viewer to a citation to “Aviram, M. *Clinical Nutrition*, 2004. Based on clinical pilot study.” No further explanation follows, and this study reference does little more than provide the appearance of scientific credibility.³²

In a similar vein, Respondents cite the 2004 Aviram study in another print advertisement with the headline “Amaze your cardiologist.” (CX0034_0001.) The headline is juxtaposed with the image of the POM Juice bottle attached to electrodes. The copy below the image declares: “Ace your EKG: just drink 8 ounces of delicious POM Wonderful Pomegranate Juice a day. It has more naturally occurring antioxidants than any other drink. Antioxidants fight free radicals . . . nasty little molecules that can cause sticky, artery clogging plaque. A glass a day can reduce plaque by up to 30%!* Trust us, your cardiologist will be amazed.” The asterisk leads the reader

³² Respondents’ linguistic expert, Dr. Butters, baldly asserts in his report (Butters Report at 23) that the use of the word “pilot” is adequate to qualify the 30% claim, but there is no evidence to support that the average consumer would understand the import of this scientific term of art, particularly when it appears in the context of the ad’s overall hard-hitting language and imagery.

to a footnote that reads “Aviram M., Clinical Nutrition, 2004. Based on a pilot study.”

Other “Dressed Bottle” print advertisements sending a similar message of cardiovascular benefit include “Decompress,” which depicts a POM Juice bottle encased in a blood-pressure cuff and statements such as “[keep] your ticker ticking and drink 8 ounces a day” and cites “\$20 million of initial scientific research from leading universities which has uncovered encouraging results in . . . cardiovascular health,” (CX0311_0001), and “Heart Therapy,” depicting the POM Juice bottle reclining on a couch accompanied by similar copy. (CX0377_0002). In each advertisement, the interplay of all of these factors unmistakably creates the net impression that daily consumption of POM Juice prevents, reduces the risk of, or treats heart disease and that clinical studies, research, and/or trials prove it.

3. Other Marketing Material Claims

The POMx shipping inserts, like the pomfills.com website that it references, touts “two groundbreaking preliminary studies [in which] patients who drank [POM Juice] experienced impressive cardiovascular results.” (Complaint Ex. I.) Respondents also disseminated a “POMx Heart Newsletter” (Complaint Exh. M) in 2007, featuring a “What’s New in the Lab by Dr. Mark Dreher” column and discussion under subheadings like, “Antioxidants: Your Ally in Fighting Heart Disease,” “The Free Radical Fighter,” “New Research Offers Further Proof of the Heart-Healthy Benefits of POM Wonderful Juice,” “30% Decrease in Arterial Plaque,” and “17% Improved Blood Flow. Again the heart disease treatment and prevention claims come through loud and clear to the targeted audience.

D. Respondents' Prostate Cancer Prevention, Reduction of Risk, and Treatment Claims

The Complaint alleges that Respondents have represented, expressly or by implication, that drinking eight ounces of POM Juice, or taking one POMx Pill or one teaspoon of POMx Liquid, daily:

- “[P]revents or reduces the risk of prostate cancer, including by prolonging prostate-specific antigen doubling time (“PSADT”).” (Complaint ¶ 19C); and
- “[T]reats prostate cancer, including by prolonging prostate-specific antigen doubling time (“PSADT”).” (Complaint ¶ 19D).

The Complaint also alleges that the Respondents have represented, expressly or by implication, that *clinical studies, research, and/or trials prove* these claims. Again, the representations were conveyed, either expressly or by implication, on POM Wonderful’s websites, in print advertisements, and in other promotional materials.

1. Website Claims

In April 2009, the “Health Benefits” section of pomwonderful.com stated, under the subheading “Prostate Health,” “[a] preliminary UCLA medical study, published by the American Association for Cancer Research, found hopeful results for prostate health. . . . After drinking 8 oz [POM Juice] daily for two years, these men experienced significantly slower PSA doubling times PSA is a biomarker for prostate cancer, and slower PSA doubling time may indicate slower disease progression.” (Complaint Ex. E-2 at 00:25). In April 2009, “The Science of POM Wonderful” page on the same website also listed this study under the bolded subheading “Cancer Studies.” (Complaint Ex. E-2 at 10:30.)

Interviews by Mrs. Resnick and Mr. Tupper discussing the specific disease benefits at issue also were posted on pomwonderful.com. (Complaint Exh. F.) In a March 2009 interview in *Newsweek*, Mrs. Resnick explicitly touted POM Juice’s purported treatment and prevention benefits for prostate cancer. When the interviewer commented that his father was “in good health. Had a bout of prostate cancer,” Mrs. Resnick responded:

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 [sic] men . . . It arrested their PSA.

Similarly, in a June 2008 interview, Matt Tupper stated, “the dose that’s been shown to be effective is eight ounces a day 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.” (Complaint Ex. E-7).

2. Print Advertisement Claims

Respondents’ print advertisements similarly conveyed express and strongly-implied claims regarding prostate cancer. A full-page print advertisement from the December 2008 issue of *Prevention* featured the headline “Drink to prostate health,” and stated “Sometimes, good medicine can taste great” and continued on to describe a “recently published preliminary medical study” on “46 men previously treated for prostate cancer, either with surgery or radiation,” who, “[a]fter drinking 8 ounces of [POM Juice] daily for at least two years . . . experienced significantly longer PSA doubling times.” (Complaint Ex. B.)

Another print advertisement depicted a flying POM Juice bottle that boldly states, “I’m

off to save prostates.” The text continued by stating that “Man by man, gland by gland. The Antioxidant Superpower is 100% committed to defending healthy prostates” and that it is “backed by \$25 million in vigilant medical research.” The advertisement also referred consumers to the health benefits section of the pomwonderful.com website for details about a prostate study.

The net impression of such references to “prostate health,” “men treated for prostate cancer,” and “significantly longer PSA doubling times” inexorably communicates the claim that POM Juice treats, prevent, and/or reduces the risk of prostate cancer and that it’s scientifically validated.

3. Other Marketing Materials

In or about the Fall of 2007, Respondents disseminated a “POMx Pills and Liquid Prostate Newsletter.” (Complaint Ex. N). Prefaced with warnings in large, bold print that “Prostate Cancer Affects 1 Out of Every 6 Men,” and “Prostate cancer is the second leading cause of cancer related death in men in the United States according to the National Cancer Institute,” the newsletter described “a preliminary UCLA medical study” under the heading “New Pomegranate Research Offers Hope to Prostate Cancer Patients.” The newsletter also featured a column, “What’s New in the Lab by Dr. Mark Dreher,” who was identified as POM Wonderful LLC’s “Chief Science Officer.” In this “What’s New” section, Respondents boasted that “[POM 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. . . .” and that “studies funded by POM represent the vast majority of human medical research ever conducted on pomegranates.”

Similarly, the portion of the POMx package insert that purported to pertain to “Prostate

Health,” explicitly focused on prostate cancer. Indeed, the text immediately below the subheading “Prostate Health,” stated that “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” and noted that “[p]atients with quick PSA doubling times are more likely to die from their cancer.” (Complaint Ex. I.) Calling POMx a “time pill,” the insert boasted that “a UCLA study of 46 men age 65 to 70 with advanced prostate cancer, drinking an 8oz glass of [POM Juice] every day slowed their PSA doubling time by nearly 350%.” A quote from “David Heber, MD, PhD, Professor of Medicine and Director, UCLA Center for Human Nutrition” appeared near this information, stating in large print, “The most abundant and most active ingredients in pomegranate juice are also found in POMx. Basic studies indicate that POMx and [POM Juice] may have the same effects on prostate health.” Complaint Ex. I.

Finally, similar claims were presented in what is referred to as a “Time Wrap,” a four-page spread on the Challenged Products wrapped around Time Magazines subscribed to and placed in urologists’ offices. Through its dissemination in urologists offices, clearly Respondents intended to send a message to prostate cancer patients that their products could prevent or stop the recurrence of prostate cancer. *See, e.g., CX03709; CX0408.*

Thus, though Respondents may attempt to argue that their advertisement merely address “prostate health,” the advertisements themselves belie this assertion with repeated references to prostate cancer, the “recent” research results of the Pantuck Study, and the targeted dissemination of the claims. In each advertisement, the interplay of the factors described unmistakably create the net impression that the Challenged Products prevent, reduce the risk of, and treat prostate cancer and clinical studies, research, and/or trials prove it.

E. Respondents' Erectile Dysfunction Prevention, Reduction of Risk, and Treatment Claims

The Complaint alleges that Respondents have represented, expressly or by implication, that drinking eight ounces of POM Juice, daily:

- “[P]revents or reduces the risk of erectile dysfunction” (Complaint ¶ 19E); and
- “[T]reats erectile dysfunction” (Complaint ¶ 19F).

The Complaint also alleges that the Respondents have represented, expressly or by implication, that *clinical studies, research, and/or trials prove* these claims. (Complaint ¶ 16). Respondents started incorporating erectile dysfunction claims into their advertising fairly recently, but, as with their advertisements relating to heart disease and prostate cancer, these representations were conveyed, either expressly or by implication, on POM Wonderful’s websites in particular, as well as in print advertisements and promotional interviews.

1. Website Claims

In April 2009, the “Backed by Science” page of the pomegranatetruth.com website, under the subheading “Erectile Dysfunction,” described “[a] pilot study released in the International Journal of Impotence Research in 2007 [that] examined 61 male subjects with mild to moderate erectile dysfunction. Compared to participants taking a placebo, **those men drinking 8oz. of [POM Juice] daily for four weeks were 50% more likely to experience improved erections.**”³³ (Complaint Ex. E-1 at 02:14 (emphasis in original)). In another section of the

³³ This refers to the study by Christopher Forest, Harin Padma-Nathan, and Harley Liker. The “Health Benefits” page of pomwonderful.com discussed above, under the subheading “Erectile Function,” presented the same information, including placing in bold the same segment of text. Complaint Ex. E-2 at 00:25.

pomegranatetruth.com website titled “The truth about our pomegranates,” Respondents stated:

Backed by science.

POM is the only pomegranate juice backed by \$25 million in medical research. To date, numerous published clinical studies have documented the benefits of drinking pomegranate juice, benefits that include improved heart and prostate health and better erectile function. **All of these studies featured patients who drank POM Wonderful 100% Pomegranate Juice, not any other brands.**

The image of the caduceus symbol appeared directly alongside this text. (Complaint Ex. E-1 at 03:48.) Respondents also cited the Forest study in April 2009 on “The Science of POM Wonderful” section of pomwonderful.com under the subheading “Erectile Function.” (Complaint Ex. E-2 at 10:30.)

On the pompills.com website, under “FAQs,” Respondents answered the question “Erectile Dysfunction: Can pomegranate juice benefit men with erectile dysfunction?” by 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.

Complaint Ex. E-8 at 9:03.

In the 2008 *Newsweek* interview noted above and posted on the website, Mrs. Resnick stated that pomegranate juice was “40 percent as effective as Viagra.” (Complaint Ex. F.)

2. Print Advertisement Claims

In 2010, Respondents disseminated a print advertisement for POMx with the headline, “THE ONLY ANTIOXIDANT SUPPLEMENT RATED X.” Like other POMx advertisements, the “RATED X” advertisement emphasizes “backed by \$32 million in medical research at the

world's leading universities" (" \$32 million in research. We're not just playing doctor."), and describes the Forest study in addition to the Pantuck and Ornish studies. Of the Forest study, the advertisement states:

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. (CX0347_0001.)

In his report, Respondents' linguistic expert referred to this advertisement as a "joking ad" and an example of Respondents' use of parody.³⁴ (Butters Report at 24.) More generally, he asserted, but did not provide any references to the academic literature on this point, that "the use of humor and parody is prevalent in the Pom Wonderful Communications, humor which works to block any inference that the Pom Wonderful Communications are intended to make definitive health claims..." Butters Report at 4. This opinion is at odds with Respondent Lynda Resnick's view that "[i]f we can make you chuckle, we have an opportunity to connect with a more serious

³⁴Respondents have argued that their advertisements and promotional materials constitute mere "puffery." The case law is clear that "[w]here a claim is merely 'exaggerated advertising, blustering, and boasting upon which no reasonable buyer would rely,' it may be un-actionable puffery. However, "specific and measurable" claims and claims that may be literally true or false are not puffery, and may be the subject of deceptive advertising claims." *FTC v. Direct Mktg. Concepts, Inc.*, 624 F.3d 1 (1st Cir. 2010) (citing *Clorox Co. Puerto Rico v. Proctor & Gamble Comm. Co.*, 228 F.3d 24, 38 (1st Cir. 2000) (quotation marks omitted). See also *Daniel Chapter One*, initial decision at 99 ("Claims regarding a product's attributes, performance, or efficacy are considered 'objective' claims, as opposed to mere sales 'puffery,' because such claims can be objectively verified") (citing *Thompson Med.*, 104 F.T.C. at 788-89 n.6). Here, Respondents' attempts to cast their health claims as puffery are thwarted by the scientific objectivity of their advertising claims and the persistence with which they tout their supporting "medical research," including detailed references to study findings, statistics, and dollars spent.

message grounded in our brand’s identity and extrinsic value.” (*Rubies in the Orchard* at 112; CX0001). Indeed, as Complaint Counsel’s rebuttal expert, Dr. David Stewart, stated in his report:

Humor can serve to break through advertising ‘clutter,’ to catch the consumer’s attention, and to disarm the consumer and reduce counter-arguing (Shabbir and Thwaites 2007). There is a rich literature on the use of humor in advertising that clearly demonstrates its power to attract attention and increase message comprehension (Duncan, Nelson, and Frontczak 1984; Sternthal and Craig 1973). Moreover, there is no evidence in the marketing literature that consumers would be skeptical of claims that employ humor and parody Eisend (2010) concludes ‘affective reactions triggered by humor can increase positive cognitions related to the ad, but reduce brand-related cognitions. By this, humor may help overcome weaknesses in advertising messages such as weak brand arguments or even negative information such as those provided in two-sided messages.’ Stewart at 7-8.

Again, as with the heart disease and prostate cancer claims, in each advertisement featuring erectile dysfunction claims, the interplay of the various factors unmistakably create the net impression that POM Juice prevents, reduces the risk of, and treats erectile dysfunction and that clinical studies, research, and/or trials prove it.

F. Respondents’ Advertising Claims Are Material

“A claim is considered material if it ‘involves information that is important to consumers and, hence, likely to affect their choice of, or conduct regarding a product.’” *Daniel Chapter One*, initial decision at 107 (quoting *Kraft*, 970 F.2d at 322 (citations omitted)); see *Novartis*, 127 F.T.C. at 691, n.16 (“it is the challenged claim that is at issue and not the ad as a whole”). 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*, 127 F.T.C. at 695 (emphasis in original).

The Commission has applied a presumption of materiality to three categories of claims: “(1) express claims; (2) implied claims where there is evidence that the seller intended to make the claim; and (3) claims that significantly involve health, safety, or other areas with which reasonable consumers would be concerned.” *Kraft*, 970 F.2d at 322-23 (citing *Colgate-Palmolive*, 380 U.S. at 392).

Respondents' advertising claims that the Challenged Products effectively treat, prevent, and/or reduce the risk of heart disease, prostate cancer, and/or erectile dysfunction cover all three categories of claims considered to be material. Respondents' claims directly relate to health concerns, and, as discussed in Sections II.A-II.E above, are often express, or so strongly implied as to be virtually express.

Although a presumption of materiality may be rebutted with extrinsic evidence that the claims are not material (*Daniel Chapter One*, initial decision at 107 (citing *FTC v. Nat'l Urological Grp.*, 2008 U.S. Dist. LEXIS 44145, at *81), Respondents' ordinary course of business consumer research actually reinforces the presumption of materiality.³⁵ Respondents hired OTX Corporation to conduct an Attitude & Usage study in June 2009. (CX0402). The study consisted of online interviews with over 200 current POM Juice users, 200 other pomegranate juice users, and 200 non-pomegranate, antioxidant fruit juice users. When asked

³⁵ Respondents did commission a consumer survey for purposes of this litigation but our rebuttal expert, Dr. Mazis, has demonstrated that multiple factors make it unreliable as evidence of materiality. Most notably, that survey failed to follow the requisites of Commission law set out above by failing to test the importance of the challenged claims.

why they “personally [drank] pomegranate juice,” eighty-five percent (85%) of current POM Juice users chose “healthy/good for my health” more often than “I like the taste,” “It’s a new/interesting food trend,” “It’s all natural,” and “I like pomegranates.” In addition, current POM Juice users who cited “health” as a reason for using pomegranate juice were asked “Which specific health reasons below describe why you personally drink pomegranate juice?” From a list of 11 reasons, these respondents cited “contains naturally occurring antioxidants” (91%), “helps promote heart health” (57%), and “helps protect against prostate cancer” (47%) (males only) most often. These results demonstrate that heart disease and prostate cancer prevention, reduction of risk, and/or treatment claims are material.

Moreover, as Respondents’ consumer comment log confirms, Respondents were fully aware that consumers often purchased the Challenged Products for their purported disease-fighting properties as promoted in Respondents’ advertising. As described in Section I, there is ample evidence that Respondents intended to make the claims alleged in the Complaint.

In addition, as the Commission held in *Kraft*, Kraft’s “persistence” in using the challenged claims in the face of warnings that a deceptive message is conveyed was a basis to infer materiality. 114 F.T.C. at 137. Here, respondents persisted with their unsupported health claims even after inquiries and warnings beginning in 2005 from the National Advertising Division of the Council of Better Business Bureaus. A host of other parties also expressed concerns, including the FTC, the FDA, the New York Attorney General’s Office, the United Kingdom’s Advertising Standards Authority, NBC, National Public Radio, and even Dr. Allan Pantuck, who led the prostate cancer study that Respondents heavily promoted in their

advertising. (CX0343_0001-8; CX1419_0001-13; CX0194_0001-4; CX0037_0001-11; CX0055_0001-48.)

For these reasons, Respondents' claims as alleged in the Complaint are material.

III. RESPONDENTS' ADVERTISING CLAIMS ARE FALSE AND UNSUBSTANTIATED AND VIOLATE SECTIONS 5 AND 12 OF THE FTC ACT³⁶

“There are two theories to prove that an advertisement is deceptive or misleading: (1) the ‘falsity’ theory or (2) the ‘reasonable basis’ theory.” *In re Daniel Chapter One*, No. 9329, Initial Decision, at *99 (F.T.C. Aug. 5, 2009), *pet. review denied*, 2010 U.S. App. LEXIS 25496 (D.C. Cir. Dec. 10, 2010) (footnote omitted) (citing *F.T.C. v. Pantron I Corp.*, 33 F.3d 1088, 1096 (9th Cir. 1994); *In re Thompson Med. Co., Inc.*, No. 9149,104 F.T.C. 648 (F.T.C. 1984), *pet. review denied*, 791 F.2d 189 (D.C. Cir. 1986)). The Complaint in this case makes allegations under both theories (Complaint ¶¶ 12-21).

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 F.T.C. LEXIS 157, at *99. As discussed in Section A - D below, Respondents' representations that clinical studies, research, and/or trials prove that the Challenged Products prevent, reduce the

³⁶ Complaint Counsel brings this case under Sections 5(a) and 12 of the FTC Act, alleging that Respondents have engaged in unfair or deceptive acts or practices, and the making of false advertisements, in or affecting commerce. Respondents admit that the acts or practices alleged in the Complaint have been in or affecting commerce. *Answer* at ¶ 8. Respondents also admit that they disseminated or caused to be disseminated advertising and promotional materials, including the materials attached to the Complaint. *Id.* at ¶¶ 9-10. POM Juice and POMx Liquid are “food,” and POMx Pills, a dietary supplement, is a “food” and/or “drug[s]” under Section 12 of the FTC Act. *See Daniel Chapter One*, No. 9329, Initial Decision, 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.”).

risk of, and treat heart disease, prostate cancer, and erectile dysfunction, are simply false, as no such clinical studies, research, and/or trials to date provide this proof.

To prevail under the “reasonable basis” theory, Complaint Counsel must prove that the advertiser did not have a reasonable basis substantiating its claims at the time the claims were made. *Daniel Chapter One*, No. 9329, Initial Decision, at *99 (citing *Thompson Med. Co.*, 104 F.T.C. at 813; *F.T.C. v. Direct Mktg. Concepts, Inc.*, 569 F. Supp. 2d 285, 298 (D. Mass. 2008), *aff’d*, 624 F.3d 1 (1st Cir. 2010). “In determining whether an advertiser has satisfied the reasonable basis requirement, it must be determined (1) what level of substantiation the advertiser is required to have for its advertising claims, and then (2) whether the advertiser possessed and relied on that level of substantiation.” *Daniel Chapter One*, No. 9329, Initial Decision, at *100.

It is well established that for health-related efficacy claims, such as those alleged in the Complaint, the appropriate level of substantiation is “competent and reliable scientific evidence.” *Daniel Chapter One*, No. 9329, Initial Decision, at *100-01 (citing *FTC v. Natural Solution, Inc.*, 2007 U.S. Dist. LEXIS 60783, at *11-12 (C.D. Cal. Aug. 7, 2007); *F.T.C. v. Nat’l Urological Group.*, 645 F. Supp. 2d 1167 (N.D. Ga. 2008), *aff’d*, 356 F. App’x 358 (11th Cir. 2009); *Direct Mktg. Concepts*, 569 F. Supp. 2d at 300, 303; *F.T.C. v. QT, Inc.*, 448 F. Supp. 2d 908, 961 (N.D. Ill. 2006); *aff’d*, 512 F.3d 858 (7th Cir. 2008)).³⁷ “Competent and reliable

³⁷ Respondents, as evidenced by the report of their expert witness Dr. Denis Miller, appear to assert that the Challenged Products in this case should be afforded a more lenient standard of substantiation because they are “pure” foods or “derivatives” of foods, and pose no safety concerns (although he admitted he was unaware of the composition of any of the Challenged Products or their bioequivalence). This argument is unavailing. First, Respondents market one of the Challenged Products, POMx Pills, as a dietary supplement not as a whole food. (See POM Wonderful, http://www.pompills.com/pills/product_pills.aspx (last visited May

scientific evidence” is typically defined as “tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.” *See, e.g., Brake Guard Prods., Inc.*, 125 F.T.C. 138 (1998). In addition, “where advertising expressly or impliedly represents that it is based on scientific evidence, the advertiser must have that level of substantiation, and, in particular, must satisfy the relevant scientific community that the claim is true.” *Removatron*, 111 F.T.C. at 299 (citing *Thompson*, 104 F.T.C. at 813; *In re Bristol-Myers Co.*, 102 F.T.C. 21, 321 (1983), *pet. review denied*, 738 F.2d 554 (2d Cir. 1984).).

As discussed in Section A - D below, Complaint Counsel consulted experts in the fields of heart disease, prostate cancer, erectile dysfunction, and epidemiology. These four experts – Dr. Meir Stampfer, Dr. Frank Sacks, Dr. Arnold Melman, and Dr. James Eastham – independently opined on the level of substantiation they would expect, as experts in their respective fields, to support Respondents’ claims that the Challenged Products prevent, reduce the risk of, and treat heart disease, prostate cancer, and erectile dysfunction. In no instance does Respondents’ evidence meet that standard.

A. The Current State of Science on the Antioxidant Theory Does Not Provide Adequate Support for Respondents’ Disease Claims

6, 2011).)
Second, the inquiry into the “type of product” element of the *Pfizer* factors, should such an analysis be warranted, has consistently called for a “high level of substantiation, such as scientific tests,” when a product is related to consumer health. *Daniel Chapter One*, No. 9329, Initial Decision, at *102.

Respondents' disease claims are founded in large part on the premise that antioxidant supplementation can play an important role in the prevention or treatment of disease. It is true that *in vitro* testing suggests that pomegranate juice may contain higher levels of antioxidants than other beverages. This fact, however, fails to substantiate claims that the POM products will prevent or treat heart disease, prostate cancer, or erectile dysfunction. The antioxidant theory of disease prevention and treatment, popular in the 1990's, has lost some of its shine in light of the results of recent, major human clinical trial research. Additionally, high levels of antioxidants shown in *in vitro* tests may or may not translate to increased antioxidant levels in the human body. Respondents' expert, Dr. Heber, concedes that *in vitro* testing does not show how an antioxidant will work in the body.³⁸

At trial, Complaint counsel will submit the expert report and testimony of Meir J. Stampfer, M.D., a Professor of Epidemiology and Nutrition, Harvard School of Public Health.³⁹ Dr. Stampfer is an expert in the fields of epidemiology; nutrition, including its relation to the

³⁸ As he notes, the term antioxidant is "a little bit misleading because what it means is in vitro you have a chemical activity but . . . antioxidant balance in a human is a stress . . . versus a defense system." Heber Fact Depo. Tr. 105. He explained, "[w]e 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." (Heber Fact Depo. Tr. 186.)

³⁹ Dr. Stampfer is also a Professor of Medicine, Harvard Medical School, a Faculty Member of the Division of Biological Sciences, Harvard School of Public Health, and a Faculty Member of the Dana Farber Harvard Cancer Center. Dr. Stampfer has authored or co-authored more than 850 articles relating to cardiology, diet and nutrition, cancer and other diseases. (Expert Report of M. Stampfer at CX1293_0002). Dr. Stampfer's research revolves primarily around four major studies: 1) the Nurses Health Study; 2) the Nurses Health Study II; 3) the Physicians' Health Study; and 4) the Health Professionals Study. (Expert Report of M. Stampfer at CX1293_0003-4). The major focus of these large cohort studies is nutrition and health outcomes including cancer, cardiovascular disease and their precursors. (Expert Report of M. Stampfer at CX1293_0004).

prevention and treatment of cardiovascular disease and prostate cancer; and clinical testing related to the prevention and treatment of cardiovascular disease and prostate cancer.

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. (Expert Report of M. Stampfer at CX1293_0011). However, according to Dr. Stampfer, “there is conflicting scientific evidence on the benefits of specific nutrients with antioxidant activity in preventing or treating diseases.” (Expert Report of M. Stampfer at CX1293_0011). Dr. Stampfer states that “although 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.” (Expert Report of M. Stampfer at CX1293_0011).

Dr. Stampfer notes that “several antioxidant nutrients have been associated with reduced risk of prostate cancer in *in vitro* and observational studies, including vitamin E, selenium, lycopene, and polyphenols.” (Expert Report of M. Stampfer at CX1293_0015). However, when vitamin E and selenium were studied in a large-scale, many-year randomized trial, researchers found no evidence of benefit. (See Expert Report of M. Stampfer at CX1293_0015). 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. (Expert Report of M. Stampfer at CX1293_0012). Dr. Stampfer states that “[o]verall, it is apparent that the suggestive associations between some specific antioxidants and CVD or prostate cancer observed in observational studies, and biological plausibility established

in *in vitro* and animal studies, has not translated to consistent protective effects in humans.” (Expert Report of M. Stampfer at CX1293_0015). He concludes “[t]his demonstrates the importance of performing randomized, double-blind, placebo-controlled trials before drawing firm conclusions regarding causality or making public health recommendations regarding nutrient supplementation.” (Expert Report of M. Stampfer at CX1293_0015). In his view, “[t]he best evidence of a causal relationship between a nutrient . . . and a disease outcome in humans is a randomized, double blind, placebo-controlled, clinical trial.” (Expert Report of M. Stampfer at CX1293_0009).

B. Heart Disease Claims Are False and Unsubstantiated

1. Overview of the type of medical research required to support claims for the prevention, reduction of risk, or treatment of heart disease.

Respondents sponsored a variety of studies that they assert support their heart disease prevention and treatment claims. At trial, Complaint Counsel will submit the expert report and testimony of Frank M. Sacks, M.D., a Professor of Cardiovascular Disease Prevention, Department of Nutrition, Harvard School of Public Health. He is an expert in the fields of nutrition, cardiovascular disease (“CVD”), coronary heart disease (“CHD”), cholesterol disorders, hypertension, and analysis of clinical studies.⁴⁰ (Expert Report of F. Sacks at

⁴⁰ Dr. Sacks is also a Professor of Medicine at Harvard Medical School, and a Senior Physician at Channing Laboratory and Cardiology Physician at Brigham and Women’s Hospital. Dr. Sacks has engaged in substantial scholarly research and writing related to CVD or CHD and the relationship between nutrition and these diseases. (Expert Report of F. Sacks at CX1291_0002). Dr. Sacks’ work includes “research relating to risk factors for CVD and CHD, including lipid profiles, hypertension, obesity, and diabetes.” (Expert Report of F. Sacks at CX1291_0002). It also includes “research into the effects on CVD, CHD, and their risk factors of consuming potential risk-modifying diets, foods, food components, and drugs, including sodium, macronutrients, various vitamins, sugars, fatty acids, fiber, statins, and estrogen replacement therapy.” (Expert Report of F. Sacks at CX1291_0002). Dr. Sacks has authored or co-authored more than 160 articles, published in peer-reviewed scientific journals, on these

CX1291_0002). Dr. Sacks concludes that the Respondents' evidence, considered as a whole, is not sufficient to support the heart disease claims.

Dr. Sacks first describes the level of evidence needed to support heart disease treatment and prevention claims. He states that the type of evidence required to substantiate a claim that a product, including a conventional food or dietary supplement, can *prevent or reduce the risk of or treat* heart disease would be the appropriately analyzed results of well-designed, well-conducted, randomized, double-blinded, controlled human clinical studies (referred to by experts in the field of clinical testing as "RCTs"), demonstrating significant changes in valid surrogate markers of cardiovascular health. The population can be persons with or without established CVD or CHD. The studies, research, and/or trials would need strong "p" values (statistical significance). The same level of evidence is needed to show that *clinical studies, research, or trials prove* that a product prevents or reduces the risk of or treats heart disease. (Expert Report of F. Sacks at CX1291_0010-1).

A controlled clinical study is one that includes not only a group of patients receiving the purported treatment (referred to as either the treatment group or the active group), but also a control group (referred to in some studies as a placebo group). There are a few reasons for this. First, when human subjects are treated by medical personnel or scientists, the mere act of being treated can cause a change or improvement in the condition being evaluated. Second, factors such as the passage of time, other environmental changes, and methodological drift (*e.g.*, calibration changes in equipment, etc.) can result in changes in the endpoint being measured. Inclusion of a control group allows the researcher to take these factors into account when

subjects. (Expert Report of F. Sacks at CX1291_0002).

evaluating a study's results. The control group should receive the same attention from the researchers as the treatment group; receive the same measurements; receive a placebo treatment that does not have any effect; and that the appearance of the placebo should be identical in all ways possible, to the active treatment being studied. (Expert Report of F. Sacks at CX1291_0011)

Randomization refers to a method by which study patients are assigned, randomly, to either the active product group or the control group. One way to accomplish this is through a computer program available to clinical researchers or, in the past, the use of a random number table. Random assignment is important to help eliminate the possibility that a researcher may consciously or subconsciously employ a selection bias, for example, assign healthier or less healthy people to the treatment group, as compared to the control group. Randomization creates a likelihood that the make-up of the treatment and control groups will be similar on all relevant characteristics. In studies of cardiovascular health, the relevant characteristics include, for example, baseline weight, blood pressure and cholesterol, severity of disease, cardiac medications, and any other measurements that are used as study outcomes or endpoints. (Expert Report of F. Sacks at CX1291_0011).

Blinding refers to efforts taken to ensure that neither the study participants nor the researchers conducting outcome measurements are aware of which group a particular patient is assigned to. In a double-blind clinical trial, the patients are not told whether they are in the active or placebo group, although they are told, as part of giving informed consent to enter the study, that they could be placed in either. This is important because awareness of group assignment can affect patient behavior and reaction to treatment. In addition, the researchers

who perform the outcome measurements are also blinded. This is important because even the most objective researcher can subconsciously provide care for or measure a subject differently if he is aware of the patient's group assignment. In some instances, where the treatment is different in appearance or taste from any possible placebo, double-blinding is not possible. In those cases, the researchers, particularly those conducting measurements, *must* be blinded. (Expert Report of F. Sacks at CX1291_0012).

Once a randomized controlled trial has been completed and all data have been collected, data for the placebo and active treatment groups must be compared through the use of appropriate statistical analyses. The data-analysis plan should have been written in the protocol in advance of any data analysis and the data analysis must follow that plan. Only if the results of the treatment group are statistically significantly different from those of the placebo group at the end of the trial can it be concluded that the tested product has an effect on heart disease. Such analysis is commonly termed as a "between group" analysis. Generally, statistical significance is recognized as being attained if the statistical test for probability, referred to as a "p" value is equal to or less than 0.05 ($p \leq 0.05$), which means that there is only a 5 percent or less chance that the difference between the groups is due to chance. In addition, results must have clinical significance, in other words, the magnitude of the treatment effect must have clinical significance. (Expert Report of F. Sacks at CX1291_0012-3).

In considering whether a study shows a benefit to cardiovascular disease, it is important to look at what endpoints have been measured. There are two kinds of endpoints: direct endpoints and surrogate markers. In the case of heart disease, direct endpoints are heart attack, unstable angina, or the need for coronary artery bypass or angioplasty. Surrogate markers are

measurements that are closely linked to the disease process such that a change in a surrogate marker can confidently be predictive of a change in the disease. In this way, a surrogate marker is validated. Validated surrogate markers are used in clinical guidelines for prevention and treatment and are specified by the FDA for product labeling and approval. Clinical guidelines and the FDA recognize the following as valid surrogate markers of cardiovascular health: blood pressure and LDL cholesterol. In addition, many qualified experts, including Dr. Sacks, recognize C-reactive protein (“CRP”), HDL cholesterol, and triglycerides (“TG”) as valid surrogate markers, although other experts may disagree on any of these. (Expert Report of F. Sacks at CX1291_0013).

Dr. Sacks also states that measures of carotid⁴¹ intima media thickness, or “CIMT,” are usually relevant to cardiovascular health. CIMT testing measures the combination of the vessel muscle and atherosclerosis (arterial plaque); although the muscle width is a type of “noise” in the measure, the plaque is relevant. He believes that if CIMT measures show consistent improvement, this would be an indicator that a treatment may be beneficial. At the same time, he would be reluctant to rely on CIMT improvements, alone, if these were the only evidence that an intervention treated existing heart disease. A second imaging study (such as a coronary imaging study) is necessary confirming evidence. In fact, he notes that there is disagreement among experts on the prognostic value of CIMT. A recent research article published in a leading cardiology journal analyzed CIMT in relation to cardiovascular events. Among 41 randomized trials combined in a meta-analysis, the authors found that “there was no significant relationship

⁴¹ The carotid arteries are the large arteries on either side of the human head that provide blood to the face and brain. They are common sites for atherosclerosis.

between IMT regression and CHD [coronary heart disease] events...CBV [cerebrovascular] events...and for all-cause death.”⁴² For this reason, there is broad consensus that at least two types of imaging studies must be obtained to make inferences on benefit to cardiovascular disease when results from clinical trials of actual cardiovascular events are not available. (Expert Report of F. Sacks at CX1291_0013-4).

Dr. Sacks notes that other factors also must be considered when evaluating the methodological soundness of a scientific study. For example, the number of tested subjects and their characteristics are important. It is necessary that there be a sufficient number and diversity of subjects tested to allow the conclusion that any measured effect can be generalized to a larger population. Similarly, the length of a study is important, as a study must be of sufficient duration to provide reliable scientific evidence that the effect will last. (Expert Report of F. Sacks at CX1291_0014).

Finally, 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. Accordingly, most scientists and researchers, including Dr. Sacks, believe that at least two well-designed studies, conducted by different researchers, and each showing strong results, are needed to constitute reliable evidence. That is why it is important to see consistent results in independently-replicated studies before concluding that a tested product is effective in preventing, reducing the risk of, or treating heart disease. (Expert Report of F. Sacks at CX1291_0014-5).

⁴² Costanzo P, Perrone-Filardi P, Vassalo E, Paolillo S, Cesarano P, Brevetti G, Chiariello M, *Does Carotid Intima-Media Thickness Regression Predict Reduction of Cardiovascular Events*, J. Amer. Coll. Cardiology, Vol. 56, No. 24, Dec. 7, 2010.

2. Respondents' evidence is inadequate to substantiate their claims that the Challenged Products prevent, reduce the risk of, or treat heart disease.

Respondents sponsored a number of human clinical studies designed to evaluate the potential heart benefits of the Challenged Products but none alone or in combination are adequate competent and reliable scientific evidence to support the challenged claims.⁴³

Chronologically, they are as follows:

- 1. The Aviram ACE/BP Study.**⁴⁴ In this unblinded, uncontrolled study, ten elderly hypertension patients drank 50 ml of a concentrated pomegranate juice product per day for two weeks. The article reports that seven of the ten patients experienced a statistically significant 36% reduction in serum angiotensin converting enzyme (ACE) activity, and that the 10 patients experienced a statistically significant 5% reduction in systolic blood pressure. (Expert Report of F. Sacks at CX1291_0016-7).

⁴³ Dr. Sacks reviewed large number of articles reporting on *in vitro* and animal studies and concluded that none of them provided reliable scientific evidence to support claims that POM Juice, POMx Pills, or POMx Liquid prevented, reduced the risk of, or treated heart disease. (Expert Report of F. Sacks at CX1291_0015-6). According to Dr. Sacks, “[a]nimals are not sufficiently analogous to humans, either biologically or psychologically” and “[m]any findings of dietary or drug effects in animals are not confirmed in human testing.” (Expert Report of F. Sacks at CX1291_0016). *In vitro* studies “may generate hypothesis for studies in humans, but only the results of RCTs in humans can form the basis to support therapeutic conclusions.” (Expert Report of F. Sacks at CX1291_0015-6).

⁴⁴ Aviram M and Dornfeld L, *Pomegranate juice consumption inhibits serum angiotensin converting enzyme activity and reduces systolic blood pressure*, 158 *Atherosclerosis* 195 (2001).

- 2. The Aviram IMT/BP Study.**⁴⁵ This study tested the effect of consuming 50 ml of concentrated pomegranate juice per day on ten patients with severe carotid artery stenosis (“CAS”).⁴⁶ The study also included a “matched” group of nine patients, also with CAS, who did not consume pomegranate juice. The study was not randomized, blinded, or placebo-controlled. Tests included blood pressure, blood analysis, and ultrasound measurements of CIMT. The article reports that, in the active group, the patients’ mean CIMT decreased by 35% over 12 months, as compared to baseline values, and their systolic blood pressure dropped by 12%. By contrast, the article reports in the untreated comparison group, the mean CIMT increased by 9% over the course of one year, and their blood pressure remained unchanged. (Expert Report of F. Sacks at CX1291_0017-8).
- 3. The Ornish MP Study.**⁴⁷ This was designed as a randomized, double-blinded, placebo-controlled study to evaluate whether daily consumption of pomegranate juice for 12 months would affect myocardial perfusion (“MP”), or blood flow to the heart in 45 patients with CHD and myocardial ischemia. Patients consumed 240 ml

⁴⁵ Aviram M, Rosenblat M, Gaitini M, Nitecki S, Hoffman A, Dornfeld L, Volkova N, Presser D, Attias J, Liker H, and Hayek T, *Pomegranate juice consumption for 3 years by patients with carotid artery stenosis reduces common carotid intima-media thickness, blood pressure and LDL oxidation*, 23 Clin. Nutr. 423 (2004).

⁴⁶ CAS refers to the narrowing of the carotid arteries.

⁴⁷ Sumner M, Elliott-Eller M, Weidner G, Daubenmier JJ, Chew MH, Marlin R, Raisin CJ, and Ornish D, *Effects of Pomegranate Juice Consumption on Myocardial Perfusion in Patients with Coronary Heart Disease*, 96 Am. J. Cardiology 810 (2005) (BATES: POM-HC0001878-1882).

(about 8 ounces) of POM Juice or a placebo beverage (modified Gatorade). Measurements included before and after imaging of blood flow to the heart, plasma lipids (cholesterol, HDL, LDL, and TG), body weight, blood sugar, and blood pressure. The report provides data on three imaging measures for a three month period only: 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). According to the report, at the end of the three month period there was a significant ($p = 0.05$) improvement in the SDS score in the pomegranate juice group, as compared to the control group, but no significant changes in the SRS or SSS scores. There were no significant changes in lipids, blood glucose, body weight, or blood pressure. (Expert Report of F. Sacks at CX1291_0019-20).

4. **Ornish IMT Study.**⁴⁸ This double-blind, placebo-controlled 73-person study measured IMT, blood pressure, and other variables at baseline, 6 months, and 12 months. According to the unpublished final report, there were no significant changes in the experimental group relative to the placebo for carotid IMT thickness or elastic properties, systolic and diastolic blood pressure, cholesterol, LDL, HDL, or triglycerides. (Expert Report of F. Sacks at CX1291_0024-5).

⁴⁸ Ornish, D, *Bev 2 Summary*, June 16, 2005.

5. Davidson FMD Study.⁴⁹ This study enrolled 45 of the subjects who were enrolled in the Davidson IMT trial, discussed below. It was a 13-week, randomized, double-blind, placebo-controlled trial to evaluate the effect of consuming POM Juice or placebo on the “flow mediated dilation” in the brachial artery of the upper arm. Testing included ultrasound measurement of the brachial artery, blood pressure, and lipid parameters. There were no statistically significant differences between the treatment and placebo groups in FMD or blood pressure from baseline to 13 weeks. (Expert Report of F. Sacks at CX1291_0030-1).

6. Davidson IMT Study.⁵⁰ This was an 18-month, 289-person randomized, double-blinded, placebo-controlled study designed to test the effect of pomegranate juice on CIMT progression rates. Subjects were middle-aged men and women with coronary heart disease (“CHD”) risk factors (high LDL, low HDL, hypertension or use of medication to treat hypertension, or cigarette smoking) and baseline posterior wall CIMT of 0.2 to 2.0 mm without significant stenosis. They consumed about 8 ounces of pomegranate juice or placebo (purple Gatorade). Tests included ultrasound measures of the carotid artery at baseline, week 52, and week 78, as well as blood pressure, lipids, and various measures of inflammation and oxidative stress. Adherence to study product consumption was assessed at each visit by reviewing a

⁴⁹ Davidson MH, *The Effects of Pomegranate Juice on Flow-Mediated Vasodilation*, (unpublished, 2004).

⁵⁰ Davidson MH, Maki KC, Dicklin MR, Feinstein SB, Witchger MS, Bell M, McGuire DK, Provost JC, Liker H, and Aviram M, *Effects of Consumption of Pomegranate Juice on Carotid Intima-Media Thickness in Men and Women at Moderate Risk for Coronary Heart Disease*, 104 Am. J. Cardiology 936 (2009).

daily consumption diary maintained by the subject. According to the Davidson IMT report, at the end of the study, there were no significant differences in CIMT progression rates between the subjects in the pomegranate juice and control groups. The “composite rate” for all measured carotid artery walls had shown a significantly smaller value at 12 months in the pomegranate juice group, but this difference was no longer significant at the end of the study. Further, the anterior wall values and rates, and the posterior wall values and progression rates did not differ significantly at any point in the trial. There also were no statistically significant changes in the measured indicators of inflammation and oxidative stress or in fasting lipoprotein lipids or blood pressure. The report also includes a “post hoc” (that is, not planned for in the protocol) exploratory analysis of changes in certain subpopulations of the study, showing significantly lower CIMT progression rates for pomegranate versus control subjects at the end of the study in certain subpopulations with higher CVD risk factors (those in the highest tertiles for apolipoprotein B, TG, TG to HDL ratio, total cholesterol to HDL ratio, and a purported marker of antioxidant function, PD-AAPH), but the authors stated that, “Because the decrease in CIMT progression in these subgroups was based on analyses that were not preplanned and had no correction for multiple comparisons (increasing the possibility of type I errors), these findings will need to be confirmed in future investigations.” (Expert Report of F. Sacks at CX1291_0026-30).

7. The Overweight Studies.⁵¹ Respondents sponsored two studies to evaluate the effect on consuming POMx pills by overweight persons. At the unblinded Denver site, 50 middle-aged subjects took two POMx capsules daily for 28 days; measurements included antioxidant, oxidative, and inflammatory markers in serum; blood pressure; and other factors. During the trial, weight increased and TBARS levels (described as “a test that measures lipid peroxidation in the blood”) decreased, but there were no changes in diastolic and systolic blood pressure or other measures. At the blinded, controlled San Diego site, 70 overweight middle-aged subjects were enrolled and randomized to take 1 POMx, 2 POMx, or 2 placebo capsules per day, for 4 weeks. Measurements included blood pressure and various antioxidant and inflammation markers. There were no apparent treatment related changes in blood pressure or any of the antioxidant or inflammation markers, including CRP, oxidized phospholipids, lipoprotein a, nitric oxide, isoprostanes, interleukins, in the groups receiving one or two POMx capsules per day. (Expert Report of F. Sacks at CX1291_0032-35).

In support of their claims that the Challenged Products can prevent or treat heart disease, including by reducing blood pressure, Respondents rely on the results of the Aviram ACE/BP and the Aviram IMT/BP studies, both of which involved consumption of pomegranate juice,

⁵¹ Heber D, Seeram NP, Wyatt H, Henning SM, Zhang Y, Ogden LG, Dreher M, and Hill JO, *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) (Denver site results plus partial results for the San Diego site); Hill JO, *Preliminary Data Analysis* (Feb. 15, 2007) (Denver site results); Heber Deposition Exhs. 1054, 1057 (San Diego site inflammatory/antioxidant marker results).

rather than one of the POMx products. As Dr. Sacks has noted, blood pressure reduction is a recognized and validated surrogate for heart disease. As previously described, however, the Aviram ACE/BP and IMT/BP studies were unblinded and uncontrolled. As a result, Dr. Sacks states that it is not possible to tell whether the purported changes in blood pressure were due to drinking pomegranate juice or some other factor. (Expert Report of F. Sacks at CX1291_0016-7). Moreover, the remainder of Respondents' studies – including the Ornish MP Study, the Ornish IMT Study, the Davidson FMD Study, Davidson IMT study, and the Overweight Studies – showed *no* change in blood pressure as a result of consuming POM Juice or POMx. Accordingly, considered as a whole, the Respondent's evidence does not support the conclusion that the Challenged Products prevent or treat heart disease, including through blood pressure.

In support of their claims that the Challenged Products can prevent or treat heart disease, including by reducing arterial plaque, Respondents rely on the Aviram IMT/BP study, combined with a portion of the results of the Davidson IMT trial. Specifically, they suggest that the 12-month data and, to some degree, the sub-group analysis at 18 months, supports the claim. This “pick and choose” analysis is unavailing. Respondents sponsored several IMT studies: the Aviram IMT/BP Study (10 patients), the Ornish IMT study (53 patients), and the Davidson IMT Study (289 patients). Because the Aviram IMT/BP study was unblinded and uncontrolled, it is not possible to determine what caused the change in IMT results over the course of the study. (Expert Report of F. Sacks at CX1291_0036). The Ornish IMT and Davidson IMT studies were blinded and controlled, and show no benefit from consuming POM Juice. As a result, the evidence, considered as a whole, does not substantiate the claim that the Challenged Products

prevent or treat heart disease, including by reducing arterial plaque. (See Expert Report of F. Sacks at CX1291_0038).

In support of their claims that the Challenged Products can prevent or treat heart disease, including by increasing blood flow, Respondents rely on the Ornish MP study. Dr. Sacks states that this study suffers from several limitations. Change in myocardial perfusion, that is, blood flow to the heart, is not a recognized surrogate marker of therapeutic effects on CHD, given that improvements in blood flow will not necessarily result in improved cardiovascular health, such as reductions in heart attack and stroke. The report shows significant changes in only one of the three measures at the end of the study – in SDS, but not SRS or SSS. The leading text of cardiology, states “... a substantial literature has validated these summed scores, *particularly the SSS* as predictors of natural history outcomes.”⁵² 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. (Expert Report of F. Sacks at CX1291_0020-4).⁵³

Dr. Sacks also expresses concern about the fact that there 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. The control group’s baseline values were worse than the pomegranate group’s. He states that, “[i]t could be predicted that the control group, having

⁵² *Braunwald’s Heart Disease* (9th edition, Chapter 17, Nuclear Cardiology, 2011) (emphasis added).

⁵³ The Ornish MP Study protocol did not identify which of these would be the primary endpoint of the study. A proper protocol identifies what the primary outcomes will be in advance, to prevent a researcher from cherry-picking positive results and ignoring negative ones. In this study, the “p” value of the reported improvement in SDS was only .05. According to Dr. Sacks, when there are three possible outcomes (that is, changes in SSS, SRS, or SDS), .05 is not considered to be a statistically significant effect. (Expert Report of F. Sacks at CX1291_0021).

worse coronary perfusion than the pomegranate group at baseline, would have a more accelerated form of the disease and show worsening on follow-up. (Expert Report of F. Sacks at CX1291_0022).

In light of the conflict between the SSS and SDS results, and additional problems in the design and conduct of the Ornish MP study,⁵⁴ Dr. Sacks states that this study does not support a conclusion that the pomegranate products used had a favorable effect on coronary perfusion. In addition, other factors, such as blood pressure, cholesterol, inflammatory biomarkers, and oxidative stress were not improved. He states that, “[t]he interpretation of this study that is most consistent with principles of clinical study design and conduct is that the treatment had no effect on any measure of cardiac health.” (Expert Report of F. Sacks at CX1291_0024).

Moreover, Dr. Sacks offers the opinion that, in this case, there are only three studies that have sufficient evidence of reliability to warrant serious consideration, in light of the quality of the studies conducted and the endpoints measured. These are the Davidson CIMT Trial; the Ornish CIMT Trial; and the Davidson FMD trial. These three studies showed that, in the populations identified in the protocol, the consumption of pomegranate juice provided no statistically or clinically significant benefit for heart disease prevention or treatment. POM Juice

⁵⁴ These include the fact that, although the publication indicates that 45 persons were enrolled in the study, and that four patients either dropped out or had unreadable data, the report only provides data on 39 patients. Alterations in the original sample size may be critical when there is a borderline “p” value. Additionally, Dr. Sacks states that his confidence in the credibility of the study results is undermined by other factors, including these: (a) the study was originally designed for 12 months, but ended after 3, at a point when the results appeared to be favorable, because Respondents cut the funding; (b) seven or eight of the placebo group patients were unblinded before their three-month data was collected, and two other “placebo” patients did not actually receive the placebo products; and (c) failure of the randomization process to produce similar active and placebo groups. (Expert Report of F. Sacks at CX1291_0022-4).

has not been shown, in these trials, to produce statistically or clinically significant changes in direct endpoints related to heart disease or in appropriate surrogate markers of heart disease. He concludes that this provides “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.” (Expert Report of F. Sacks at CX1291_0038). Similarly, they provide no evidence that POMx Pills or POMx Liquid provides any such benefit. (*Id.*)

3. Respondents’ studies do not prove claims that the Challenged Products prevent, reduce the risk of, or treat heart disease.

Dr. Sacks concludes, based on the analysis set forth above, 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.” (Expert Report of F. Sacks at CX1291_0010). Moreover, Respondents recognize that they lack proof that the challenged products prevent or treat CVD, based on reducing blood pressure. (Email from M. Tupper to B. Gillespie re: research portfolio overview document, dated May 11, 2009, at CX1058_0004; Tr. of S. Resnick, *POM v. Tropicana*, at CX1372_0073-74). Finally, Respondents themselves concede that in the area of heart benefits, their “current body of research only viewed as “3” on a scale of 1-10 by MDs.” (Email from M. Tupper to B. Gillespie re: research portfolio overview document, dated May 11, 2009, at CX1058_0004.)

C. Prostate Cancer Claims Are False and Unsubstantiated

1. Respondents did not possess or rely upon competent and reliable scientific evidence to substantiate their claims that the Challenged Products prevent or reduce the risk of prostate cancer.

At trial, Complaint Counsel will submit 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.⁵⁵ He is an expert in the fields of urology, including the prevention and treatment of prostate cancer; and clinical testing related to the prevention and treatment of prostate cancer.

In his report, Dr. Eastham states 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” to support claims that the POM Juice, POMx Pills, and POMx Liquid prevent prostate cancer. (Expert Report of J. Eastham at CX1287_0012). 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.” (*Id.*). 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.” (*Id.* at CX1287_0014). Recent prostate cancer prevention trials have lasted from 4 to 7 years. (*Id.*) . Dr. Eastham states that “[t]he primary endpoint in a prostate

⁵⁵ Dr. Eastham is also a Professor of Urology at Weill Cornell Medical College in New York City. A board-certified urologist, Dr. Eastham has treated more than 2000 patients with prostate cancer, some of whom experienced a rise in PSA after receiving initial therapy. As Director of Clinical Research at Memorial Sloan Kettering, Dr. Eastham has extensive experience in designing and developing protocols for clinical trials studying prostate cancer. In addition, Dr. Eastham is a member of the Data Safety Monitoring Board for the Selenium and Vitamin E Cancer Prevention Trial, the largest prevention trial studying antioxidants and prostate cancer. (Expert Report of J. Eastham at CX1287_0002-3).

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.” (*Id.*).

Dr. Eastham reviewed numerous documents and studies submitted by Respondents in support of their claims, including the published results of the Pantuck Phase II study, [REDACTED] [REDACTED] [REDACTED] (*Id.* at CX1287_0017-24). To date, the POM Products have not been studied in healthy men. All of the clinical studies examining the effect of POM Juice, POMx Pills, and POMx Liquid 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. Therefore, Dr. Eastham opines that there is no competent and reliable scientific evidence supporting a claim that POM Juice, POMx Pills, or POMx Liquid prevents prostate cancer. (*Id.* at CX1287_0016).

In addition, the principal investigators of both the Pantuck Phase II Study and [REDACTED] [REDACTED], and Respondents’ own documents support Dr. Eastham’s view. At trial, Complaint Counsel will present the deposition testimony of Dr. Allan Pantuck, the principal investigator of the Pantuck Phase II trial and [REDACTED] [REDACTED]. Both Drs. Pantuck and [REDACTED] testified that the results of their clinical trials do not demonstrate that POM Juice or POM Pills prevents prostate cancer. (Tr. of A. Pantuck Dep. at CX1341_0109; Tr. of [REDACTED] [REDACTED]). More importantly, Respondents have admitted in their own internal documents that “POM currently has a research gap; no data on prevention, prior to radiation or

prostatectomy.” (Email from M. Tupper to B. Gillespie re: research portfolio overview document, dated May 11, 2009, at CX1058_0005).

2. Respondents did not possess or rely upon competent and reliable scientific evidence to substantiate their claim the Challenged Products treat prostate cancer.

To date, the Pantuck Phase II study is the only published clinical trial examining the effectiveness of POM Juice on prostate cancer. It evaluated the effect of POM Juice consumption on 46 men who previously underwent either radiation therapy or surgery for prostate cancer. Eligible study participants had a detectible prostate specific antigen (“PSA”) level that was documented as rising. In this open label, single-arm clinical trial, study participants drank eight ounces of POM Juice daily, and their PSA levels were measured every three months. Those measurements were used to calculate the participants’ PSA doubling time (“PSADT”). Usually measured in months, PSADT is the time it takes for PSA levels to double. At the conclusion of the study, the investigators found that the mean PSADT significantly increased from a mean of 15 months at baseline to 54 months after treatment. The Pantuck Phase II study investigators noted in their study report that “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. They also stated that further research was needed to address the limitations of their study, namely the lack of a blinded control group.

In his report, Dr. Eastham states that this study “fails to provide competent and reliable scientific evidence.” (Expert Report of J. Eastham at CX1287_0018). First, the study lacked a placebo (control) group and “without a control group, it is not possible to conclude that POM Juice alone had an effect on the patients’ PSA.” (*Id.*). At his deposition, Dr. Pantuck testified

that the lack of “blinded control” group was the “greatest limitation “ of his study. (Tr. of A. Pantuck at CX1341_0111). 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.” (*Phase II Study of Pomegranate Juice for Men with Rising Prostate-Specific Antigen Following Surgery or Radiation for Prostate Cancer*, Clin. Cancer Res. 2006; 12(13) July 1, 2006, at CX0815_0008).

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.” (Expert Report of J. Eastham at CX1287_0019). 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.” (*Id.* at CX1287_0010). “To date, PSADT has not been accepted by experts in the field as a surrogate endpoint for survival.” (*Id.* at CX1287_0026). 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.” (*Id.* at CX1287_0019). 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.” (*Phase II Study of Pomegranate Juice for Men with Rising Prostate-Specific Antigen Following Surgery or Radiation for Prostate Cancer*. Clin. Cancer Res. 2006; 12(13) July 1, 2006, at CX0815_0008). Respondents’ prostate cancer expert Dr. Jean deKernion, also confirmed Dr. Eastham’s view in his report, stating that “there are no studies

that have been performed for sufficient length to determine an impact [of PSADT] on survival.” (Expert Report of J. deKernion at 4).

Third, the average pretreatment PSADT for the study participants was 15 months. Patients with a PSADT of 15 months are considered to have the lowest risk of dying from prostate cancer. According to Dr. Eastham, “[e]ven if POM Juice prolonged PSADT, it is unclear whether that outcome is truly clinically significant.” (Expert Report of J. Eastham at CX1287_0019).

Finally, the results from the Pantuck Phase II study cannot be used to support claims for POMx Pills and POMx Liquid. As evidenced by Respondents’ own documents, POM Juice is not identical to POMx Pills and POMx Liquid. 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.” (*Id.* at CX1287_0020). 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.” (*Id.*). More importantly, Respondents’ own internal documents recognize that research on POM Juice cannot be used to support claims for POMx. (Email from D. Kuyoomjian to M. Perdigao et al. re New POMx Pills Ad, January 12, 2009, at CX0266).

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] (Tr. of M. Carducci Dep. at CX1340_0096). [REDACTED]

[REDACTED] (*Id.* at

CX1340_0090)}. Moreover, Respondents, at least with respect to POMx Pills, recognize that they lack adequate substantiation for a treatment claim. Their own internal documents acknowledge that “PSA will not be accepted as an endpoint,” that they “have no clinical data beyond PSA,” that “2 studies” are needed, and that the “possible endpoints” for such studies are “death” or “cancer progression.” (Tr. of M. Aviram Dep. at CX_1058).

3. Clinical studies, research, and/or trials do not prove that the Challenged 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. Dr. Eastham states that to his knowledge, there are no randomized, double-blind, placebo-controlled trials studying the effect of POM Juice, POMx Pills, or POMx Liquid on prostate cancer using accepted, clinically meaningful outcomes as a primary endpoint. (*Id.* at CX1287_0025). Respondents’ prostate cancer expert, Dr. Jean deKernion, implicitly acknowledges this in his expert report, stating that “[n]o Phase III randomized trial has been completed to absolutely

prove that POM products prolong the life of patients” (Expert Report of J. deKernion at 11). Therefore, the clinical studies, research, and/or trials conducted thus far on the Challenged Products do not prove that drinking eight ounces of POM Wonderful pomegranate juice, or taking one POMx Pill or one teaspoon of POMx Liquid, daily prevents, reduces the risk of, or treats prostate cancer.⁵⁶ (Expert Report of J. Eastham at CX1287_0025-6). Again, neither of Respondents’ expert witnesses offer an opinion that such evidence exists.

D. Erectile Dysfunction Claims Are False and Unsubstantiated

1. Respondents did not possess or rely upon competent and reliable scientific evidence to substantiate their claims that the Challenged Products prevent, reduce the risk of, or treat erectile dysfunction.

At trial, Complaint Counsel will submit the Expert Report and testimony of Arnold Melman, M.D., a Professor and Chairman of the Department of Urology at the Albert Einstein College/Montefiore Medical Center in New York.⁵⁷ Dr. Melman is an expert in the evaluation of

⁵⁶ In addition to the clinical trials, Dr. Eastham reviewed several animal and *in vitro* studies examining the effect of POM products on prostate cancer. According to Dr. Eastham, *in vitro* and animal studies cannot support claims that a product works in men because “the results in a test tube may yield different results in humans” and “a treatment agent may behave differently in different species.” (Expert Report of J. Eastham at CX1287_0014-5). Without a well-conducted, randomized, double-blind, placebo-controlled clinical trial with an appropriate endpoint, Dr. Eastham concludes that Respondents’ lack competent and reliable scientific evidence to support their claims that POM Juice, POMx Pills, or POMx Liquid prevents, reduces the risk of, or treats prostate cancer. (Expert Report of J. Eastham at CX1287_0006).

⁵⁷ A board-certified urologist, Dr. Melman is a practicing urological surgeon whose areas of speciality include erectile dysfunction, Peyronie’s disease, reconstructive surgery, and radical perineal prostatectomy. Dr. Melman has authored and published more than 200 papers relating to urology in peer reviewed scientific journals, including The Journal of Sexual Medicine, The Journal of Urology, and the International Journal of Impotence Research. Many of these articles relate to erectile dysfunction. Dr. Melman is also a former president of the North American Society for the Study of Impotence. (Expert Report of A. Melman at CX1289_0002).

whether a product prevents, reduces the risk of, or treats erectile dysfunction, and in the design and conduct of clinical trials involving erectile dysfunction.

In his report, Dr. Melman states that “[t]o constitute competent and reliable scientific evidence, experts in the field of erectile dysfunction would require at least one clinical trial, involving several investigatory sites, that is well-designed, randomized, placebo-controlled, and double-blinded.” (Expert Report of A. Melman at CX1289_0004). According to Dr. Melman, “[a] study must use standardized, objective criteria for . . . measuring treatment outcomes.” This is “essential for obtaining meaningful data and for ensuring useful comparisons of research outcomes obtained by different investigators.” (Expert Report of A. Melman at CX1289_0010). Dr. Melman notes that “[c]urrently, the International Index of Erectile Function (“IIEF”) is the accepted, validated instrument for measuring erectile function.” (*Id.*). In addition, a clinical trial must have a total sample population “large enough to produce clinically significant results and a statistical significance of $p < 0.05$.” (Expert Report of A. Melman at CX1289_0004).

The Forest Study was a double-blinded, placebo-controlled study of the effect of POM Juice on 53 subjects with mild to moderate erectile dysfunction. [REDACTED]

[REDACTED]

[REDACTED] (POM’s Resp. to Req. for Admissions at CX1379_0020-0021).

Patients were randomized into two groups for a four-week study period, during which they consumed either POM Juice or a placebo beverage. Following a two-week washout, they were provided with the opposite study beverage for a second four-week treatment period. 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 International Index of Erectile Function (IIEF), a widely-used, validated multi-dimensional questionnaire based on five domains of male sexual function.

Dr. Melman opines that the Forest study 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).⁵⁸ In addition, the Forest study failed to show clinical significance, the study treatment period was not long enough to measure effectiveness, the differences between the placebo and treatment beverages' taste and appearance would have eliminated the study's blinding, the study failed to include verification by a partner of the participant's erectile function, the study used "weak inclusion criteria regarding whether participants had previously taken any PDE-5 inhibitors," and the mean age of the study population was too low for an erectile dysfunction study. (Expert Report of A. Melman at CX1289_0013-15). Finally, "because the participants already had mild to moderate erectile dysfunction at the time of enrollment, the Forest Study fails to provide support for claims that POM Wonderful pomegranate juice prevents or reduces the risk of erectile dysfunction in healthy men." (Expert Report of A. Melman at CX1289_0016).

It is significant to note that Dr. Melman's opinion is supported by Dr. Harin Padma-Nathan, an author of the Forest Study. At trial, Complaint Counsel will submit the deposition

⁵⁸ The court in *FTC v. QT, Inc.* found that "[i]f statistical significance is not achieved, the treatment cannot be said to have had an effect." 448 F. Supp. 2d 908, 939 (N.D. Ill. 2006), *aff'd* 512 F.3d 858 (7th Cir. 2008). 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 ($p \leq 0.05$)." 448 F. Supp. 2d at 939.

testimony of Dr. Padma-Nathan. Dr. Padma-Nathan testified that the Forest Study did not demonstrate that POM Juice prevents, reduces the risk of, or treats erectile dysfunction. (Tr. of H. Padma-Nathan Dep. at CX1338_0157-58). With regard to the GAQ, Dr. Padma-Nathan said that the GAQ is “not a very strong instrument” as a “standalone.” (*Id.* at CX1338_0089). He also testified that the Forest Study was a “pilot study” or a “proof of concept” study designed to determine whether there is a “signal” or some evidence of a treatment effect. (*Id.* at CX1338_0087-88). As such, Dr. Padma-Nathan said, there is a “need for further studies to confirm” any potential benefit. (*Id.* at CX1338_0184).

Dr. Melman also reviewed the *in vitro* and animal studies Respondents submitted in support for their claims. Dr. Melman notes that neither *in vitro* nor animal studies provide support that a product works in humans. (Expert Report of A. Melman at CX1289_0017). Although nitric oxide has a role in erectile function, Dr. Melman states that “studies on the relationship between nitric oxide and antioxidants . . . do not directly involve the issue of erectile function in humans, and cannot alone prove that POM Wonderful pomegranate juice, or any other pomegranate product treats, reduces the risk, or prevents erectile dysfunction in humans.” (*Id.* at CX1289_0017-18).

In addition, Respondents’ erectile dysfunction and nitric oxide experts fail to opine that there is competent and reliable evidence to support the conclusion that POM Juice prevents, reduces the risk of, or treats erectile dysfunction. Respondents’ erectile dysfunction expert, Dr. Irwin Goldstein, opines that “existing body of *in vivo*, *in vitro*, and preliminary clinical trials constitute competent and reliable scientific evidence to support the conclusion that pomegranate juice promotes erectile health.” (Expert Report of I. Goldstein at 10). Similarly, Respondents’

nitric oxide expert, Arthur Burnett, M.D. was only willing to opine that there is sufficient evidence “to support the conclusion that there is a beneficial effect in using pomegranate juice for promoting the health of erectile vascular tissues.” (Expert Report of A. Burnett at 6).

2. Clinical studies, research, and/or trials do not prove that the Challenged 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. Other than the Forest Study, Dr. Melman states, to his knowledge “there are no other clinical trials of POM Wonderful pomegranate juice, or any other pomegranate product, demonstrating this product’s efficacy on erectile dysfunction.” (Expert Report of A. Melman at CX1289_0018). 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 Wonderful pomegranate juice daily prevents, reduces the risk of, or treats erectile dysfunction.” (*Id.*) Again, neither Dr. Goldstein nor Dr. Burnett offers an opinion to the contrary.

E. Disease claims for foods must be supported by competent and reliable scientific evidence.

All of Respondents’ science experts appear to argue that because the POM products at issue are “foods,” a standard less than randomized, placebo-controlled, double-blind studies is acceptable to substantiate claims that such products will prevent, reduce the risk of, or treat diseases such as heart disease, prostate cancer or erectile dysfunction. In fact there is no different rule for foods. The Commission made this clear in its 1994 Enforcement Policy Statement on Food Advertising, which stated that the Commission’s standard for health claims for foods is that they be supported by “competent and reliable scientific evidence.” (FTC

Enforcement Policy Statement on Food Advertising at CX0002_0018). The Commission noted that this standard had 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.

Id. The Commission stated that it regards the “significant scientific agreement” standard to be the principal guide to what experts in the field of diet-disease relationships would consider reasonable substantiation for unqualified health claims. *Id.* at 19. The Commission continued that it was thus “likely that the Commission will reach the same conclusion as FDA as to whether an unqualified claim about the relationship between a nutrient or substance in a food and a disease or health-related condition is adequately supported by the scientific evidence.” *Id.*

The Commission and the federal courts have required clinical studies for cancer, heart disease, and erectile dysfunction claims for dietary supplements, which are types of foods. *See, e.g., FTC v. Direct Mktg. Concepts, Inc.*, 569 F.Supp.2d 285, 303-04 (D. Mass. 2008), (“it seems well-accepted that double-blind, placebo-controlled studies are necessary to substantiate health-related efficacy claims” and defendants’ study does not support cancer, heart disease, diabetes, or arthritis treatment and prevention claims for their dietary supplement), *affd.* 624 F.3d 1 (1st Cir. 2010); *FTC v. Nat’l Urological Group*, 645 F. Supp. 2d 1167, 1202-03 (N.D. Ga. 2008) (erectile dysfunction claims would require well-designed, placebo-controlled, randomized, double-blind clinical trials), *Daniel Chapter One*, No. 9329, Initial Decision (stating that a claim that a dietary supplement prevents, treats, or cures cancer must be substantiated by controlled

clinical testing of the product on humans). Federal courts have also applied such a standard for claims that are arguably less significant than those at issue in this case. *See, e.g., FTC v. Pantron I*, 33 F.3d at 1097-98 (placebo-control required for hair growth product); *FTC v. Removatron*, 884 F.2d at 1498-1500 (upholding requirement for double-blind clinical test to substantiate performance claims for hair removal device); *FTC v. SlimAmerica*, 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 [weight loss product].”); *FTC v. QT, Inc.*, 448 F. Supp.2d 908, 962 (well-conducted, placebo-controlled, randomized, double-blind study needed to substantiate pain relief claim); *FTC v. Sabal*, 32 F. Supp.2d 1004, 1008-09 (N.D. Ill. 1998) (rejecting study as valid substantiation for hair loss product claims, in part, because it was not blinded or placebo-controlled); *FTC v. California Pacific Research, Inc.*, 1991 U.S. Dist. LEXIS 12967, at *12-13 (D. Nev. Aug. 27, 1991) (rejecting hair growth studies that were not placebo-controlled or double-blinded clinical studies as failing to meet “the most basic and fundamental requirements for scientific validity and reliability”). *See also, Schering Corp.*, 118 F.T.C. 1030, 1080 (double blind, placebo-controlled, clinical trials required to evaluate efficacy of a weight-loss product) (Initial Decision). In short, complaint counsel’s expert witnesses’ opinions find full support in the well-established case law.

IV. CORPORATE RESPONDENTS POM AND ROLL ARE LIABLE FOR THE DECEPTIVE AND FALSE ADVERTISING

POM and Roll are each liable for their involvement in making the false and unsubstantiated health claims discussed in section I. POM is liable for claims made in its advertisements for its products; Roll is liable because of its role in creating POM’s advertisements through Fire Station, promoting POM products through its public relations

employees, and sponsoring and funding research on POM products. Additionally, Roll and POM are also 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.” *F.T.C. v. Nat’l Urological Group*, 645 F. Supp. 2d 1167, 1182 (N.D. Ga. 2008) (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.” *F.T.C. v. Bay Area Bus. Council, Inc.*, No. 02 C 5762, 2004 WL 769388, at *12 (N.D. Ill. Apr. 9, 2004) (finding a common enterprise where the corporate defendants were owned by the same person, operated by the same people, had shared offices, done 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) (internal quotation marks omitted); *In re Telebrands Corporation*, No. 9313, 2004 WL 3155567, at *48 (F.T.C. Sept. 15, 2004) (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”). “[T]he pattern and frame-work of the whole enterprise must be taken into consideration[,]” *Nat’l Urological Group*, 645 F. Supp. 2d at 1182, and courts look for vertical or horizontal commonality. *F.T.C. v. Network Servs. Depot, Inc.*, 617 F.3d 1127, 1143 (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). 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.” *Nat’l Urological Group*, 645 F. Supp. 2d at 1182. “It is not necessary that the FTC prove any particular number of entity connections and any specific connection. Instead, it must be proved that the defendants maintained an ‘unholy’ alliance.” *F.T.C. v. Kennedy*, 574 F. Supp. 2d 714, 722 (S.D. Tex. 2008).

As discussed in section I, Stewart and Lynda Resnick own and control their closely held corporations, Roll and POM, which are affiliated companies housed in the same office building. The corporations are completely intertwined. To begin, despite having no official position in POM, Mrs. Resnick characterizes her involvement in the business as a partnership with Mr. Tupper since 2003. (*Rubies in the Orchard*, CX_0001 at 197.) As discussed in section I, Roll is a “‘shared services’ provider of legal, consulting, accounting, tax, information technology, advertising, and human resources for its subsidiaries and affiliates, including POM.” (POM Wonderful/Roll Organization Structure at CX0476_0002; Answers and Defenses of Respondents ¶ 2.) [REDACTED]

[REDACTED] (Tr. of R. Bryant at CX1354_0041-42, 0049-50, 0055-64; see also Tr. of D. Kuyoomjian Dep. at CX1357_0234-236 (noting that Roll’s consulting group worked with POM’s marketing staff on a consumer research project).)

Moreover, Roll’s interrogatory response acknowledged that Roll has provided various services over the years to POM relating to the challenged products “with *some* portion charged back to

POM” (Roll’s Supplemental Resps. to First Set of Interrogs. at CX1383_0014, emphasis added.)

Roll fully participated in POM’s business activities at issue in this matter. Fire Station, or previously Teleflora, employees have worked closely with POM’s marketing staff, Mrs. Resnick, and Mr. Tupper to create, disseminate, and monitor POM’s advertisements (Tr. of M. Perdigao Dep. at CX1348_0018-21, 0023-26, 0200-201) while Roll’s Vice President of Corporate Communications worked on public relations projects for POM for several years. (Tr. of M. Tupper Dep. at CX1353_0037 (stating that there was a period of time when Fiona Posell, a corporate communications and public relations employee, was working for POM and Roll); Tr. of F. Possell Dep. at CX00486_0022-24.)

Roll was intimately involved in POM’s scientific studies. [REDACTED]

[REDACTED]

[REDACTED] (Letter from Dr. Liker to Mr. Resnick dated January 24, 2005 at CX0706; Letter from Dr. Liker to Mr. Resnick dated January 8, 2002 at CX0548.) While ostensibly Medical Director of POM, Dr. Liker has signed medical research agreements on behalf of Roll as medical director for Roll for POM research. (E.g. Protocol agreement dated May 3, 2005 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 at CX0739_0003; Letter of Intent dated May 1, 2003 for a medical study by Dr. Davidson involving heart disease listing Roll as the study’s sponsor at CX0588.) While POM ostensibly was the sponsor of the erectile dysfunction study on pomegranate juice, Karen Edwards, a Roll employee, provided the study beverages and assisted the researchers in

writing the manuscript. (Tr. of C. Forest Dep. at CX1337_0060, 0061, 0182-187.) Roll's Chief Financial Officer signed an agreement on behalf of POM and Roll with the Prostate Cancer Foundation. (Letter regarding Nutraceutical Program dated February 3, 2005 at CX0710.)

Additionally, Roll has been listed as the sponsor in clinical trial agreements even though the

[REDACTED] study was funded by the Resnick Trust. [REDACTED]

[REDACTED]

[REDACTED] at CX0785_0013; M. Davidson, Effect of Consumption of Pomegranate

Juice on Carotid Intima-Media Thickness in Men and Women at Moderate Risk for Coronary

Heart Disease at CX1199.) Mr. Resnick has stated that it is all his money.

Finally, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] (Tr. of R. Bryant Dep. at CX1354_0023-27, 0052-53.)

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] (*Id.* at 0067 (describing cash management as an

interface between Roll and POM.))

Because they are under the Resnicks' control, share office space and employees, and have intertwined business operations relating to the financing and sponsoring of scientific research, and the marketing, public relations, and advertising of POM's products, Roll and POM operated as a common enterprise. *See Telebrands Corporation*, 2004 WL 3155567, at *48 (finding a common enterprise where the corporations shared office space, and were controlled by the same person who "[i]ndividually or in concert with his officers and employees, . . . formulate[d], direct[ed], or control[led] the policies, acts, or practices" of both entities).

V. RESPONDENTS STEWART A. RESNICK, LYNDIA RAE RESNICK, AND MATTHEW TUPPER ARE INDIVIDUALLY LIABLE

"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*, No. 9329, Initial Decision, at * 118 (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).

Clearly, the Resnicks are in charge and control both corporate respondents. Mr. Resnick, Chairman of POM Wonderful and Chairman and Director of Roll, met regularly with Mr. Tupper and made decisions about the finances, investments, and expansion of POM. Mr. Resnick also decided whether and how to publish studies' results, reviewed Mr. Tupper's hiring recommendations for key positions at POM, and occasionally weighed in on POM's advertising. Tr. of S. Resnick Dep. at CX1360_0020-21.

Mrs. Resnick, Vice-Chairman and Director of Roll, is credited with creating the business model for POM. From POM's inception, she has directed the creative development of the company and the vision of POM Juice and POMx advertising campaigns. Over the years, Mrs. Resnick has been involved on a day-to-day basis in marketing and advertising decisions and had regular meetings with POM marketing and Fire Station advertising personnel. She reviewed and approved various marketing materials for all forms of media, including print and internet advertisements, was involved in developing in-house market research (Tr. of L. Resnick Dep. at CX1359_0077), and participated in decisions regarding whether to refer to a study in a POM advertisement. Tr. of M. Tupper Dep. at CX1353_0198.

Mr. Tupper, President and Chief Operating Officer of POM Wonderful, formulated, directed, and controlled the policies, acts, or practices of POM. Mr. Tupper has been intimately involved in POM's operations, including overseeing management of POM Juice and the development of POMx, and the marketing and sales of the POM's products. Throughout his tenure, he has participated in decisions involving research, reviewed advertising, and has been responsible for the hiring and firing of key marketing and science executives.

As discussed in sections II and III, 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.

VI. THE NOTICE ORDER SETS FORTH RELIEF APPROPRIATE FOR THIS CASE

In the 1952 *Ruberoid* case, the Supreme Court described the Commission's authority to craft orders against FTC Act violators:

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 roadblock 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 bypassed 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 (1952); *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 612, and it must be sufficiently clear and precise that its requirements can be understood, *FTC v. Colgate-Palmolive Co.*, 380 U.S. 374, 392 (1965). Pursuant to this authority, the courts have affirmed Commission orders requiring remedies as diverse as prohibitions on individual use of zone pricing,⁵⁹ cancellation of existing contracts,⁶⁰ mandated divestiture of assets to create a competitor,⁶¹ requirements for varying levels of substantiation for future claims,⁶² disclosure requirements,⁶³ and trade name excision,⁶⁴ to name just a few. In each instance, the underlying inquiry has been

⁵⁹ *FTC v. National Lead Co.*, 352 U.S. 419 (1957).

⁶⁰ *North Texas Specialty Physicians v. F.T.C.*, 528 F.3d 346 (5th Cir. 2008).

⁶¹ *Chicago Bridge & Iron Co N.V. v. FTC*, 534 F.3d 410 (5th Cir. 2008).

⁶² *See, e.g., Sears, Roebuck & Co. v. FTC*, 676 F.2d 385 (9th Cir. 1982) (requiring competent and reliable evidence for future performance claims for major household appliances); *Thompson Medical Co. v. FTC*, 791 F.2d 189 (1986) (requiring at least two adequate and well-controlled, double-blinded clinical studies for future efficacy claims for a topical analgesic).

⁶³ *Porter & Dietsch, Inc. v. FTC*, 605 F.2d 294, 307 (1979).

⁶⁴ *Continental Wax Co. v. FTC*, 330 F.2d 475 (1964).

the same: what remedy is needed to ensure that respondents do not again violate the FTC Act? *See FTC v. Colgate-Palmolive Co.*, 380 U.S. 374 (1964) (Commission may frame its order broadly enough to prevent respondents from engaging in similarly 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. 648, 833 (1984), *aff'd*, 791 F.2d 189 (D.C. Cir. 1986).⁶⁵

Respondents in this case have shown a “ready willingness to flout the law.” *See Sears, Roebuck*, 676 F.2d at 392. They engaged in a calculated, years-long effort to promote POM Juice and POMx as products that were “backed by science”—described as “\$25 million” or “\$32 million” in “medical research.” 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 IMT and Ornish IMT studies), they described their research to consumers as “real studies, real results.”⁶⁶ Indeed, respondents made some of the challenged claims in the face of substantial contrary information. For example, as of 2010 their website continued to tout blood pressure reduction results from the unblinded, uncontrolled 2001 and 2004 Aviram studies despite the fact that at least five

⁶⁵ 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. v. FTC*, 676 F.2d 385, 392 (9th Cir. 1982); *Porter & Dietsch*, 605 F.2d 294, 306 (7th Cir. 1979), *cert. denied*, 445 U.S. 950 (1980); *Thompson Medical*, 104 F.T.C. at 648.

⁶⁶ The sole exception is the Ornish MP study; respondents were aware, however, that this study was deeply flawed, having been cut short at 3 months, after a substantial proportion of the placebo patients had been unblinded.

subsequent controlled studies – including the Ornish IMT data, the Ornish MP data, the Davidson IMT data, the Davidson BART data, and the Heber Overweight studies – consistently showed *no* reduction in blood pressure from use of POM Juice or POMx. Similarly, they continued to promote the results of the unblinded Aviram IMT study after receiving the results of the Ornish IMT and Davidson IMT studies, both of which showed *no* benefit to the overall population studied. They also made erectile dysfunction claims even though the sole human study they conducted failed to produce a statistically significant result. The seriousness of these violations is affected both by the fact that the claims related to significant diseases, and by the fact that consumers could not readily judge the truth or falsity of the claims respondents were making. Finally, the violations at issue – misrepresentation of health benefits – are readily transferrable to the other foods or dietary supplements sold by respondents, and to representations related to other health conditions.⁶⁷ Thus, fencing-in relief is not only appropriate, but essential, in this case. *See, e.g., Brake Guard Prods., Inc.*, 125 F.T.C 138, 253 (1998) (misrepresentations related to motor vehicle safety were serious); *Thompson Med.*, 104 F.T.C at 834 (long-term, deliberate, transferrable violations warrant fencing-in relief); *Schering Corp.*, 118 F.T.C 1030, 1121 (1994) (Initial Decision) (violations were serious where claims

⁶⁷ Respondents have made a variety of representations – which are not challenged by the Commission’s Complaint – about the potential benefits of their products for other conditions, including but not limited to Alzheimer’s Disease, arthritis, colds and flu, and exercise recovery. (POM Wonderful: Medical Research Portfolio Review, dated January 13, 2009, at CX1029). Other pomegranate-based products sold by Respondents include POM Coffee, POMx Tea, POMx Bars, and POMx Shots, and other foods sold by respondents include Cuties tangerines, Wonderful brand pistachios and almonds, and various salad toppings. *See* Roll Global Website, at www.roll.com (last visited Apr. 30, 2011).

consciously made despite flaws in the studies respondent relied on and because consumers were not able to assess the validity of the claims).⁶⁸

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 – 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 application, or labeling approval under regulations promulgated pursuant to the Nutrition Labeling and Education Act of 1990 (“NLEA”). 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.” Finally, Part II of the Notice Order prohibits, in connection with the marketing of any Covered

⁶⁸ 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., National Lead*, 352 U.S. at 431.

Product, misrepresentations about the existence, content, validity, results, conclusions or interpretations of any test, study, or research.

Under this Order, if the respondents disseminate advertising, the net impression of which is that a POM Product is effective in the diagnosis, cure, mitigation, treatment, or prevention of disease, those claims must be FDA-approved under Part I. If respondents disseminate advertising that, in a carefully qualified manner characterizes limited scientific evidence supporting the relationship between a POM product and reductions in disease risk, creating a net impression other than that the product is effective, that claim would be covered by Parts II and III.

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."⁶⁹ Deference to the FDA's standards and its evaluation of scientific

⁶⁹ For example, a claim that POM Juice reduces 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 "significant scientific agreement among experts qualified by scientific training and experience to evaluate such claims, considering the totality of publicly available scientific evidence" that the claim is supported. NLEA, 21 U.S.C. § 343(r)(3)(B)(i). Compare, FTC, *Enforcement Policy Statement on Food Advertising*, p. 19 (1994) (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). This standard is similar to the FTC's substantiation standard for health benefit claims. See, e.g., *Daniel Chapter One*, D-9329 (Op. at 20) (competent and scientific evidence, consisting of controlled clinical studies, are required to support disease claims); FTC, *Dietary Supplements: An Advertising Guide for Industry*, available at <http://business.ftc.gov/documents/bus09-dietary-supplements-advertising-guide-industry>

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 647. The Part I relief proposed here also is consistent with the relief approved in two recent Commission settlements. *Nestle HealthCare Nutrition, Inc.*, C-4312 (Jan. 12, 2011); *FTC v. Iovate*, 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. By contrast, given the body of research presented by respondents which, while facially impressive, does not support their advertising claims, the staff anticipates that it would be highly difficult for the Commission to enforce an order requiring substantiation by “competent and reliable scientific evidence,” or even “at least two clinical studies.” 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 future disease-related claims.

(requiring competent and reliable scientific evidence).

Respondents have argued that the requirement for FDA approval places too high a burden on them. It should be noted, however, that respondents already shifted focus to obtaining FDA approvals for their claims. [REDACTED]

[REDACTED] at CX1107; [REDACTED] at CX1152). They hired

a new scientific director with the experience needed to help them focus on drug approval. (Tr. of S. Resnick Dep. at CX1360_0029). [REDACTED]

[REDACTED] at CX1093; [REDACTED] at CX1125). Respondents are aware, however, that their

evidence falls short of what FDA requires for claims approval.⁷¹ This fact points not to a problem with the proposed remedy here, but to a problem with Respondents' substantiation.

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 is an appropriate resolution of the issues.

⁷⁰ Additionally, Respondents have obtained numerous patents on the POMx products, to protect their proprietary interest in the formulations. *See eg.*, U.S. Patent No. 7,611,738 (Filed May 26, 2005).

⁷¹ For example, [REDACTED] (POM Wonderful: Medical Research Portfolio Review, dated January 13, 2009, at CX1029).

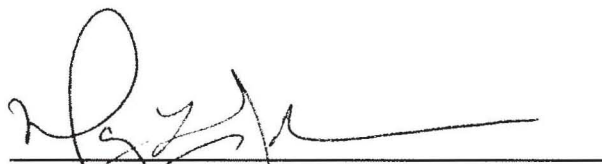
The remaining Order provisions are standard. Part IV contains safe harbors, permitting respondents to make representations approved by FDA. Part V is a record-keeping requirement. Part VI sets forth Order distribution requirements. Part VI and VII require the corporate and individual respondents, respectively, to file notifications about changes in structure and employment. Part IX sets forth compliance reporting requirements. Finally, Part X is the sunset provision.

VII. CONCLUSION

For the reasons stated above, Respondents' practices, as alleged in the Complaint, constitute unfair or deceptive acts or practices, and the making of false advertisements, in or affecting commerce, in violation of Sections 5(a) and 12 of the FTC Act. Complaint Counsel respectfully requests that the Court enter the relief proposed in the Commission's Notice Order.

Date: May 12, 2011

Respectfully submitted,



Mary L. Johnson (202) 326-3115

Elizabeth K. Nach (202) 326-2611

Federal Trade Commission

Bureau of Consumer Protection

600 New Jersey Avenue, NW, Room NJ-3212

Washington, DC 20580

Errata Sheet to Complaint Counsel's Pre-Trial Brief

| Page | Erratum |
|----------------------|---|
| Pages iii-iv | Provided page numbers for case citations in Table of Authorities. |
| Page 5, Line 19 | Changed “participated in the hiring and decisions of” to “participated in the hiring and firing of.” |
| Page 31, Line 5 | Provided complete citation to <i>Zauderer v. Office of Disciplinary Council</i> . |
| Page 35, Footnote 28 | Corrected quote from CX0456_0002-5: “Our advertising campaign is created with the intent” |
| Page 37, Line 1 | Provided citation. |
| Page 37, Footnote 30 | Provided citation. |
| Page 46, Line 13 | Corrected quote from Complaint Ex. N: “Prostate cancer is the second leading cause of cancer related death in men in the United States” |
| Page 48, Line 8 | Provided missing citation. |
| Page 52, Line 9 | Changed Sections III.A.-III.E. to Sections II.A.-II.E. |
| Page 52, Line 13 | Replaced “.” with a “,” after mid-sentence citation to <i>Daniel Chapter One</i> . |
| Page 87, Line 16 | Deleted “the opinions of.” |
| Page 92, Line 22 | Corrected citation. |
| Page 93, Lines 7-8 | Corrected citation. |
| Page 93, Line 9 | Corrected citation. |
| Page 93, Line 17 | Changed “virture” to “virtue.” |
| Page 93, Line 18 | Changed “paricipation” to “participation.” |
| Page 95, Line 17 | Changed “2003” to “2004.” |
| Page 96, Footnote 67 | Provided citation. |

CERTIFICATE OF SERVICE

I certify that on May 13, 2011, I caused the filing and serving of the public version of *Complaint Counsel's Pre-Trial Brief [Corrected]* as follows:

One electronic copy via the FTC E-Filing System to:

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

One paper copy via hand delivery and one electronic copy via email to:

The Honorable D. Michael Chappell
Administrative Law Judge
600 Pennsylvania Ave., N.W., Room H-110
Washington, DC 20580
Email: oalj@ftc.gov

One electronic copy to:

John D. Graubert, Esq.
Skye L. Perryman, Esq.
Covington & Burling LLP
1201 Pennsylvania Ave., NW
Washington DC 20004-2401
Email: jgraubert@cov.com; sperryman@cov.com

Kristina Diaz, Esq.
Roll Law Group
Email: kdiaz@roll.com
Attorneys for Respondents

Bertram Fields, Esq.
Greenberg Glusker
Email: bfields@greenbergglusker.com
Attorneys for Respondents Stewart Resnick and Lynda Resnick

Dated: May 13, 2011

/s/ Elizabeth K. Nach
Elizabeth K. Nach
Complaint Counsel